# Analysis of the socio-economic impacts of a harmonised classification for titanium dioxide ($TiO_2$)

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## Draft Final Report for Downstream User Consultation

prepared for

## Titanium Dioxide Industry Consortium

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RPA
Risk & Policy Analysts

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# Executive Summary

Titanium dioxide ($TiO_2$) is by far the highest volume and most versatile globally-used white pigment. No other comes close to matching its exceptionally high opacity, bright whiteness and UV absorbing, protective properties. It is manufactured in 18 plants in the European Economic Area (EEA) with an annual production volume of ca. 1,100 ktonnes and an estimated market value of ca. €2.66 billion. Most $TiO_2$ is used in paints and coatings (architectural: 36%; industrial: 17%; inks: 4%), followed by plastics (25%), paper (12%) and specialty applications (6%) (based on Cefic data for 2013). Approximately 1-2% of all $TiO_2$ is made in non-pigmentary forms for use in many high value-added applications including cosmetic sunscreens and environmental, clean air technologies.

The French proposal for the classification for $TiO_2$ as a Carcinogen Category 1B by inhalation (H350i) substance is based on effects seen in inhalation studies when rats are exposed to exceptionally high concentrations of all poorly soluble dusts, not just $TiO_2$, effects that have been scientifically demonstrated not to be relevant to humans[1]. The proposal would have severe adverse consequences as a result of (a) the absence of technically feasible alternatives for $TiO_2$, and (b) the triggering of a series of automatic changes in how the marketing and use of $TiO_2$ is treated under a variety of chemical safety regimes in the EEA. These regulatory changes would mostly disregard the importance of the $TiO_2$ exposure pathway in the manifestation of adverse health effect in humans.

### *Impacts on titanium dioxide manufacturers and their suppliers*

It is estimated that 25-50% (if not more) of current demand for $TiO_2$ would be lost, leading to the collapse of the EEA's $TiO_2$ manufacturing base and the shutdown of several production plants. This would have a significant knock-on effect on both EEA-based and non-EEA supply chains as exports account for one-third of EEA manufacture while some $TiO_2$ grades are only produced by European plants.

The Gross Added Value of $TiO_2$ manufacture to the EEA economy is €473 million; the industry employs ca. 8,150 workers and is responsible for the creation of a further 22,800 support jobs. The French proposal would also cause market losses for two Norwegian feedstock manufacturers, it would affect the trade of ca. 4 million tonnes of raw materials used in the manufacture of $TiO_2$ and would also cause a reduction in production and sales of large volumes of economically important by-products of $TiO_2$ manufacture.

### *Impacts on downstream users of titanium dioxide*

The French proposal would impact upon a multitude of downstream user sectors with a combined Gross Value Added of hundreds of billions of Euros; paints and plastics alone, the most important uses for $TiO_2$, account for over €120 billion. Downstream users might consider the reformulation of their products, however, in the vast majority of cases this could not be successful due to the lack of technically feasible alternative pigments; in any case, substitution of $TiO_2$ would be costly (example estimates: €0.05-60 million per company), take considerable time (2-20 years) and invariably be a case of regrettable substitution. Additional required workplace safety measures could have an investment cost of between a few thousand Euros and €20 million per plant, while waste regulations would impact upon recycling of waste and might impose an additional cost of up to €0.35 million per site for the disposal of waste classified as hazardous;

The French proposal would automatically mean the removal from the market of a multitude of consumer formulations such as Do-It-Yourself (DIY) paints (the vast majority of which contain $TiO_2$), coatings, adhesives, sealants and detergents. The elimination of DIY paints alone, worth an estimated €3.5 billion per year, would

[1] For additional information, the reader is referred to the material presented at the International Scientific Symposium on $TiO_2$ (http://www.tio2symposium.com/), held in Paris on 15-16 November 2016.

drive up significantly the cost of residential housing renovation and restrict consumer choice. The French proposal would also prevent the marketing of numerous cosmetics, food products, pharmaceutical and nutraceutical products, medical devices, biocides and toys, unless exemptions could be secured. Where such exemptions could be feasible, the cost of obtaining them would be of the order of millions of Euros.

### *Impacts on EEA competitiveness*

EEA business would become less competitive both domestically and overseas and, over time, parts of the value chains would relocate outside the EEA, unless the proposed classification was also adopted by non-EEA jurisdictions. SMEs in the EEA would be particularly vulnerable to the loss of a critical raw material or articles that depend on it.

### *Impacts on EEA workers*

$TiO_2$ its formulations and articles are used by millions of workers; by way of example, 1 million workers apply paints/coatings and 4.5 million workers are involved in the use of plastics. Even if the French proposal would cause the loss of jobs for only a modest percentage of this workforce, the total number of jobs lost across all EEA would be significantly high. Impacts would not be limited to industries that use $TiO_2$ as a raw material; the re-classification of $TiO_2$-containing products such as coatings would significantly impact employment in downstream industries that use these products.

### *Impacts on the marketing and use of other minerals*

The handling, processing and use of minerals that contain $TiO_2$ impurities at up to 4% by weight (e.g. kaolin, a mineral often referred to as a potential partial replacement for $TiO_2$, bentonite, perlite, mica, diatomite, ball clays, vermiculite, refractory materials and zircon) would be affected. Combined, these minerals are used in the EEA in a volume of over 20 million tonnes per year and have a market value of over €6.2 billion. The volumes and market value of downstream products of these minerals are even larger.

In addition, acceptance of the French proposal for $TiO_2$ would open the pathway for the harmonised classification of other poorly soluble powders, including many minerals that might be considered to be potential partial substitutes for $TiO_2$.

### *Impacts on consumers*

Consumers would face a reduction in product availability and choice, increased market prices, increased costs for redecoration and maintenance tasks, loss of performance, poorer aesthetics and also loss of a safe, effective UV filter in sunscreens and other cosmetics if use of $TiO_2$ was banned.

### *Conclusion*

This impact analysis demonstrates that the French proposal would result in severe social and economic impacts for a diverse range of industry sectors and would impact on the marketing and use of a vast array of industrial, professional and consumer products as well as on the employment of millions of workers. Since the French proposal is based on the effects of poorly soluble powders in rat lung overload studies it would be relevant for many potential alternatives. Furthermore, in light of the reasonably anticipated occurrence and levels of inhalation exposure during industrial, professional and consumer use of $TiO_2$ and its products, the demonstrated adverse socio-economic impacts would be highly disproportionate to any human health benefits that could theoretically be attributed to the proposed harmonised classification.

# 1 Introduction to the analysis

## 1.1 Background to this report

The French authorities have submitted a proposal for a new harmonised classification (CLH) for titanium dioxide ($TiO_2$). The proposal is to classify the substance as a carcinogen category 1B by inhalation and it was made available for public consultation on the ECHA website on 31 May 2016 with a deadline of 15 July 2016 for submission of comments. During this period, the Titanium Dioxide Manufacturers Association (TDMA) submitted extensive comments as did numerous other stakeholders, the vast majority of whom have expressed severe reservations over the validity of the scientific arguments made in the French proposal but have also highlighted the potential adverse effects from the proposed classification across the $TiO_2$ supply chains.

Indeed, a harmonised classification of Carc Cat 1B would clearly have significant repercussions on the manufacture and use of the substance in the EEA. Furthermore, the presence of $TiO_2$ in several minerals placed on the market at discernible concentrations and the commonality of the key principles on which carcinogenicity is claimed in the French proposal between $TiO_2$ and other poorly soluble powders could mean that the proposed harmonised classification might have significant direct and indirect adverse impacts on other supply chains.

Risk & Policy Analysts Ltd (RPA), an independent consultancy, has been contracted by the Titanium Dioxide REACH Industry Consortium (TDIC) to prepare a review of the regulatory impacts and an analysis of socio-economic impacts from the proposed harmonised classification. This is a Draft Final report which summarises the findings of all four Tasks outlined in our proposal to the TDIC.

**This draft document is not intended for publication as is**. Comments on this document will be taken into account and then the document will be finalised and prepared for publication by the TDIC.

## 1.2 Consultation

The analysis presented herein is based to a large degree on information collected from numerous actors along the $TiO_2$ supply chain, information was also collected from concerned stakeholders outside of the supply chain. Consultation was undertaken in two phases.

The first phase was conducted between mid-May 2016 and end of June 2016 and consisted of the circulation of a short initial questionnaire. A total of 165 completed questionnaires were submitted by trade associations and individual companies. As had been expected, paints and plastics accounted for the majority of applications (over 80%). Printing inks and cosmetics also appeared to be widespread applications among the sample of respondents. Information collected included details of the $TiO_2$ concentration in products (0.01% wt. to 80% and even close to 100% in pigment formulations), the presence of SMEs in key industry sectors and the availability of alternatives (two out of three downstream users (or their representatives) had no knowledge of alternatives and the minority of respondents who have identified specific alternatives for $TiO_2$ indicated obsolescence, technical inferiority and lower cost-effectiveness than $TiO_2$). The vast majority of respondents (over 80%) indicated that the proposed classification would have significant socio-economic impacts.

The second phase of the consultation was conducted in the period between August 2016 and October 2016. A large number of trade associations and individual companies-downstream users of $TiO_2$ were contacted with a more detailed questionnaire. In addition, trade associations representing the producers of other poorly soluble powders were contacted with a separate questionnaire.

As of 4 October 2016, a total of 116 completed questionnaires were submitted by 31 trade associations and 85 individual companies. Again, paints accounted for the majority of responses. Information collected included details of the tonnages of $TiO_2$ used and the value of the products containing it, the availability of alternatives and the potential impacts from the proposed classification. The information collected has been used in the preparation of this report. Information submitted by individual companies is generally used anonymously for reasons of confidentiality.

# 2 Properties of titanium dioxide

$TiO_2$ consists of four-valent titanium and two-valent oxygen ions. It is a solid under normal conditions and it first begins to melt at over 1800 °C. Its stability, even at high temperatures, and its pronounced slowness of reaction are worthy of note. A peculiarity of $TiO_2$ is its ability to lose relatively easily a small part of its oxygen from the crystal lattice. These very small oxygen losses cause great changes in the optical and electrical behaviour of $TiO_2$. On the one hand, it makes itself apparent in colour-shifts towards blue-grey and, on the other hand, the dielectric properties and the electrical conductivity are influenced to an unexpectedly high degree. This peculiarity is partly the reason for the striking photoelectric properties of $TiO_2$ (Kronos, 1968).

$TiO_2$ is insoluble in water, in organic solvents, in all alkalis and acids with the exception of sulphuric and hydrofluoric acids and it is polymorphous. Its three modifications, rutile, anatase and brookite are all found in nature. Rutile and anatase are the technically important ones.

$TiO_2$ has a range of very significant properties that drive its usability in a wide range of applications. These are summarised below but are also frequently referred to in the rest of this report.

1. **Highest light scattering among known white pigments, which is responsible for the good hiding power, opacity and ability to lighten coloured media.**
2. **Acts as a base for the development of a very wide range of colours.**
3. **High efficiency, as only small additions can deliver the desired pigmentation.**
4. **Confers exceptional stability to heat, light and weathering.**
5. **High absorptive power in the UV region which prevents the ageing of materials, the spoilage of packaging contents and the adverse effects of UV radiation on human skin.**
6. **It is approved as safe for use in foodstuff, pet foods, packaging, pharmaceuticals and cosmetics.**
7. **Its photocatalytic activity allows its use in many novel products, such as self-cleaning surfaces and air cleaning materials.**
8. **Favourable processing characteristics as $TiO_2$ pigments can be readily dispersed, achieve rapid wetting at low viscosities and remain inert in the presence of other formulation components.**
9. **Its ability to reflect light also enables heat to be reflected thus enabling lower energy use in cooling buildings or other infrastructure.**
10. **It is a perfect support for catalysis and especially the Selective Catalytic Reduction (SCR) of $NO_x$. These $TiO_2$-based SCR catalysts have been used since the 1980s in power plants to allow them to meet $NO_x$ emissions standards with an estimated removal of 110 million tonnes of $NO_x$ in the last 35 years** (Pasquier, 2016).

# 3 Supply chain overview

## 3.1 Titanium dioxide feedstock and production

### 3.1.1 Titanium dioxide feedstocks

The mineral sands[2] industry is the main supplier of titanium raw materials for the production of $TiO_2$ feedstocks. $TiO_2$ is produced from ilmenite, rutile or titanium slag. According to the US Geological Survey (USGS, 2016), the global mine production of ilmenite in 2015 was estimated at being 5.6 million tonnes, while mine production for rutile was estimated at 0.48 million tonnes. Major producers of ilmenite include China, Australia, Vietnam, Mozambique, Kenya and Norway, while for rutile major producers include Australia, Sierra Leone, Ukraine, Kenya and South Africa (USGS, 2016). Overall, the largest producers of titanium dioxide feedstock are China (18%), Australia (17%), South Africa (15%) and Canada (11%) (Iluka, 2015).

There is no mining operation in the EU, but Titania AS (owned by Kronos) operates a mine in Tellnes, Norway. The ilmenite ore deposit was discovered in 1954 and is one of the world's largest[3]. Another facility, also in Norway, operated by TiZir Titanium & Iron produces titanium slag from ilmenite imported from Senegal. Production in Tyssedal, Norway started in 1986[4].

### 3.1.2 Titanium dioxide production processes

The overall process of manufacture is to take an impure $TiO_2$ feedstock and to convert this into the pure white $TiO_2$ pigment. In essence the process sounds very simple but to achieve this it is necessary to chemically convert the impure $TiO_2$ into another chemical, separate out the impurities then to convert back to pure $TiO_2$ — in effect a chemical purification (McNulty, 2012). Pure $TiO_2$ is produced by two processes, the sulphate process and the chloride process, see **Figure 3–1**. The following table highlights some key technical differences between the two production processes.

**Table 3–1: Comparison of the processes used to produce $TiO_2$**

| Sulphate process | Chloride process |
|---|---|
| Older process - since 1920s | Newer process - since 1950s |
| Lower grade feedstock used | Higher grade feedstock used |
| Can produce both rutile and anatase | Produces only rutile |
| Dominates in China, significant capacity in Europe | Dominates in North America and more widespread than sulphate in Rest of World |
| In Europe, 55% $TiO_2$ is produced via sulphate route | In Europe, 45% of $TiO_2$ is produced via chloride route |

2 Mineral sands are old beach sands that contain concentrations of the important minerals, rutile, ilmenite, zircon and monazite. These minerals are heavy and are also called 'heavy minerals'. The relative density of common sand minerals such as quartz is around 2.65.

3 Information available at http://kronostio2.com/en/manufacturing-facilities/hauge-norway (accessed on 25 October 2016).

4 Information available at http://www.tizir.co.uk/projects-operations/tyssedal-tio2/ (accessed on 2 November 2016).

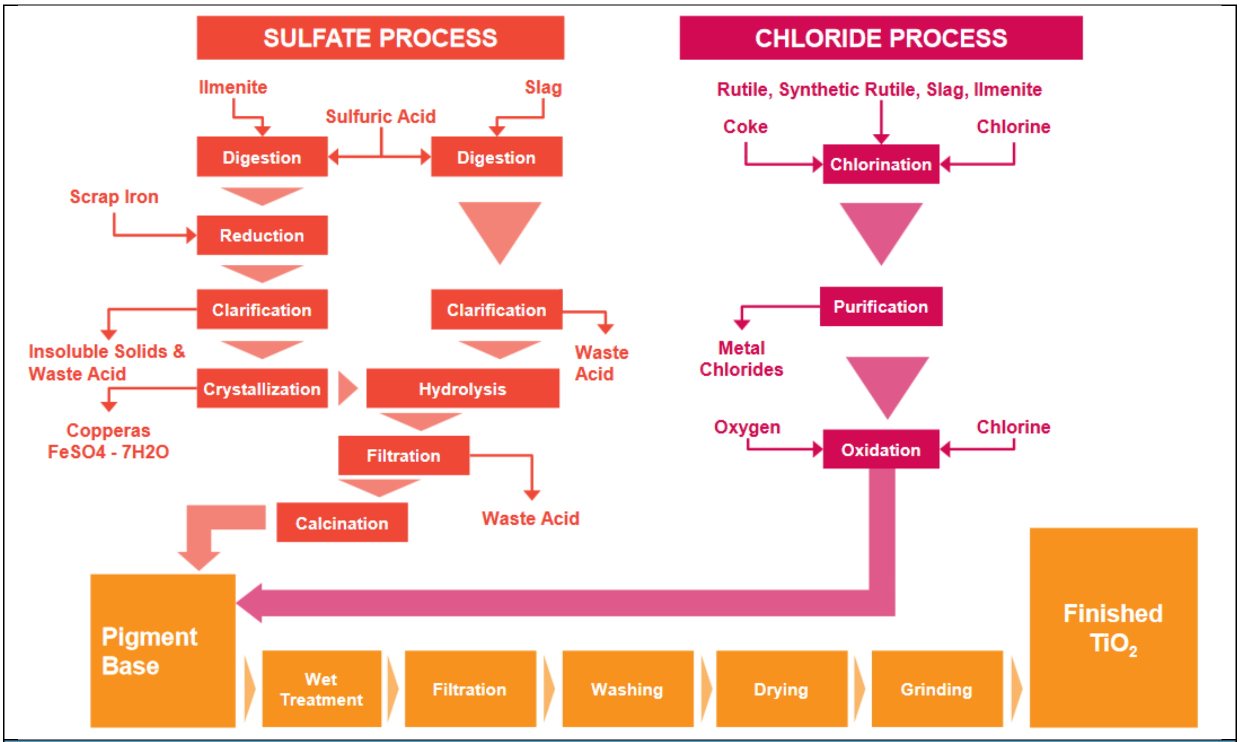



**Figure 3–1: Chloride and sulphate $TiO_2$ production processes**
*Source: Chemours* (2015)

The overall chemistry of the sulphate process can be represented as (McNulty, 2012):

$$FeTiO_3 + 2H_2SO_4 \rightarrow TiOSO_4 + FeSO_4 + H_2O$$

$$TiOSO_4 + H_2O \rightarrow TiO_2n.H_2O + H_2SO_4$$

$$TiO_2n.H_2O \rightarrow TiO_2 + n.H_2O$$

The sulphate process is more complicated in terms of the number of unit operations involved. On the other hand, the overall chemistry of the chloride process can be represented as (McNulty, 2012):

$$TiO_2 + C + 2Cl_2 \rightarrow TiCl_4 + CO + CO_2$$

$$TiCl_4 + O_2 \rightarrow TiO_2 + 2Cl_2$$

In general higher grade (% $TiO_2$) feedstocks are used for the chloride process than for the sulphate process (McNulty, 2012). Australia produces mainly chloride feedstocks, South Africa predominantly produces sulphate ilmenite which is upgraded to chloride slag with ilmenite also produced in other African countries, including Madagascar and Mozambique. Canada produces sulphate slag and upgraded slag, while China mines mainly sulphate ilmenite from hard rock deposits which is sold directly or upgraded to sulphate slag (Iluka, 2015).

It is reported that 90% of global $TiO_2$ feedstocks is used in the manufacture of pigment. The rest is used for the production of welding rods (for example, in steel construction and the ship building industry), or titanium metal (via sponge) for a variety of high-tech aerospace and military applications, medical and sporting equipment (Iluka, 2015).

## 3.2 Titanium dioxide pigment production

### 3.2.1 Types and forms of titanium dioxide pigment

***Differentiation by crystal form***

$TiO_2$ is a polymorphous and simple inorganic compound, existing in three fundamental crystal forms. All three forms, anatase, rutile and brookite, occur naturally but the latter is rare, and although it has been prepared in the laboratory it is of no commercial interest (Gázquez, et al., 2014). The chloride production process allows the production of only rutile $TiO_2$ and is primarily suited for large volume production of standard $TiO_2$ grades. The sulphate production process is capable of producing both the rutile and anatase grade of $TiO_2$ (Rockwood, 2012). The key differences between the two commercial crystal forms are shown below.

**Table 3–2: Comparison of the two commercial crystal forms of $TiO_2$**

| Parameter | Rutile | Anatase |
|---|---|---|
| Stability | More stable | Less stable |
| Lattice structure | Titanium is surrounded octahedrally by six oxygen ions. Each octahedron shares two of its twelve edges | Titanium is surrounded octahedrally by six oxygen ions. Each octahedron shares four of its twelve edges |
| Density | 4.2 g/cm$^3$ | 3.9 g/cm$^3$ |
| Refractive index, opacity | It has the highest refractive index of any white mineral and so it can confer very high opacity | Delivers sufficient opacity, not as high refractive index |
| Dispersion | Good dispersion | Better dispersion |
| Production process | Made with both sulphate and chloride processes | Made only by sulphate plants |
| Global market share | More widely used | Less widely used |
| Main use sectors: paints, coatings, plastics, paper, inks | Main area of use | May be used |
| Minor use sectors: fibres, food, cosmetics, pharmaceuticals | Typically not used in food, pharmaceuticals, fibre applications. Preferred in cosmetics where UV absorbance is important | Used in food, pharmaceuticals, fibres. Not preferred where UV absorbance is important |
| *Source: Kronos* (1968)*; Rockwood* (2012) | | |

***Differentiation by particle size***

There are two grades of $TiO_2$ in respect of the particle size: pigmentary $TiO_2$ and nano-form $TiO_2$.

Pigment grade $TiO_2$ has primary particles mainly in the size range of 200–350 nm (TEM[5]) as this is the optimum for scattering visible light; the surface area is typically from 6 to 60 m$^2$/g (coated and uncoated). Pigmentary $TiO_2$ is used due to its excellent light-scattering properties, white opacity and brightness and absorbance of UV light. When $TiO_2$ is incorporated in a polymer, it minimises degradation of the system (embrittlement, fading and cracking) (TDMA, 2013).

On the other hand, nano-form (also known as ultrafine) $TiO_2$ is engineered to have primary particles less than 100 nm with a surface area varying typically from 50 to 200 m$^2$/g (coated and uncoated).

5 Transmission Electron Microscopy.

This is a product used when different properties such as transparency, semi-conductive properties and maximum UV light absorption are required. Approximately 1-2% of the total production of $TiO_2$ is in this ultrafine form (TDMA, undated)

Applications of nano-form $TiO_2$ include (Rockwood, 2012; IHS, 2015; StatNano, 2014; TiPMC, 2015; TDMA, undated; Gázquez, et al., 2014):

- Cosmetic sunscreens (for UV ray absorbance);
- Generation of innovative colour variations for paints and coatings ("frost effect");
- Photocatalysis applications such as surface self-cleaning and wood protection;
- Arsenic removal in wastewater treatment;
- Catalysts supports in the automotive industry to remove harmful exhaust gas emissions, and in power stations to remove nitrous oxides ($NO_x$);
- Precursors for electronics and energy storage materials; and
- Colour pigment precursors and intermediates for special (electro) ceramics, including dye-sensitized solar cells ("DSSC").

Nano-form $TiO_2$ represents only a small proportion of total $TiO_2$ pigment production. In 2010, it was estimated that the volume of nanoscale $TiO_2$ would increase at the global scale from ca. 50,000 t/y (representing only 0.7% of the market) to over 200,000 t/y (Research and Markets, 2011). This increase has not yet materialised; instead it has been indeed estimated to be limited to ca. 1% of the $TiO_2$ market (TiPMC, 2015).

## 3.2.2 Titanium dioxide production capacity and locations

***Global producers of titanium dioxide***

The first commercial $TiO_2$ pigment manufacturing plant was set up in 1918 by Titan Co A/S, forerunner of Kronos Titan (Chemours, 2015). According to the US Geological Survey, global $TiO_2$ production capacity in 2015 was 7.2 million tonnes with largest players being China (3 million tonnes), United States (ca. 1 million tonnes), Germany (0.46 million tonnes), Japan (ca. 0.3 million tonnes) and the United Kingdom (0.3 million tonnes). As of 2015, the most prominent global producers of $TiO_2$ (i.e. those holding at least 5% of the global market) include, in descending order:

- The Chemours Company;
- Huntsman Pigments;
- Cristal;
- Henan Billions + Lomon;
- Kronos Worldwide; and
- Tronox LLC.

***EEA producers of titanium dioxide***

Focusing on the EEA, the main $TiO_2$ producing countries are shown in **Figure 3–2**. Germany, the United Kingdom, and Finland combined represent over 60% of EEA production capacity. The figure takes into account recent closures of capacity in France (ICIS, 2016; ICIS, 2007b). Overall capacity is at ca. 1,500 ktonnes.

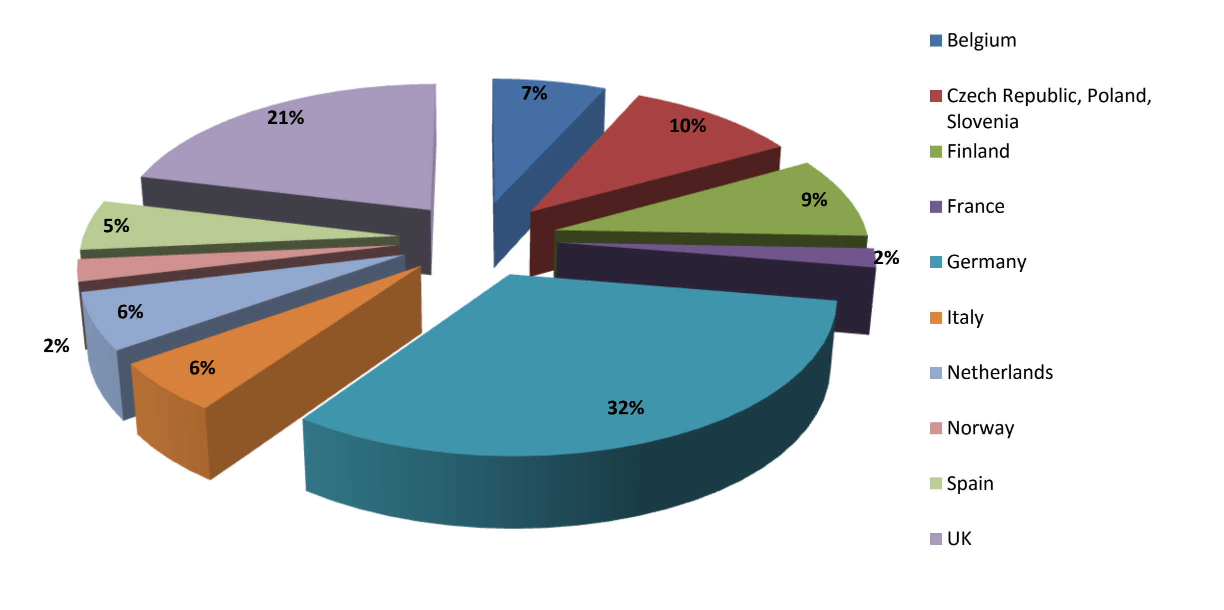



**Figure 3–2: Main $TiO_2$ producing countries in the EEA (shares based on nameplate production capacities)**
*Source: USGS (http://minerals.usgs.gov/minerals/pubs/commodity/titanium/mcs-2016-titan.pdf) and data from TDMA members*

**Table 3–3** (overleaf) presents all eighteen EEA $TiO_2$ production plants. **EEA production represents almost 20% of the total worldwide production**. It is further known that some $TiO_2$ production also occurs in Ukraine (by the companies Krymsky Titan and Sumykhimprom).

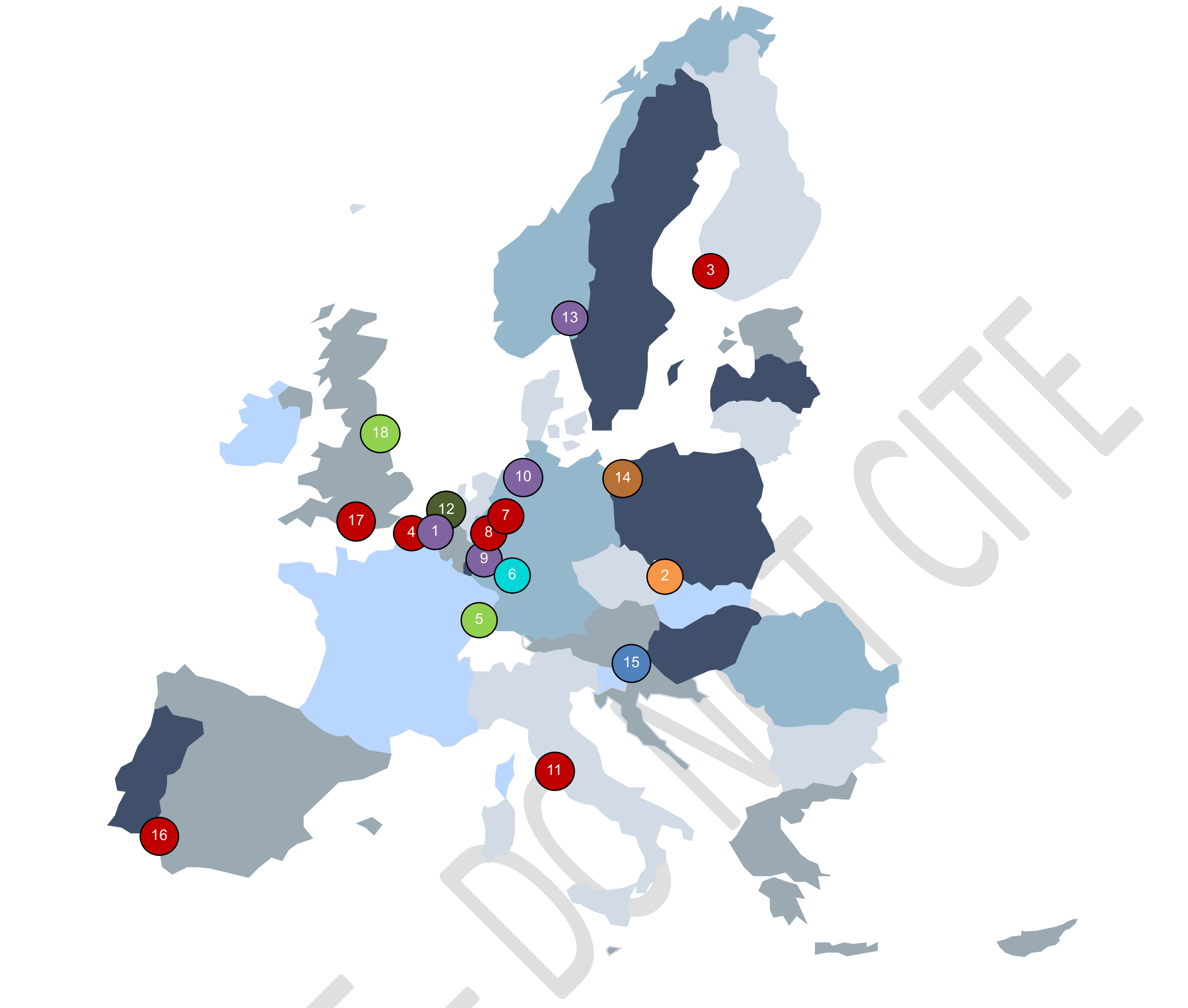
The following EU companies are full members of the Titanium Dioxide Manufacturers Association at Cefic:

- Cinkarna Celje d.d.;
- Cristal;
- Evonik Resource Efficiency GmbH;
- Grupa Azoty Zaklady Chemiczne “Police” S.A.;
- Huntsman Pigments;
- Kronos;
- Precheza AS; and
- Tronox LLC.

Associate members include the Chemours Company and Tayca.

Finally, as regards the production of nano-form $TiO_2$, the global production capacity is only a fraction of total $TiO_2$ production and amounts to an estimated 80,000 t/y (TiPMC, 2015).

**Table 3–3: $TiO_2$ production facilities in the EEA**




| # | Country | Company | Location | Process |
|---|---|---|---|---|
| 1 | Belgium | Kronos | Langerbrugge | Chloride |
| 2 | Czech Republic | Precheza | Prerov | Sulphate |
| 3 | Finland | Huntsman Pigments | Pori | Sulphate |
| 4 | France | Huntsman Pigments | Calais (finishing only) | Sulphate |
| 5 | France | Cristal | Thann | Sulphate |
| 6 | Germany | Evonik | Hanau | “Chloride” |
| 7 | Germany | Huntsman Pigments | Duisburg-Homberg | Sulphate |
| 8 | Germany | Huntsman Pigments | Krefeld-Uerdingen | Sulphate |
| 9 | Germany | Kronos | Leverkusen (2 plants) | Both |
| 10 | Germany | Kronos | Nordenham | Sulphate |
| 11 | Italy | Huntsman Pigments | Scarlino | Sulphate |
| 12 | Netherlands | Tronox LLC | Rotterdam-Botlek | Chloride |
| 13 | Norway | Kronos | Fredrikstad | Sulphate |
| 14 | Poland | Grupa Azoty Zakłady Chemiczne "Police" SA | Police | Sulphate |
| 15 | Slovenia | Cinkarna | Celje | Sulphate |
| 16 | Spain | Huntsman Pigments | Huelva | Sulphate |
| 17 | UK | Huntsman Pigments | Greatham | Chloride |
| 18 | UK | Cristal | Stallingborough | Chloride |

*Source: based on AEA Energy and Environment* (2007) *and information from TDMA members*

## 3.3 Consumption of titanium dioxide pigments

There are several sources of information regarding the consumption of $TiO_2$ in the EEA and its origin. Having considered electronic sources and information available to TDMA members, the following key figures are established as relevant to this analysis:

- The demand (consumption) of $TiO_2$ in the EEA was ca. **1,100 ktonnes** in 2015 compared to a global demand of just below 6 million tonnes;
- EEA demand accounts for ca. 20% of global demand for $TiO_2$;
- EEA demand comprises 67-68% EEA-produced $TiO_2$ and 32-33% $TiO_2$ imported from outside the EEA, the majority coming from the USA, Mexico and China[6]; and
- EEA exports of $TiO_2$ amounted to 360 ktonnes in 2015.

This breakdown is presented in **Figure 3–3**. To put these figures into further perspective, $TiO_2$ is the one of the most consumed pigments globally alongside widely used substances such as calcium carbonate, kaolin and carbon black.

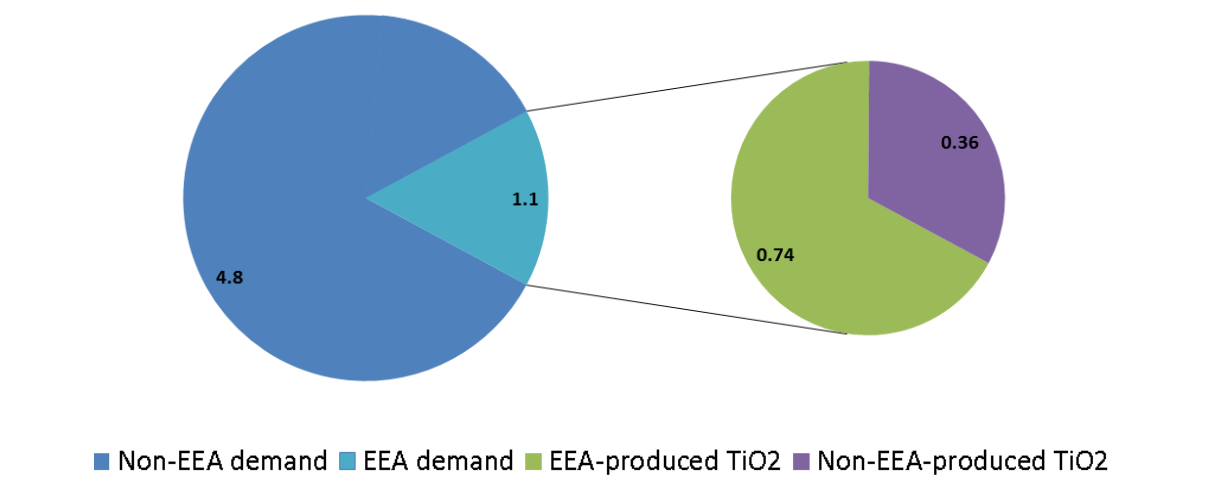



**Figure 3–3: Demand and origin of EEA consumption of $TiO_2$ (2015) – All figures in million tonnes per year**
*Source: information from TDMA members*

There are several drivers behind future demand for $TiO_2$ pigments, as shown in **Figure 3–4**. Location-wise, the real driver to growth is China, where the coatings and plastics industries continue to expand at high rates (IHS, 2015). Per capita consumption of $TiO_2$ in China is about 1 kilogram per year, compared with 2.7 kilograms for Western Europe and the USA (IHS, 2015).

[6] An analysis prepared by the European Commission in 2014 on the basis of 2012 data had found that 31% of EEA consumption was being imported into the EU and of this, the largest share (14%) came from North America, 7% came from the Asia-Pacific Region, 5% was imported from Latin America, 5% was imported from other European countries and 1% was imported from Africa and the Middle East. The EEA exported 399 ktonnes and imported 342 ktonnes $TiO_2$ in 2012. Except for the NAFTA region, the EEA was a net exporter vis-à-vis every other world region (European Commission, 2014).

## Main drivers (gross market size)

- GDP growth rate
- Housing market
- Durable goods sales
- Automotive sales
- Packaging sales

## Secondary drivers (desirable $TiO_2$ qualities)

- Increased use of tint base paints
- Laminate substitution of wood cabinets/flooring
- Down gauging of packaging films
- Increased uniformity in opacity/packaging UV protection

**Figure 3–4: Key drivers behind demand for $TiO_2$ pigments (2014)**
*Source: Chemours* (2015)



## 3.4 Applications for titanium dioxide

### 3.4.1 Overview

**Table 3–4** summarises publicly available information on the breakdown of the global consumption of $TiO_2$ pigments for the years 2013[7]. Other sources are available with somewhat variable percentages for specific market segments over the years.

**Table 3–4: Global $TiO_2$ pigments consumption breakdown by end-use sector**

| End-use sector | Year: 2013 |
|---|---|
| Paint | 53% (assumed architectural 36% and industrial 17%) |
| Plastic | 25% |
| Paper | Laminates: 10%; Paper: 2% |
| Inks | 4% |
| Specialty | Food, Pharma, etc.: 1%; Catalysts: 1%; Other: 4% |

*Source: Cefic, aggregates of TDMA members' data*

The table identifies four key market segments: paints (incorporating functional coatings and construction products), plastics, paper and inks. These typically account for over 90% of total $TiO_2$ pigment consumption in the world. These are described below as "mass applications" of $TiO_2$ with the remainder grouped in "specialty applications". An overview of the applications that are discussed below is given in **Figure 3–5** overleaf. The following paragraphs describe these applications, the role of $TiO_2$ and its technical advantages in detail.

[7] Note that more recent figures may be available; this is currently under investigation.

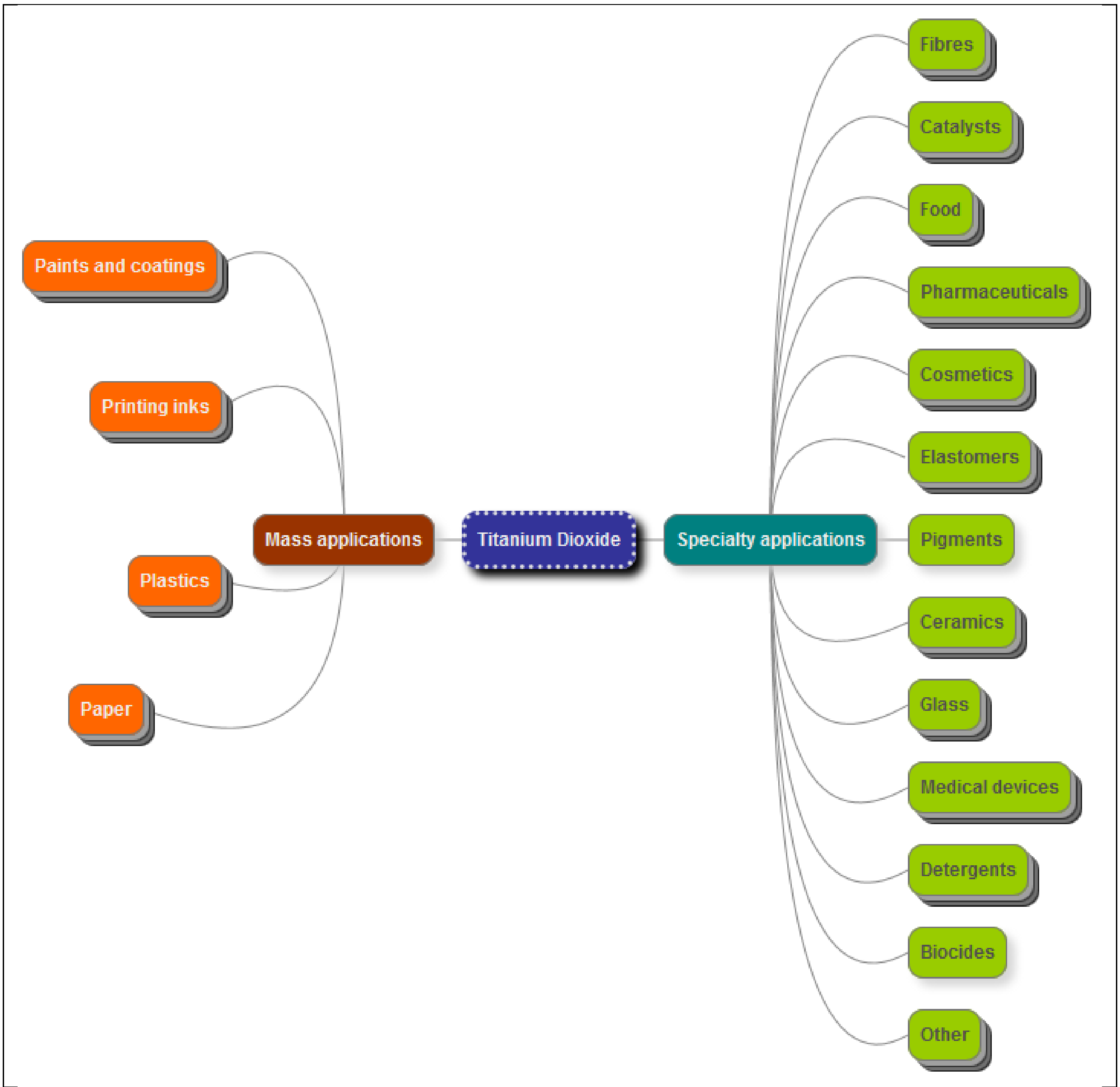



**Figure 3–5: Overview of applications of $TiO_2$ pigments**

The table overleaf summarises the key technical performance characteristics and advantages of $TiO_2$ in its different application areas. These are expanded upon later in the document when each application is considered in turn.

**Table 3–5: Overview of key technical performance characteristics and advantages of $TiO_2$ use in its different applications**

| Properties | Paints and coatings | Plastics | Paper | Inks | Construction products | Fibres | Catalysts | Food | Pharmaceuticals | Cosmetics | Elastomers | Pigments | Ceramics | Glass | Medical devices | Detergents | Biocides |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Good hiding power/opacity | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | ✓ | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | | |
| Ability to lighten coloured media | ✓ | ✓ | | ✓ | ✓ | | | ✓ | | | | ✓ | | | | | |
| Base for colour development | ✓ | ✓ | | ✓ | | | | ✓ | ✓ | | | ✓ | | ✓ | | | |
| Whiteness and brightness | ✓ | ✓ | ✓ | ✓ | ✓ | | | ✓ | | | ✓ | | ✓ | | ✓ | ✓ | |
| Stability to heat, light and weathering | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | ✓ | | | ✓ | ✓ | | | | | ✓ |
| Thermal stability and flame retardancy | ✓ | ✓ | | | ✓ | | | | | | | | | | | | |
| Light reflection | ✓ | ✓ | | | | | | | | ✓ | | | | | | | |
| UV absorbance | ✓ | ✓ | | ✓ | ✓ | ✓ | | ✓ | ✓ | ✓ | | | | ✓ | | | |
| Offers support for catalysts | | | | | | | ✓ | | | | | | | | | | |
| Photocatalytic activity | ✓ | | | | | | | | | | | | | ✓ | | | |
| Approved for use in specific areas | | ✓ | | | | | | ✓ | ✓ | ✓ | | | | | | | |
| High efficiency | ✓ | ✓ | ✓ | ✓ | ✓ | | | ✓ | ✓ | | | | ✓ | | ✓ | ✓ | |
| Easy dispersion and particle distribution and processability | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | | | ✓ | ✓ | ✓ | ✓ | | | | |
| Inertness in the presence of other components | ✓ | ✓ | | | ✓ | ✓ | | ✓ | | ✓ | ✓ | | | | | | |
| Purity | ✓ | | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | | | | | | | |
| Other | ✓ | ✓ | | | ✓ | ✓ | | | | ✓ | | | ✓ | ✓ | | ✓ | ✓ |

### 3.4.2 Paints and industrial coatings

***Range of applications***

As a white pigment, $TiO_2$ is by far the most important raw material for paints and coatings. Paint and coating applications for $TiO_2$ are numerous and diverse and can generally be broken down into architectural and industrial.

**Architectural paints** such as interior coatings ("wall paints"), façade coatings and wood and "trim" coatings, are used extensively in both DIY and professional applications. Examples include emulsions, lacquers, primers, sun protection (black-out) coatings, trim, floor (polyurethane, epoxies), woodcare varnishes and stains, garden paints and roof coatings, to name a few. These coatings are applied both on the interior and exterior of residential and commercial buildings and are applied to a variety of substrates.

**Figure 3–6: White paint and industrial coatings, the major use of $TiO_2$ pigment**
*Source: Brilliant White (http://brilliantwhite.life/), Cristal*

**Industrial coatings** provide aesthetics and functionality in a wide range of applications in a broad range of environments. Based on consultation with downstream users and literature, the key market segments include (Huntsman, 2016b; Chemours, 2016; VCI, 2016):

- Automotive coatings;
- Aerospace coatings;
- Marine coatings (yacht, etc.);
- Coil coatings;
- Can coatings;
- Anti-corrosion coatings;
- Powder coatings;
- Natural paints;
- UV-resistant coatings;
- Durable and non-durable powder coatings; and
- Road marking paints.

Under the industrial coatings heading, a very diverse range of less common coatings may be found. Examples include:

- **Flooring and other functional coatings**: here $TiO_2$ is used primarily for its white colour but also as a performance additive (conferring, for instance, UV resistance and fire retardancy). Example applications include:
  - Sports flooring coatings;
  - Floor coverings for heavy duty industrial floors;
  - Surface protection systems for concrete components;
  - Functional coatings in cars to e.g. eliminate squeaking as windows move up and down;
  - Functional coatings on wind turbines to aid movement; and
  - Ablatives and fire resistant coatings and intumescents;

- **Photoactive coatings (construction and air cleaning materials)**: many new applications are based on the photo-activity of $TiO_2$, including:
  - *Coatings on building materials* (e.g. glass, concrete, stone, plaster, paints, plastics) where outdoor photocatalysis (under UV light) decomposes pollutants such as nitrogen oxides and carbon monoxide and coatings for the protection of facades, roofs, other building components and PV modules against algae and mould;

  - *Self-cleaning materials for outdoor use*, for example in anti-fogging coatings and self-cleaning windows (ICIS, 2007) but also textiles (Montazer & Pakdel, 2011). When used as a photocatalytically active concrete additive to eliminate $NO_x$, exposure of the concrete surface to light causes the photocatalytic reaction to occur while, at the same time, the reaction of $TiO_2$ with the light also generates a superhydrophilic surface. Particles of dirt, soot and organic substances are undermined by the water and flushed off by the next rainfall. This special cement can be used in concrete block paving, concrete road surfaces, noise barriers, roof tiles and facades, for example, to create durable photocatalytic active surfaces; and

  - *Dispersions for indoor use*; $TiO_2$ pigments can also be used behind glass, with standard light bulbs and energy-saving lamps, in twilight, in scattered light and in the presence of UV radiation. They can effectively remove undesirable odours, degrade organic stains on surfaces, protect surfaces against germs and mould, and eliminate numerous pollutants, such as nicotine and tar; ammonia and amines; aldehydes and alcohols (e.g. formaldehyde, acetaldehyde, methanol); phenols and other aromatic compounds (e.g. benzene, p-chlorophenol, PCBs) (Kronos Worldwide, 2012; Calderone, 2015):

  Such $TiO_2$ photocatalysts have been found to be less susceptible to attack by various algae, fungi and bacteria (Kronos Worldwide, 2012) making them suitable for applications such as medical devices, food preparation surfaces, air conditioning filters and sanitary ware surfaces (ICIS, 2007) as well as textiles (Montazer, et al., 2011); and

- **Other functional applications**: these include castings for electrical and decorative applications where $TiO_2$ is used as a white pigment.

### *Typical concentrations of titanium dioxide*

Typical concentrations of $TiO_2$ in paints are given in **Table 3–6**.

| Table 3–6: Concentration of $TiO_2$ in paints and industrial coatings | |
|---|---|
| **Application** | **Typical $TiO_2$ concentration (by weight)** |
| Professional and DIY paints | From 0.1% (varnishes) to 50% (and up to 70% for filling compounds) |
| General industrial coatings | up to 30% |
| Anti-corrosion coatings | up to 20% |
| Automotive refinishing coatings | 25% |
| Eco-friendly natural paints | up to 40% |
| Wood paints | up to 20% |
| Road markings | 0.2-15% |
| *Source: data from consultation and VCI (2016)* | |

### *Technical characteristics and advantages*

$TiO_2$ is the most widely used pigment for white colours and white is the reference colour in domestic appliances and in most products used for buildings. $TiO_2$ offers an unrivalled array of beneficial effects, as shown in **Table 3–7**.

| Table 3–7: Advantages of $TiO_2$ use in the manufacture of paints | | |
|---|---|---|
| **Properties** | **Relevant key advantages** | **Notes, comments and sources** |
| Good hiding power/opacity | ✓ | Allows the manufacture of fully opaque coating systems |
| Ability to lighten coloured media | ✓ | |
| Base for colour development | ✓ | The colour can be engineered to provide users with a broad range of pigments to choose from (Huntsman, 2016). $TiO_2$ is not only used in white shades, but in other shades as well. It is the only white raw material that makes it possible to produce colours according to relevant standards (RAL, NCS) in a controlled way |
| Whiteness and brightness | ✓ | High brightness level, delivering whites which meet the expectations of end users (for example, high brightness makes road markings clearly visible to the road user at all times, including day and night time and inclement weather conditions) |
| Stability to heat, light and weathering | ✓ | $TiO_2$ displays humidity and light resistance and thermal stability |
| Thermal stability and flame retardancy | ✓ | It is thermally stable, not combustible and nearly insoluble in water. Thus, it shows retardancy performance; no other additive in combination with intumescent additives gives the same level of fire performance.<br>$TiO_2$ is stable at the high temperature needed for production and application of adhesives (curing may take place at 400 °C and few pigments will withstand such temperature) where the colour of the glue line is relevant and prevents the yellowing of the pigment |
| Light reflection | ✓ | |
| UV absorbance | ✓ | $TiO_2$ protects the polymer matric from effects of UV radiation by absorbing UV rays that would degrade the organic binder but also offers protection of the substrate on which paint is applied |

**Table 3–7: Advantages of $TiO_2$ use in the manufacture of paints**

| Properties | Relevant key advantages | Notes, comments and sources |
|---|---|---|
| Photocatalytic activity | ✓ | Two types of photochemical reaction occur on the surface of $TiO_2$ when appropriately irradiated: one is the photo-induced redox reaction of adsorbed substances, and the other is the photo-induced hydrophilic conversion of the $TiO_2$ itself. The combination of these two functions is the basis of numerous novel photocatalytic application |
| High efficiency | ✓ | $TiO_2$, having by far the greatest light scattering power of all white pigments, is the only white pigment showing sufficient hiding properties at relatively low dosage as a result of high tinting strength without a strong, undesirable viscosity increase |
| Easy dispersion and particle distribution and processability | ✓ | Due to its good wettability and dispersion, the formation of a large amount of sediment is prevented.<br>$TiO_2$ is relatively easy to process and does not generally require the use of specialised milling equipment |
| Inertness in the presence of other components | ✓ | Thickening which is caused by reactions with the vehicle remains excluded due to the chemical inertness of $TiO_2$. No impairment in the technical properties of the surface coating occurs, even if the container is repeatedly opened for the withdrawal of small portions (Kronos, 1968).<br>It is compatible with most polymer systems within the paint industry. It also has a low oil absorption value, which allows paints to maintain good flow and levelling properties even when used at high levels. In addition, the low oil absorption allows the formulation of high gloss finishes which retain their gloss for longer |
| Purity | ✓ | |
| Other | ✓ | **Anticorrosion effect**: when attempting to reduce the $TiO_2$ content in coil paints, the corrosion resistance of the whole coil coated galvanised steel may be reduced.<br>**Advantageous application properties**: flow, levelling, printing and transfer of coatings and desirable film build character (it allows increased film thickness to be applied).<br>**Low coefficient of friction / reduced abrasion**: this is important for numerous functional coatings |

### 3.4.3 Plastics

***Range of applications***

According to the European Plastics Converters (EuPC), $TiO_2$ finds wide use in the plastic conversion industry. The plastics converting area covers a variety of sectors where $TiO_2$ may be used such as packaging, building and construction, automotive, electric and electronic equipment, medical, household, leisure, footwear, clothes and advertising. The main sectors are packaging, building (flooring, wallcovering, furniture, playground and sports surfaces), construction (window profiles, thermal cladding, rainwater and drainage, wood replacement articles, roof, wall, ceiling and flooring coatings, heat reflective panels, water tanks), transport (automotive panels, automotive protective film, caravans, motorhomes, trucks, trains, tarpaulins, road markings), marine (motor boats, yachts, small craft, corrosion resistant coatings, off-shore wind turbines), clothing and sporting goods (EuPC and WSL (2016)).

**Figure 3–7: Examples of $TiO_2$ use in plastic articles**
*Source: Cristal*

In addition to colouring objects white, $TiO_2$ is also used to brighten colours, increase colour strength or to opacify otherwise transparent polymer materials. White is often used to provide contrast to other colours enabling e.g. to display text, symbols or logos. It is therefore used in any application where optics are important (such as packaging, including sleeves on bottles; automotive; and construction, both residential (e.g. white PVC window profiles) and commercial applications). Thermoplastic films are used for road markings and waterproofing membranes for construction and highways.

In the medical sector, $TiO_2$ finds use in pharmaceutical containers and coloured plastics used for medical container closures to provide increased opacity and a stable base colour. As the white component in both pigments and masterbatches, it has been used over the past 20 years in polymer materials for medical catheter tubing and injection moulded components.

A significant proportion of the $TiO_2$ used in this sector is not added directly as a powder but through the inclusion of masterbatches or compounds by the converters. In masterbatch, the $TiO_2$ is dispersed at high concentrations into a plastic resin, which is then used by plastics converters in film applications as well as in the manufacture of articles by injection moulding and sheets (plastic containers, bottles, packaging and agricultural films (Kronos Worldwide, 2016)). In a coloured masterbatch, more than half the composition of a colourant may be $TiO_2$; for example, the colourant may contain up to 60% $TiO_2$, with the colourant being used around at 2% in the desired plastic parts (SPI, 2016). Notably, the plastic masterbatch sector comprises companies of a variety of sizes, including many SMEs and each company will use $TiO_2$ pigments in quantities of several hundred tonnes per annum.

**Figure 3–8: $TiO_2$-containing plastic packaging**
*Source: Cristal*



In terms of the types of polymers that may contain $TiO_2$, these include:

- Polyolefin (Polyethylene and Polypropylene) for blow moulding, blown film, cast film, extrusion coating, high temperature cast film, injection moulding, liquid colourant, often used in packaging;

- PVC, mainly for construction applications (interior rigid, exterior rigid, flexible, plastisol);

- Engineering plastics for automotive and consumer goods (Acrylonitrile butadiene styrene (ABS), Polystyrene (PS) and High Impact Polystyrene (HIPS), Polycarbonate (PC) and PC blends, Polyamide (PA), Polybutylene terephthalate (PBT), Polyethylene terephthalate (PET), Polyphenylene ether (PPE), Polyphenylene sulphide (PPS), Polysulphone (PES), acrylics (PMA and PMMA), etc.); and

- Composites (e.g., EP and UP resin-based materials).

***Typical concentrations of titanium dioxide***

Consultation has revealed the following typical concentrations of $TiO_2$ in a range of plastic products:

- Masterbatches: up to 80%;
- Plastics (engineering and decorative): 1-10%;
- uPVC windows: 2-4%;
- PVC plastisol: 5%; and
- Packaging films and containers: 1-20%.

***Technical characteristics and advantages***

In plastics, $TiO_2$ is used as a white pigment, UV stabiliser, filler, inorganic flame retardant and mechanical/technical property enhancer. It is present in white masterbatches and is also used in a wide number of colour formulations to obtain the desired colour (NB. white masterbatches are mainly used in films, injection moulding and sheets). In these applications, the known advantages of $TiO_2$ include those shown in **Table 3–8**.

| Table 3–8: Advantages of $TiO_2$ use in the manufacture of plastics | | |
|---|---|---|
| **Properties** | **Relevant key advantages** | **Notes, comments and sources** |
| Good hiding power/opacity | ✓ | |
| Ability to lighten coloured media | ✓ | |
| Base for colour development | ✓ | Desirable colour whiteness and tone (bluish versus yellowish) |
| Whiteness and brightness | ✓ | |
| Stability to heat, light and weathering | ✓ | Light stabilisation and weatherability, particularly for products such as window profiles |
| Thermal stability and flame retardancy | ✓ | |
| Light reflection | ✓ | |
| UV absorbance | ✓ | Resistance to outdoor conditions and UV light and reflection of incident light. The ability to protect the polymer from the natural elements and degradation via UV attack allows long-term colour stability and, more importantly, the retention of physical performance, preventing the polymer becoming brittle, cracked or easily damaged. $TiO_2$ is the only white pigment that is stable for outdoor applications. It offers a desirable absorption profile of light wavelengths, preventing certain wavelengths from passing through and affecting materials' properties or the properties of the contents (food, medicines, etc.) |
| Approved for use in specific areas | ✓ | See above on food contact materials and pharmaceutical packaging |
| High efficiency | ✓ | |
| Easy dispersion and particle distribution and processability | ✓ | |
| Inertness in the presence of other components | ✓ | Optimal surface chemical treatment which enhances effectiveness and compatibility with a wide range of polymeric carriers to minimise the impact on mechanical/technical properties of the polymeric matrix used.<br>Neutral effect on nucleation of semi-crystalline polymers |
| Purity | | |
| Other | ✓ | Due to their high dielectric constant and their low loss angle, $TiO_2$ pigments open up the possibility of increasing the dielectric constants of plastics without considerably changing other properties (such as loss angle, dielectric strength and specific resistance) (Kronos, 1968) |



### 3.4.4 Paper

***Range of applications***

$TiO_2$ is mostly used as an opacifier and less frequently for its whitening, brightness and surface finishing properties in:

- Décor paper for laminate flooring and furniture;
- Packaging, including board;

- Printing and writing;
- Wallpapers; and
- Paper filling.

In paper laminates, several layers of paper are laminated together using melamine resin under high temperature and pressure. The top layer of paper contains $TiO_2$ and plastic resin and is the layer that is printed with decorative patterns (e.g. wood effects). Paper laminates are used to replace materials such as wood and tile in counter tops, furniture and wallboard (Kronos Worldwide, 2016). Here, a high opacity is required to stop the substrate underneath the printed material showing through following lamination. The $TiO_2$ is modified to provide excellent colour stability in the laminated article which enables longer life for the final product.

In packaging, papers that contain $TiO_2$ are used in food packaging where they are waxed prior to use in packing fatty or greasy foods; to prevent the paper becoming translucent during this process, the paper needs to have a high opacity. $TiO_2$ is also used in labels, for instance, C1S (e.g. Coated One Side) label papers where one side of the paper is coated for good printability and outlook whereas the reverse side is not (as it is typically attached to a surface (bottle, can, other packaging, etc.) by means of an adhesive). In cartons (board), coatings that contain $TiO_2$ improve the surface smoothness and gloss which are required to achieve high quality printing.

LWC (Lightweight Coated), Ultra Lightweight Coated (ULWC) and super-calendered low grammage papers are used when printing telephone directories, bibles, diaries or patient information sheets for inclusion in pharmaceutical products. $TiO_2$ can be used to enhance the opacity of such extremely thin, lightweight papers so they can be printed on both sides without the printing showing through (Huntsman, 2016d).

$TiO_2$ pigments ensure that wallpapers have very good adhesive properties, are light and have a brilliant wet opacity. Ideally wallpapers can be manually coated or printed using common printing processes. $TiO_2$ pigments give the paper all these properties and high lightfastness (Huntsman, 2016d). Without the opacity and surface texture/smoothness provided to the wallcovering base material by $TiO_2$, printing would be practically impossible for most printing methods. For many specialty papers, such as deco papers, $TiO_2$ is essential as no dull fibre type can be produced without it.

**Figure 3–9: $TiO_2$-containing paper**
*Source: Cristal*

***Typical concentrations of titanium dioxide***

$TiO_2$ levels can typically be in the 20-40% range of the décor paper. In wallpapers, $TiO_2$ may be found in concentrations in the range of 1-10%.

*Technical characteristics and advantages*

Use of $TiO_2$ in paper is accompanied by significant technical advantages as shown in **Table 3–9**.

**Table 3–9: Advantages of $TiO_2$ use in the manufacture of paper**

| Properties | Relevant key advantages | Notes, comments and sources |
|---|---|---|
| Good hiding power/opacity | ✓ | It ensures that paper and board maintains its high opacity during the conversion process (calendering, waxing, impregnation) |
| Whiteness and brightness | ✓ | |
| Stability to heat, light and weathering | ✓ | It assists in preventing the paper material from fading or changing colour after prolonged exposure to sunlight and other weathering agents (Kronos Worldwide, 2016) |
| High efficiency | ✓ | $TiO_2$ has good S (light scattering coefficient) and K (light absorption coefficient) values. Other pigments, such as calcium carbonate and calcinated clay, may have only one good value, either S or K value. Thus, although $TiO_2$ is not the cheapest opacifier in terms of cost per kilogram, it is cost-effective and helps maintain important paper/board properties at low dosage.<br>Due to their high tinting strength and hiding power, it is possible to prepare very good white and opaque printing papers even from cheap raw materials by means of a quite thin coating of pigment (Kronos, 1968) |
| Easy dispersion and particle distribution and processability | ✓ | $TiO_2$ adheres well to the paper fibre |

## 3.4.5 Inks

*Range of applications*

$TiO_2$ has been used for several decades in toners, inks, backings for inkjet printing substrates, coated layers on specialty foils, and incorporated into PET for some applications (I&P Europe, 2016). Notable applications include (Huntsman, 2016e):

- **Inks for packaging**: in flexible packaging (such as plastic or aluminium films), the consistency and performance of the white ink are crucial for the quality of the printed image. The white ink should deliver excellent hiding power to allow high quality colour printing. $TiO_2$ pigments offer a broad performance spectrum: high gloss, excellent hiding power, superb opacity and low abrasion, sparkling effects where desired, and are suitable for use in solvent, water and oil-based inks as well as in UV curable inks. They perform well in flexo, gravure and screen printing with gravure inks, pad printing, inkjet or sheet fed offset applications and are suitable for flexible, paper and card or metal packaging. Because of the high opacity of $TiO_2$, the white layer reduces the metallic effect in laminates containing alu-foil or metallised plastic film;

- **Labels**: UV curable printing inks for the narrow to mid–web may contain $TiO_2$ and are used in self-adhesive labels, wrap around labels, lidding, shrink sleeve, in-mould labelling, etc. $TiO_2$ is used to produce high opacity white printing inks to allow the conversion of clear/metallic materials;

- **Toner**: $TiO_2$ pigment offers free flow and charge control;

- **Writing materials and children's modelling materials**: these include coloured pencils, crayons, finger paints, school tempera paints, lacquers and modelling clays (NB. $TiO_2$ is present in almost all plastic parts of pens and related products); and

- **Inks for textiles and leather**: $TiO_2$ pigments can support the delivery of a strong opaque colour that helps printed textiles stand out.

***Typical concentrations of titanium dioxide***

Typical concentrations of $TiO_2$ in inks and related products are given in **Table 3–10**.

**Table 3–10: Concentration of $TiO_2$ in inks and related products**

| Application | Typical $TiO_2$ concentration |
|---|---|
| White printing inks | Up to 50-60%, even 70% in dispersions |
| Printing pastes | White concentrate: 80%<br>Ready-to-use compound: 20-30% |
| Shaded inks | 5-10% |
| Pencils and similar products | 3-35% |
| Correction fluids | Up to 50% |
| Artists' colours | 0.1-100% |
| Toner | 1-5% |
| Erasers | ca. 1% |
| *Source: data from consultation* | |

***Technical characteristics and advantages***

$TiO_2$ offers the following technical advantages to inks and ink-related products.

**Table 3–11: Advantages of $TiO_2$ use in the manufacture of inks**

| Properties | Relevant key advantages | Notes, comments and sources |
|---|---|---|
| Good hiding power/opacity | ✓ | In graphic arts (printing), ink is usually applied in a much thinner film than a normal coating (a few microns), and for that very fine particles of titanium dioxide are used. Ink correction fluid for paper relies on $TiO_2$ to hide errors. Inks for concealed writing (scratch-off lottery tickets) likewise use $TiO_2$ because of its superior hiding power (Gázquez, et al., 2014) |
| Ability to lighten coloured media | ✓ | |
| Base for colour development | ✓ | $TiO_2$ is used as white pigment, but also for colouration support in allowing (a) the dyes of the formula to be fixed; and (b) the development of a wide range of colours to create pastel shades and increase the colour gamut of the available pigment range |
| Whiteness and brightness | ✓ | |
| Stability to heat, light and weathering | ✓ | |
| UV absorbance | ✓ | $TiO_2$ protects inorganic pigments from light through UV absorbance |
| High efficiency | ✓ | |

| Table 3–11: Advantages of $TiO_2$ use in the manufacture of inks | | |
|---|---|---|
| **Properties** | **Relevant key advantages** | **Notes, comments and sources** |
| Easy dispersion and particle distribution and processability | ✓ | $TiO_2$ can be readily dispersed, achieve rapid wetting at low viscosities. $TiO_2$ allows inks to achieve very high print quality (excellent gloss) while not interfering with the technical requirements of printing machinery, including low abrasion, high printing speed and high temperatures (Kronos Worldwide, 2016) |
| Purity | ✓ | $TiO_2$ is accompanied by high purity and high definition of particle size |

## 3.4.6 Construction products

***Range of applications***

There are several products, typically in a coating form, which may contain $TiO_2$ and can be used alongside architectural paints. These include applications which might be considered to be affiliated to either paints or plastics. In these, historically, $TiO_2$ has replaced other white pigments like "white lead" (lead carbonate) which is toxicologically unsafe (VCI, 2016). Examples of relevant applications include:

- **Construction products**: a wide variety of construction products may contain $TiO_2$ as a colouring pigment. These include:
    - Plasters (synthetic plasters, emulsion bound, mineral plasters);
    - Fillers (such as wood and wall fillers);
    - Caulks;
    - Pigmented mortars (e.g. jointing grouts); and
    - Synthetic resin screeds;
- **Adhesives**, for example:
    - Liquid polyaddition, polycondensation and polymerisation adhesives like polyurethanes, epoxides, silane modified polymers, acrylates and anaerobically curing adhesives and adhesive films;
    - EVA- and PE-based thermoplastic hot melts;
    - Outside the construction sector, natural water-based gelatine adhesive for the paper and cardboard industry. These glues are generally yellow, brown or beige. $TiO_2$ is used to whiten the adhesive without changing other technical properties like other fillers would do. The whitened adhesives are used, for instance, in the back lining of books;
    - Water based PVA dispersion glue. $TiO_2$ is used to whiten the dispersion so it can be used as a master batch and colour can be added by a downstream user. The customer


**Figure 3–10: $TiO_2$ can be found in adhesives**
*Source: royalty-free photo*

then uses this adhesive to glue textile fibres to paper to make wallpaper. $TiO_2$ gives a whitening aspect no other product can provide. All produced products are in liquid form;
  - Pigmentation of black-out foils and films; and
  - Flock adhesives; and

- **Sealants**: $TiO_2$ is used as a white pigment in roles similar to those for adhesives. One such example includes silicone sealants.

As a constituent of adhesive formulations, $TiO_2$ is not only used in the construction sector but also in the paper and packaging industries, the construction of motorcars, railway vehicles, ships and airplanes, in electrical and electronic applications, the dental sector and other industries. $TiO_2$ may also be found in coloured adhesives (e.g. light green adhesive to glue artificial lawn or red adhesive to glue tartan tracks) which are first brightened with $TiO_2$ and then coloured with the desired colour. Often, the use of $TiO_2$ enables the use of coloured natural resins. Without pigment, application would not be possible with a visible bond seam (VCI, 2016).

***Typical concentrations of titanium dioxide***

Based on consultation findings and literature (VCI, 2016), typical concentrations of $TiO_2$ in construction products include:

- Concrete, mortars, grout, plaster: 0.1-10%; and
- Sealants and adhesives: 1-15%.

***Technical characteristics and advantages***

The technical advantages $TiO_2$ offers to construction products are largely those described earlier for paints and industrial coatings.

### 3.4.7 Fibre applications

***Range of applications***

*Textile and leather applications*

Anatase grades may be used for delustering man-made fibres. Delustering plays a leading role in the complex production of man-made fibres such as polyester, polyamide, acrylic, viscose, rayon, but also cellulose acetate fibres. A melt-conditioning process helps to provide the fibre producer with greater flexibility in changing between various degrees of delustration (i.e., between lustrous, semi-matte and full-dull grades) (Huntsman, 2016g).

Fibres of variable dullness (depending on the proportion of $TiO_2$ used[8]) may be used in consumer textiles, including high-class, high-fashion textile products of the most well-known and prestigious fashion brands where dull lustre and handfeel is sought after.

[8] In the field of synthetics fibres, a physical parameter named "ahine" is often used, defined as the amount of reflected light. This is controlled by the amount of $TiO_2$ added in the manufacturing process or polymerisation; bright contains 0.06% $TiO_2$; semi-opaque, 0.3% $TiO_2$; and opaque, 2% $TiO_2$ (Gázquez, et al., 2014).

When $TiO_2$ is used as white pigment, it may act as (VCI, 2016):

- A component of a coating applied on commercial textiles such as those for sun protection (black-out, dim-out) / roller and vertical blinds / decorative textile ceilings;
- A component of printing inks (e.g. inkjet, digital print) and in printing pastes for pigment print;
- A carrier material for biocides; and
- A component for the pigmentation of leather (i.e. pigment dispersions in polymer matrices which are sprayed onto leather to produce pigmented leathers).

Another textiles-related but not fibre-based application for $TiO_2$ is the pigmentation of thermotransfer coatings used on textiles.

*Non-textile applications*

$TiO_2$ may also be used in the delustering (matting) of man-made fibres, e.g. for white pigmentation of glass fibre nonwovens, for example cigarette filter tow, where cellulose acetate fibre is used.

***Typical concentrations of titanium dioxide***

$TiO_2$ is used in delustering within the range of 0.1-1.5% with the level depending on the lustre required by end users (CIRFS, 2016).

***Technical characteristics and advantages***

The key technical advantages of $TiO_2$ in its fibre applications are shown in **Table 3–12**.

**Table 3–12: Advantages of $TiO_2$ use in the manufacture of fibres**

| Properties | Relevant key advantages | Notes, comments and sources |
|---|---|---|
| Good hiding power/opacity | ✓ | Originally transparent man-made fibres are delustered to differing degrees using $TiO_2$, thus losing their transparency. The delustering process makes use of anatase pigments' scattering power, which causes the fibre to appear optically whiter, more opaque, more matte and duller |
| Stability to heat, light and weathering | ✓ | $TiO_2$ special surface treated grades ensure good adherence to the substrate and high light-fastness and non-colour fading performance (i.e. UV resilience), which is paramount for man-made fibres designed for outdoor applications. Pigments for textile fabrics are also sweat fast |
| UV absorbance | ✓ | See above |
| Easy dispersion and particle distribution and processability | ✓ | Anatase pigments reduce reflection in screen printing processes, permitting much more reliable and faster thread guidance and weaving behaviour, and thus enhancing productivity (Huntsman, 2016f) and have an effect on colour impression |
| Inertness in the presence of other components | ✓ | $TiO_2$ is chemically inert thus does not react in processing; the $TiO_2$ grades used are practically free of any coarse fraction and show minimal abrasion, which ensures good filter-pack lives at the spinnerets and decreased amounts of filament breakage during production |

| Table 3–12: Advantages of $TiO_2$ use in the manufacture of fibres | | |
|---|---|---|
| **Properties** | **Relevant key advantages** | **Notes, comments and sources** |
| Other | ✓ | Anatase pigments, which have a lower Mohs hardness than rutile counterparts and are always used for applications in which lower abrasiveness will generate a technical benefit, are selected for this purpose. Their addition impacts on the touch of the articles |

## 3.4.8 Catalysts

$TiO_2$ is used as a catalyst support in Selective Catalytic Reduction (SCR) processes for the reduction of oxides of nitrogen in exhaust gases, not only in mobile applications such as road, rail and marine engines, but also in stationary installations such as power-generating and other industrial plants.

**Figure 3–11: $TiO_2$-based catalysts**
*Source: Cristal*

$TiO_2$ is the catalyst of choice for the desulphurisation of crude oil (Claus process, where $TiO_2$ has the technical advantage that it is a sulphur-resistant carrier material), for the oxidative synthesis of organic compounds, and in a large range of other chemical processes (Huntsman, 2016l). $TiO_2$ is used both as a carrier material and as an acidic catalytically active material for the selective conversion of feedstocks into the desired end products (e.g., phthalic anhydride). Its use as an ingredient of the catalyst in the process reduces raw material cost (e.g., *o*-xylene, naphthalene) for customers, reduces by-product formation (generation of waste), reduces emissions in the process (e.g. lower $CO_x$), ensures long catalyst lifetimes, and thus less cost for customers and reduction of waste from spent catalyst.

## 3.4.9 Food and feed additives and packaging

***Range of applications***

*Titanium dioxide as a food component*

In the EU, $TiO_2$ (E171) is listed in Annex I of Directive 94/36/EEC as a permitted colour in foodstuff and it is presumed as safe. E171 is accompanied by specific purity criteria (Commission Regulation (EU) No 231/2012) and its use is authorised by Regulation (EC) No 1333/2008 on food additives. It can be found at *quantum satis* (i.e. as much as needed) in many foods, for instance:

- Dairy analogues, including beverage whiteners;
- Edible ices – $TiO_2$ is a key ingredient in a range of pearlescent colourants that are used to colour ice cream coatings and chocolate/confectionary pieces that are used to decorate ice cream products;
- Confectionery including breath refreshening microsweets (where it is often used to provide a barrier between different colours);
- Chewing gum and lollipops;
- Decorations, coatings and fillings, except fruit based fillings;
- Fine bakery wares;
- Casings, coatings and decorations for meat (except edible external coating of pasturmas);
- Soups and broths;
- Cottage and mozzarella cheeses, where it is used to increase opacity (EUFIC, 2016);
- Sauces - including pickles, relishes, chutney, horseradish sauce and piccalilli – excluding tomato-based sauces;
- Salad and savoury based sandwich spreads;
- Flavoured drinks - excluding chocolate milk and malt products, to increase rich texture and turbidity (European Commission, 2014);
- Processed nuts; and
- Desserts.

**Figure 3–12: Examples of $TiO_2$ use in foodstuff**
*Source: Brilliant White (http://brilliantwhite.life/) and royalty-free photos*

$TiO_2$ is also used as a dyestuff/pigment in dyes for egg shell decoration.

It is also present as an approved colourant feed additive in Annex I of Regulation 1831/2003/EC. In pet foods, it is used to obtain uniformity of colour and appearance (Kronos Worldwide, 2016; Huntsman, 2016j; TDMA, 2013).

*Titanium dioxide as a component of food packaging*

Beyond its use as an additive within food, $TiO_2$ can be found in food contact materials. $TiO_2$'s entries in the Union List of Additives for Food Contact Materials (European Regulation (EU) 10/2011)[9] are shown in **Table 3–13**Errore. L'origine riferimento non è stata trovata.. It has a high SML (specific migration limit) of 60 mg/kg from plastic materials and articles intended to come into contact with food.



[9] It is worth noting that **coated and printed plastic materials** and articles are covered by the scope of European Regulation (EU) 10/2011. Plastics held together by adhesives are also covered by its scope. However, substances used only in printing inks, adhesives and coatings are not included in the Union list because these layers are not subject to the compositional requirements of the Plastics Regulation. The only exceptions are substances used in coatings which form gaskets in closures and in caps. The requirements for printing inks, adhesives and coatings are intended to be set out in separate specific Union measures. Until such measures are adopted, they are covered by national law. If a substance used in a coating, a printing ink or an adhesive is listed in the European Union list, the final material or article has to comply with the migration limit of this substance, even if the substance is used in the coating, printing ink or adhesive only. Even though **colourants** fall under the definition of additives, they are not covered by the Union list of substances. Colourants used in plastics are covered by national measures and are subject to risk assessment in line with Article 19 of the European Union List Regulation.

**Table 3–13: Food Contact Material Union list entries for $TiO_2$**

| Entry | Chemical name | Use | Restrictions |
|---|---|---|---|
| 610 | Titanium dioxide | Additive or polymer production aid | |
| 805 | Titanium dioxide, coated with a copolymer of n-octyltrichlorosilane and [aminotris(methylenephosphonic acid), penta sodium salt] | Additive or polymer production aid | The content of the surface treatment copolymer of the coated titanium dioxide is less than 1% w/w |
| 873 | Titanium dioxide reacted with octyltriethoxysilane | Additive or polymer production aid | Reaction product of titanium dioxide with up to 2% w/w surface treatment substance octyltriethoxysilane, processed at high temperatures. |

As discussed earlier in this report, the presence of $TiO_2$ can be established in:

- **Packaging**: $TiO_2$ can be found in plastic and paper as a whitener, food-contact coatings, food-packaging adhesives, food-contact polymers, paper/paperboard in contact with aqueous/fatty foods, filler in food-contact rubber articles for repeated use, food-contact textiles/fibres; and
- **Printing inks for food packaging**: $TiO_2$ is used as a dye for inks.

***Technical characteristics and advantages***

$TiO_2$ (E171) is the most widely used white food colour because of key advantages, as shown in **Table 3–14Errore. L'origine riferimento non è stata trovata.**.

**Table 3–14: Advantages of $TiO_2$ use in foodstuff**

| Properties | Relevant key advantages | Notes, comments and sources |
|---|---|---|
| Good hiding power/opacity | ✓ | |
| Ability to lighten coloured media | ✓ | |
| Base for colour development | ✓ | In conjunction with E555 (Potassium aluminium silicate - mica) $TiO_2$ has a unique use to produce 'glitter' powders which are widely used as decorations for fine bakery wares |
| Whiteness and brightness | ✓ | |
| Stability to heat, light and weathering | ✓ | |
| UV absorbance | ✓ | $TiO_2$ can prevent premature spoilage in foods that react with UV light |

| Table 3–14: Advantages of $TiO_2$ use in foodstuff | | |
|---|---|---|
| **Properties** | **Relevant key advantages** | **Notes, comments and sources** |
| Approved for use in specific areas | ✓ | As noted above, $TiO_2$ is considered to be safe by oral ingestion and is authorised under the EU Additives Regulation (EC) No 1333/2008 at Annex II as a Group II food colour which may be used in most foods at *quantum satis*. A recent EFSA opinion on the re-evaluation of its safety for use as a food additive published on 14 September 2016 concluded that available data on $TiO_2$ in food do not indicate health concerns for consumers[10] |
| High efficiency | ✓ | |
| Easy dispersion and particle distribution and processability | | |
| Inertness in the presence of other components | ✓ | $TiO_2$ is chemically very stable and inert with very low bioavailability. It does not react with other substances present in foods (for example, food acids) and it will withstand cooking/baking processes unchanged |
| Purity | ✓ | |

## 3.4.10Pharmaceuticals

***Range of applications***

$TiO_2$ is presented in Ph Eur monograph 0150[11]. $TiO_2$'s chemical purity meets the requirements of important official pharmaceuticals standards, such as the European pharmacopoeia (Ph. Eur/EP), the Japanese pharmacopoeia (JP) and the US pharmacopoeia (USP) (Huntsman, 2016k). In addition, $TiO_2$ is the only opacifying agent for materials used for containers that is named in the European Pharmacopoeia's Section 3.1.

Similar to food applications, $TiO_2$ applications in pharmaceuticals can be both as an additive to medication and as an additive to packaging:

- **Medicine component**:
  - *Excipient (colourant)*: ultra-high purity $TiO_2$ as per Ph Eur is used in many medicinal products as excipient, mainly as the colourant E171. Its toxicological safety for dermal or oral applications makes titanium dioxide an ideal and safe excipient. It can be found in liquid medicines where it provides uniformity of colour. The use of $TiO_2$ along with other colourants enables pharmaceuticals manufacturers to produce products with a great variety of colours. Such colour variety is extremely important to avoid medication errors. Without $TiO_2$, the available colour palette would be much more limited.
  - *Film coating*: $TiO_2$ is used in the film-coating of tablets and (gelatine) capsules (both pharmaceuticals and nutraceuticals). The pigment is added because this adheres to and covers the tablet core best. Without the use of $TiO_2$ the colour is not as smooth and the

10 Available at http://www.efsa.europa.eu/en/efsajournal/pub/4545 (accessed on 24 October 2016).

11 See http://www.drugfuture.com/Pharmacopoeia/EP7/DATA/0150E.PDF (accessed on 20 June 2016).

colour, spots or different coloured powder particles would come through and the surface would not be smooth and homogeneous;

**Figure 3–13: Nutraceutical tablets and pharmaceutical capsules that contain $TiO_2$**
*Source: royalty-free photos*

- **Packaging**: $TiO_2$ is used in the manufacture of glass containers, opaque child-resistant pharma blister packages and medical container closures as it offers a guarantee of chemical inertness for pharmaceutical applications. $TiO_2$ achieves the colour and spectral characteristics required by the current regulations and physicochemical characteristics required by current standards for pharmaceutical vessels. It also offers protection from UV radiation in certain bandwidth, which is important when protecting medication in its containers from the damaging effects of light, helping extend product shelf life (Kronos Worldwide, 2016; Huntsman, 2016k). According to MedPharmPlast (2016), there are currently at least 275 light-sensitive oral prescription drugs (King, 2009) and over 300 light-sensitive injectable medicinal products (University of Illinois at Chicago College of Pharmacy, 2014). These drugs thus require pharmaceutical packaging that is able to prevent the passage of light, particularly in the spectrum 290 to 450nm to prevent degradation of the pharmaceuticals. This requirement is defined in US Pharmacopeia <671> and is critical for obtaining marketing authorisation for light-sensitive pharmaceuticals. To reduce transmission, colours that filter (e.g. amber) need to be added. In the case of transparent packaging or in other cases an opacifying agent needs to be added to the polymer.

***Typical concentrations of titanium dioxide***

Typically, $TiO_2$ is present at concentrations of up to 3%.

***Technical characteristics and advantages***

**Table 3–15** summarises the technical advantages of $TiO_2$ in pharmaceutical applications.

| Table 3–15: Advantages of $TiO_2$ use in pharmaceuticals | | |
|---|---|---|
| **Properties** | **Relevant key advantages** | **Notes, comments and sources** |
| Good hiding power/opacity | ✓ | |
| Base for colour development | ✓ | |
| UV absorbance | ✓ | Offers protection to the active pharmaceutical ingredients (APIs) of medicinal products |
| Approved for use in specific areas | ✓ | Established to be safe (being recognised as the E171 food additive) |
| High efficiency | ✓ | |
| Purity | ✓ | |

## 3.4.11 Cosmetics

***Range of applications***

$TiO_2$ is currently listed in Annex IV of the Cosmetics Regulation EC 1223/2009 (list of colorants allowed in cosmetic products); and Annex VI (list of UV filters allowed in cosmetic products), as shown in **Table 3–16**Errore. L'origine riferimento non è stata trovata..

| Table 3–16: Cosmetics Regulation entries for $TiO_2$ | | | |
|---|---|---|---|
| **Annex** | | **Entry No.** | **Notes** |
| IV | List of colorants allowed in cosmetic products | 143 | Purity criteria as set out in Commission Directive 95/45/EC (E 171) |
| VI | List of UV filters allowed in cosmetic products | 27 | Maximum concentration in ready for use preparation: 25%[12] |
| VI | List of UV filters allowed in cosmetic products | 27a | Titanium Dioxide (nano):Maximum concentration in ready for use preparation: 25%[13] |

More specifically, $TiO_2$'s colour, opacity and UV absorbance qualities mean that it can find many applications in cosmetics, including:

- **Sunscreens**: $TiO_2$ (INCI name Titanium Dioxide and Titanium Dioxide (nano)) at the non-nano and nano-scale is an effective inorganic UV-filter and, in the case of the nano-form, colourless. This UV-filter has been recognised as safe by the European scientific body (SCCS) up to a maximum concentration of 25% in cosmetics, when applied on healthy, intact or sunburnt skin. $TiO_2$ is one

[12] It is understood that in other jurisdictions (e.g. Japan) no upper limit has been established.

[13] Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation. Only nanomaterials meeting the characteristics set out in the Regulation are allowed. In case of combined use of Titanium Dioxide and Titanium Dioxide (nano), the sum shall not exceed 25%.

of the very few globally approved UV filters/sunscreen actives which are of relevance for global formulations (CosmeticsEurope, 2016);

- **Colour cosmetics (make-up) and skin care products**: $TiO_2$ (INCI name CI 77891) as a colorant can confer satiny effects, lustre effects and interference colours. It can be found in products such as foundation and face powder. Due to its light diffusing qualities, its pearlescent effects find use in lipstick, eye-shadow and blushers. For these applications, no limit concentration has been established;

**Figure 3–14: Example of a $TiO_2$ use in cosmetics – Sunscreens and face creams**
*Source: Brilliant White (http://brilliantwhite.life/) and royalty-free photo*

- **Soaps (liquid and solid), shampoos and shower gels and depilatory products and other products**: $TiO_2$ acts as a pearlescent colourant and has opacifier effects due to its high refractive index;

- **Toothpaste**: $TiO_2$ can be used both as white pigment and abrasive;

- **Hair colour formulations**: $TiO_2$ is used as an opacifier;

- **Nail polishes**: $TiO_2$ is used as a colourant and opacifier in UV-curing nail polishes and gels that are sold into the professional and retail cosmetics markets. It may also be present in nail (anaerobic) adhesives; and

- **Other**: $TiO_2$ is also used as filler in various cosmetic functions (Huntsman, 2016i).

***Typical concentrations of titanium dioxide***

Example concentrations of $TiO_2$ in consumer formulations are as follows (NB. this list is not exhaustive and is based on a limited number of consultee contributions):

- As colouring pigment: Variable (e.g. applications as a filler require higher dosage);
- Sunscreens: up to 25%;
- Toothpaste: 0.5-2%; and
- Nail polish: 0.1-10%.

***Technical characteristics and advantages***

The wide use of $TiO_2$ in cosmetics derives from key properties of the pigment, as shown below.

**Table 3–17: Advantages of $TiO_2$ use in the manufacture of cosmetics**

| Properties | Relevant key advantages | Notes, comments and sources |
|---|---|---|
| Good hiding power/opacity | ✓ | When the pigment size becomes bigger, visible light is blocked by $TiO_2$ and skin appears white. This is particularly useful in decorative cosmetics, such as make-up sticks and powders, where the consumer may want to hide skin problems or simply improve his/her appearance and confidence. In oxidative hair colourants (which represent a fragile, reactive chemical environment), small amounts (0.1%) of $TiO_2$ boost opacity of the mass, thus increasing mass visibility on hair. This allows stylists or consumers to apply the correct amount of product (i.e. avoids overdosing). In addition to this technical performance and efficacy, $TiO_2$ does not adversely affect the stability of the colour tint, an undesirable effect which may occur with other (less efficient) opacifiers |
| Light reflection | ✓ | $TiO_2$ provides a very good SPF performance (protection against UVB radiations) and a significant UVA protection. The particles form a protective film on the uppermost skin layer and scatter and absorb the UV rays of the sun. In this manner, the skin is protected against UV radiation and its harmful effects to health (sunburn, DNA damage, skin aging, etc.). Particularly good sunscreen effects can be achieved through the combination with other filter substances. Nanoscale $TiO_2$ in sunscreen products is invisible to the human eye and leaves no whitish film on the skin, which motivates consumers to use more generous applications that are absolutely essential to achieve sun protection (VCI, 2016) |
| UV absorbance | ✓ | |
| Approved for use in specific areas | ✓ | Approved as a UV filter in sunscreens |
| Easy dispersion and particle distribution and processability | ✓ | |
| Inertness in the presence of other components | ✓ | $TiO_2$ shows good compatibilities with several organic filters to allow a broad coverage of the whole UV-range and ensure true broad spectrum protection from the sun's damaging rays. $TiO_2$ is one of the very few globally approved UV filters / sunscreen actives relevant for global formulations. $TiO_2$ is the UV filter of choice for SPF15 or higher products whilst providing a non-greasy feel, a preferable attribute for e.g. secondary sunscreen products (face creams with UV benefit). It can also demonstrate good stability and processability in formulation processes |
| Purity | ✓ | |
| Other | ✓ | **Skin tolerance**: another outstanding feature of $TiO_2$ is its optimal skin tolerance; intolerances or allergic reactions to $TiO_2$ are practically unknown (VCI, 2016) |

## 3.4.12Elastomers

***Range of applications***

$TiO_2$ is used as a filler and pigment in rubber-based applications including:

- **Tyres**: $TiO_2$ is used as a white pigment in tyres to produce white sidewalls (thanks to its excellent tinting strength which allows the use of very small quantities) and in the manufacture of general rubber goods (GRG), including food contact materials, construction materials, and other industrial products;

- **Rubber-to-substrate parts**: $TiO_2$ is used in elastomer bonding agents as a pigment, UV protector and filler required at the vulcanisation step to produce a matrix in which the functional crosslinkers are dispensed. $TiO_2$ is heat resistant, insoluble in water and resistant to aggressive rubber chemicals. End uses include rubber-to-substrate parts such as mounts, stators, bushings, brake pads, etc. Rubber-metal parts with essential functionality in the automotive industry include airbag absorbers, anti-vibration elements, damping sleeves, chassis parts, steering parts, engine bearings and several others;

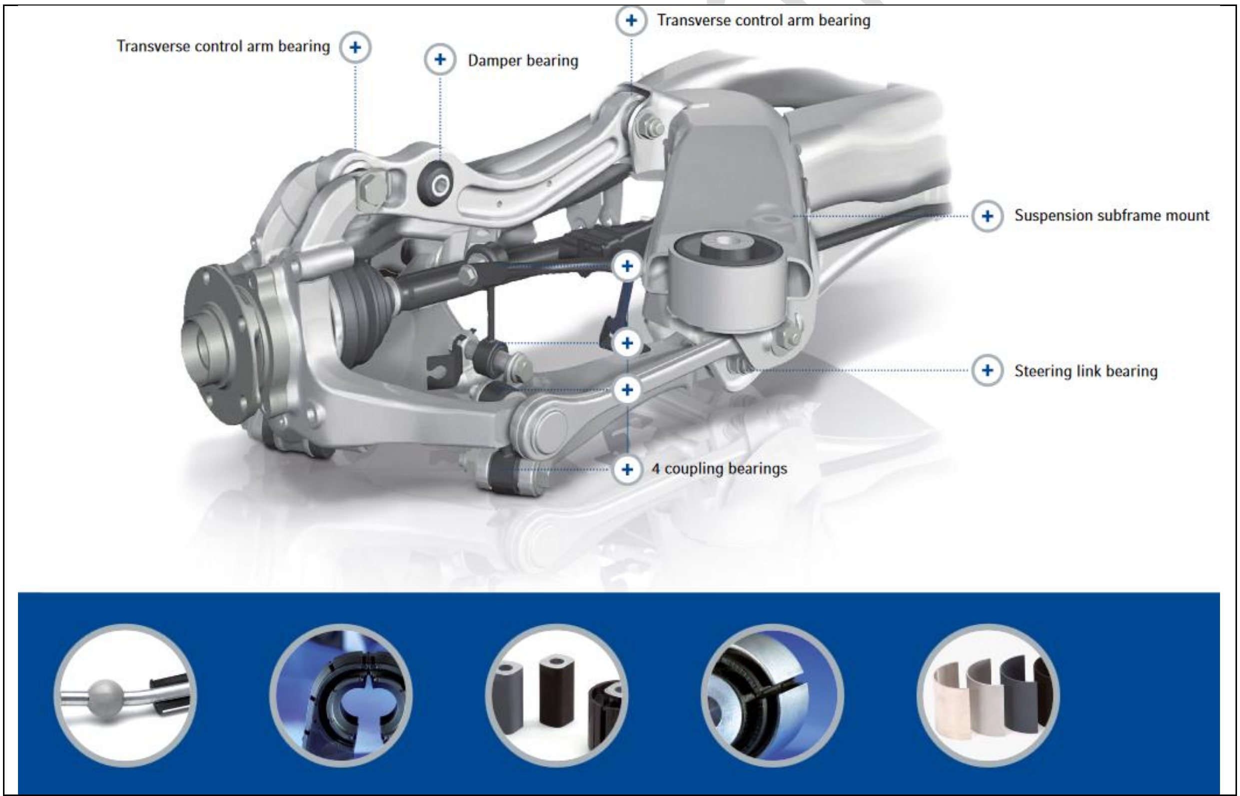



**Figure 3–15: Illustration of an automobile front axle. Parts such as damper bearing, steering link bearing or suspension subframe mount those highlighted in the picture are parts made with $TiO_2$ elastomer bonding agents**
*Source: GOTEC Gorschlüter Gmbh (available at [http://gotec-gmbh.de/user-data/downloads/gotec_IB_ENG.pdf](http://gotec-gmbh.de/user-data/downloads/gotec_IB_ENG.pdf), accessed on 14 December 2016)*

- **Pastes**: $TiO_2$ is used for heat stabilisation in (pastes for) silicone rubber; and

- **Fluorinated rubber**: $TiO_2$ is used in fluorinated rubber and rubber thread.

***Typical concentrations of titanium dioxide***

Typical concentrations of $TiO_2$ in the above products include:

- Colour pastes for silicone rubbers: 30-55%;
- Silicone: 1-5%;
- General rubber goods (GRG): 0.5-20% (depending on the application); and
- Tyres: <1%.

***Technical characteristics and advantages***

$TiO_2$ offers the following technical advantages to rubber products.

**Table 3–18: Advantages of $TiO_2$ use in the manufacture of elastomers**

| Properties | Relevant key advantages | Notes, comments and sources |
|---|---|---|
| Whiteness and brightness | ✓ | |
| Stability to heat, light and weathering | ✓ | |
| Easy dispersion and particle distribution and processability | ✓ | $TiO_2$ is not soluble in water and can be dispersed in a solvent system |
| Inertness in the presence of other components | ✓ | $TiO_2$ does not impair the weather resistance and light fastness of the rubber articles. It is resistant to aggressive rubber chemicals. It has no noticeable effect on the mechanical and vulcanisation properties of the rubber |

### 3.4.13Pigment manufacture

***Range of applications***

*Overview*

$TiO_2$ is by far the most prominent raw material for the manufacture of pigments and pigment preparations. Pigments and pigment preparations containing $TiO_2$ are initially used in industrial (e.g. high quality coatings, paintings, printings inks, plastics, paper, ceramics) and professional (dispersion paints and varnishes) applications and, secondly, in the field of private consumer applications (e.g. cosmetics, pharmaceuticals, ceramics and glass) (Eurocolour, 2016).

It is worth pointing out that $TiO_2$ is a raw material that is used even by SMEs, e.g. manufacturer of complex inorganic pigments, frits and preparations, in quantities up to several hundred thousand tonnes per year each (ANFFECC, 2016).

*Titanium dioxide as a consumed raw material in pigment manufacture*

$TiO_2$ is used as starting material for the synthesis of important inorganic coloured pigments (e.g. with rutile type structure), see **Table 3–19Errore. L'origine riferimento non è stata trovata.**. Here, $TiO_2$ is fully converted during the production process. As a structure-giving component, $TiO_2$ is the indispensable basis for the manufacture of these colour pigments (ANFFECC, 2016). The key functionality of $TiO_2$ is the creation of a crystalline structure that is very stable at high temperatures.

Furthermore, $TiO_2$ generates a stable structure for all kind of atmospheres. This stability prevents defects in the end product.

| Table 3–19: Complex Inorganic Pigments based on $TiO_2$ | | | | |
|---|---|---|---|---|
| EC No. | CAS No. | Name | Formula | Structure |
| 269-052-1 | 68186-90-3 | Chrome antimony titanium buff rutile | $(Ti,Cr,Sb)O_2$ | Cassiterite-Rutile |
| 269-054-2 | 68186-92-5 | Chrome tungsten titanium buff rutile | $(Ti,Cr,W)O_2$ | Cassiterite-Rutile |
| 232-353-3 | 8007-18-9 | Antimony nickel titanium oxide yellow | $(Ti,Ni,Sb)O_2$ | Cassiterite-Rutile |
| 270-185-2 | 68412-38-4 | Manganese antimony titanium buff rutile | $(Ti,Mn,Sb)O_2$ | Cassiterite-Rutile |
| 269-047-4 | 68186-85-6 | Cobalt titanite green spinel | $CoTi_2O_4$ | Spinel |
| 269-054-2 | 68187-05-3 | Spinels, cobalt tin grey | $CoSn_2O_4$ | Spinel |
| 603-450-1 | 1310-39-0 | Pseudobrookite | $Fe_2TiO_5$ | Pseudobrookite |

These highly durable exterior and temperature-resistant pigments require not only the purely colouring properties of the pigments, but also additional physical and chemical functions, such as chemical resistance, high resistance to UV light and effective reflection of infrared radiation (Huntsman, 2016n). These certain grades of orange/yellow/brown complex inorganic pigments are used mainly in the ceramic sector and also in other surface applications like plastics and coatings.

Planar structures based, inter alia, on white and also transparent $TiO_2$ particles coated with various inorganic coloured pigments form the basis for complex inorganic pigments. These "particle sandwiches" are thus able to combine the outstanding chemical and physical properties of titanium dioxide with virtually boundless colour highlights in the finished coating system (Huntsman, 2016n).

Notably, these pigments have been registered under the REACH Regulation according to the paradigm that these represent toxicologically inert substances because of their crystalline (largely rutile or spinel) structures (IP Consortium, 2016).

*Other pigments*

$TiO_2$ is used as the most important white pigment, for example in pigment formulations such as (VCI, 2016):

- Organic and inorganic pigments (including effect pigments/pearlescent pigments) as constituent and for finishing and coating;
- Iron oxides and ferrites, as a set-up agent for colorimetric properties;
- Pigment preparations (powder, liquid, paste);
- Masterbatches for subsequent colouring of polymers; and
- Artists' and school colours.

These products are discussed separately later in this section of the document.

Because of its excellent brightening capacity vis-à-vis coloured media, $TiO_2$ is also used as filler (VCI, 2016).

***Typical concentrations of titanium dioxide***

The presence of $TiO_2$ in pigment preparations ranges between 1% and nearly 100%. Typical concentrations of $TiO_2$ are given in **Table 3–20Errore. L'origine riferimento non è stata trovata.**.

| Table 3–20: Concentration of $TiO_2$ in pigments and pigment preparations | |
|---|---|
| **Application** | **Typical $TiO_2$ concentration** |
| Complex Inorganic (rutile) pigments | Nil |
| Pearlescent pigments | 10 - 100 % (and ultimately 2-25/50% in the final product) |
| Iron oxides and ferrites | <5% |
| Ceramic decorating colours | 5-60% |
| Ceramic glass colours | 5-25%; |
| White organic colours | 30-60% |
| Pigments preparations | Up to 100% |
| Blended pigments | depends on the application |
| *Source: data from consultation and VCI (2016)* | |

***Technical characteristics and advantages***

The following table summarises the key technical advantages of $TiO_2$ in this application area.

| Table 3–21: Advantages of $TiO_2$ use in the manufacture of pigments | | |
|---|---|---|
| **Properties** | **Relevant key advantages** | **Notes, comments and sources** |
| Good hiding power/opacity | ✓ | |
| Ability to lighten coloured media | ✓ | (ANFFECC, 2016) |
| Base for colour development | ✓ | |
| Stability to heat, light and weathering | ✓ | Exceptional light-fastness (ANFFECC, 2016) |
| Easy dispersion and particle distribution | ✓ | Optimal particle size distribution in the range of 0.2 - 0.35 μm |

## 3.4.14 Ceramics

***Range of applications***

Ceramics is a broad term which encompasses a range of applications and is interconnected with applications presented elsewhere, namely pigment manufacture and glass manufacture. In addition to optical performance properties, the main focus of $TiO_2$ applications is on chemical purity, reactivity and sintering properties. Under ceramics, the use of $TiO_2$ may include:

- **Pigments**: as shown in Section 3.4.13, $TiO_2$ is a key raw material in the manufacture of Complex Inorganic Pigments which find applications in ceramics (but also in plastics and coatings). There are also more innovative applications such as the use of the substance as an additive to the body composition of ceramic tiles to generate the desired yellow pigmentation by means of digital printing. Complex Inorganic Pigments are largely used for yellow and brown colours in the ceramic tile industry. This industry is still of great importance to some Italian and Spanish regions;

- **Frits, glazes and enamels**: a frit is a ceramic composition that has been fused in a special fusing oven, quenched to form a glass, and granulated. Frits form an important part of the batches used in compounding enamels and ceramic glazes; the purpose of this pre-fusion is to render any soluble and/or toxic components insoluble by causing them to combine with silica and other added oxides. Put simply, a frit is the result of the chemical reaction between a mixture of inorganic raw materials (usually metal oxides, e.g. $TiO_2$). $TiO_2$ is mainly used as an opacifier in the production process. Frits may then be used in the manufacture of glazes and enamels. $TiO_2$

is essential in order to obtain very opaque white frits for the production of porcelain enamels (enamels used to coat metallic surfaces) at low temperature (500-800 °C). It is also necessary to obtain no watermark opaque engobes and slips, used in the production of ceramic products. Key products include:

- White flatware, cookware, hollowware (both decorated and non-decorated) and eventually also other white kitchenware. At least some of these or similar articles can be found in almost every home, restaurant, hotel, school and hospital kitchen;
- Sanitaryware enamels;
- Hot water tanks;
- Silos;
- Ovens and cooktops; and
- Architecture;

- **Electroceramics**: high-purity pigment grades are used in the production of ceramic materials for electronic components as well as high-quality electroceramics, such as capacitors, PTC resistors, and piezoceramic elements. Examples are barium titanate (BT), lead zirconate titanate (PZT), strontium titanate, magnesium titanate, bismuth titanate and many others. $TiO_2$ may be used in vitreous enamels for electrodes as well as to act as a stabiliser in the electric arc in the coating of welding electrodes (Huntsman, 2016m);

- **Abrasives**: $TiO_2$ is an essential raw material for the production of different types of abrasive products (inorganic bonded abrasives, organic bonded abrasives and coated abrasives). Abrasives are essentially required in Europe by various industries such as automotive, aeronautic, turbine industry, mechanics, medical, stone and construction, etc.; and

- **Other**: rutile is added to ceramic materials such as $Al_2O_3$ and $ZrO_2$ to improve mechanical and/or thermal properties. In addition, $TiO_2$ is, at the same time, an important input material in the production of titanium carbides, titanium-tungsten carbides and titanium borides.

***Typical concentrations of titanium dioxide***

Typical concentration ranges include:

- Frits: 3-20% depending on the application (ANFFECC, 2016);
- Porcelain enamels: 5-25%;
- Ceramic pigments: 5-60% (VCI, 2016); and
- Complex Inorganic Pigments: no $TiO_2$ present.

***Technical characteristics and advantages***

$TiO_2$ offers the following technical advantages to ceramic products.

**Table 3–22: Advantages of $TiO_2$ use in the manufacture of ceramics**

| Properties | Relevant key advantages | Notes, comments and sources |
|---|---|---|
| Good hiding power/opacity | ✓ | |
| Whiteness and brightness | ✓ | Porcelain and sanitaryware enamels need to be white. $TiO_2$ crystallises out of the oversaturated enamel frit during the firing of the enamel coating on the metal substrate to give the enamel its brilliant white colour |
| UV absorbance | | $TiO_2$ increases UV absorption in glass and improve the mechanical, thermal and electrical properties of glass fibres |
| High efficiency | ✓ | In addition, due to the thinness of the layer, the bending and impact strength of the enamel is noticeably increased (Kronos, 1968) |
| Easy dispersion and particle distribution and processability | ✓ | $TiO_2$ is well dispersed and also easily soluble in the glaze melt or, if occasion arises, in the frit batch (Kronos, 1968). It can be readily fused in vitreous enamels (and glass) |
| Other | ✓ | The susceptibility of glazes to crazing is reduced by an addition of $TiO_2$ and the gloss of transparent glazes is improved (Kronos, 1968). $TiO_2$ enhances mechanical and thermal resistance in ceramic glazes.<br>In porcelain enamels, without $TiO_2$, the chemical resistance against acids is inferior. It is important that cookware enamel has very good resistance against citric acid and acetic acid, while for enamels used in industrial applications (for example heat exchangers, architectural panels, chemical vessels) a good resistance against sulphuric acid and hydrochloric acid is needed |

## 3.4.15Glass

***Range of applications***

$TiO_2$ applications in glass include:

- Glass with enhanced hardness and higher resistance to abrasion;
- Glass with sun protection properties, good light, anti-reflection and energy performance for window glass in buildings and in cars. Such glasses are of interest for manufacturing electric lights for automobile headlights and heat-stable light filters. It is established that the characteristic yellow-orange colour is due to the formation of chromophoric centres containing products from the interaction of cerium and titanium oxides (Trusova, et al., 2009). Its chemical structure makes it a unique material for some types of coated glass;
- Glass with self-cleaning properties in buildings (see photocatalysts, above);
- Radiation protection in the UV range for the pharmaceuticals industry (containers etc.);
- Glass with special optical properties;
- Glass for ophthalmic and optic applications;
- Glass-to-metal-seals for lithium batteries used in medical implantable devices such as pacemakers, heart defibrillators, and neuro-stimulators; and
- Paints and decorating inks used to produce white-colour glass.

These uses are necessary for medical/public health protection, drug safety (inertness of medical drug containers), eye protection and visual correction, and high end medical applications that save lives. Moreover, these uses contribute to the EU sustainable policy, for instance by extending building lifetime and reducing maintenance (e.g. self-cleaning windows or sun protection and energy performance) (Glass Alliance Europe, 2016).

Notably, for some special glass applications, following intense research to substitute lead oxide, new formulations are used in which $TiO_2$ is used instead of the lead compound.

$TiO_2$ is used by some companies from the flat glass and special glass sector.

There is no $TiO_2$ in the glass products (except for self-cleaning coatings where titanium dioxide is present as a very thin layer on the surface), but titanium ions are present in the glass matrix.

***Typical concentration of titanium dioxide***

Consultation has revealed the following typical concentrations of $TiO_2$:

- Ceramic glass colours: 5-25%; and
- Special glass: 1-25%.

Technical characteristics and advantages

The advantages of $TiO_2$ pigments in glass applications can be summarised as follows.

**Table 3–23: Advantages of $TiO_2$ use in the manufacture of glass**

| Properties | Relevant key advantages | Notes, comments and sources |
|---|---|---|
| Good hiding power/opacity | ✓ | |
| Base for colour development | ✓ | |
| UV absorbance | ✓ | Reduces transmission of UV light, viscosity of the glass melt and coefficient of expansion |
| Photocatalytic activity | ✓ | Self-cleaning properties when used as coating in window glass |
| Other | ✓ | A high refractive index leads to a reduction of the thickness of the glass in optical application.<br>It increases hardness and abrasion resistance as well as resistance to acids<br>Acts as a crystallisation initiator or crystallisation accelerator |

## 3.4.16Medical devices

***Range of applications***

Various medical devices contain $TiO_2$ as a pigment in bound form, e.g. as dental impression or dental filling or dental temporary or dental lab materials and luting cements. Products include:

- Dental impression materials: these are used by dentists to perform impressions on teeth;
- Dental filling materials: these are used by dentists to fill cavities (instead of silver-mercury amalgam);

- Dental luting cements: these are used by dentists to lute indirect restorations (crowns, bridges, inlays, onlays) to the tooth structure;
- Dental temporary materials (cements, crown and bridge materials): these are used by dentists to prepare temporary crowns or bridges or to lute such temporary restorations to the tooth; and
- Dental lab materials: these are used by dental technicians for a variety of uses.

**Figure 3–16: Example of dental impression materials that contain $TiO_2$**
*Source: royalty-free photo*

Furthermore, $TiO_2$ is present in various plastic parts in medical equipment/medical devices where it provides two main benefits: firstly, its light resistance provides UV-protection which, in turn, improves the stability of the product; and secondly the white colouration enables dirt and other soiling to be instantly seen, which is beneficial in terms of hygiene (German Medicines Manufacturers Association, 2016). $TiO_2$ may also be used in surgical medical tapes, wound dressings and bandages. Also, as noted earlier, $TiO_2$ is extensively used in the medical plastics industry to protect light sensitive pharmaceutical compounds from photolysis.

Although $TiO_2$ has been used for decades in medicinal products and medical devices, as well as in other applications, there are no known examples of adverse reactions caused by the substance (German Medicines Manufacturers Association, 2016).

***Typical concentrations of titanium dioxide***

The following information is available for $TiO_2$ in dental formulations:

- Dental impression materials: 0.01 to <1%;
- Dental filling materials: 0.1-4%;
- Dental luting cements: 0.01-0.5%;
- Dental temporary materials: 0.01-0.1%; and
- Dental lab materials: 0.01-0.8%.

***Technical characteristics and advantages***

These $TiO_2$-based products have the following advantages:

- Highly improved readability of impressions by dentists. Only materials containing $TiO_2$ can be well read by optical scanners used in digital dentistry; and

- $TiO_2$ is the white pigment giving best results to obtain aesthetic colours for dental materials. With the lowest pigment concentration possible, the most aesthetically pleasing dental products can be achieved.

### 3.4.17 Detergents

$TiO_2$ is present in certain detergent products at levels <1% (with vast majority <0.1%). It is used in the following detergent applications:

- **Laundry and cleaning products**: $TiO_2$ is used as a colourant (whitening) for granular enzymes. It also gives important stability functionalities for the enzymes. Granular enzymes are key cleaning agents in granular detergents and automatic dishwashing products. It can also be found in curtain/fabric whiteners; and

- **Toilet solid rim blocks**: $TiO_2$ is a white colourant and a process aid (extrusion).

### 3.4.18 Biocides

Consultation with downstream users of the substance indicates that $TiO_2$ is used as a carrier and light stabiliser of special biocidal active substances based on silver (AgCl on $TiO_2$). These are used as in-can preservatives, additives for hygienic paints, additives to extend shelf life (e.g. paints), co-biocides, etc. The substance is currently listed as "under review" in the form of "reaction mass of titanium dioxide and silver chloride" for 7 product types. The product types covered are:

1 – Human hygiene;

2 – Disinfectants and algaecides not intended for direct application to humans or animals;

6 – Preservatives for products during storage;

7 – Film preservatives;

9 – Fibre, leather, rubber and polymerised materials preservatives;

10 – Construction material preservatives; and

11 – Preservatives for liquid-cooling and processing systems.

Also, Annex V (list of preservatives allowed in cosmetic products) of the Cosmetics Regulation EC 1223/2009 (list of colourants allowed in cosmetic products) lists "*silver chloride deposited on titanium dioxide. 20 % AgCl (w/w) on $TiO_2$*" with the accompanying requirement, "*Not to be used in products for children under 3 years of age, in oral products and in eye and lip products*".

### 3.4.19 Other minor applications

Several less widespread applications of $TiO_2$ exist. Some that have been identified in the course of preparing the present report include:

- Liquid chromatography;
- Growth promoter pigment for horticulture (greenhouse applications); and
- Lubricants.

# 4 Impact analysis

## 4.1 Drivers behind the impacts from the proposed classification of titanium dioxide

There are four key drivers behind the impacts that would arise from the proposed classification of $TiO_2$ and these are described below.

The first driver is **existing regulatory requirements** that accompany substances that are classified as Carc Cat 1B. There is a wide range of legislative instruments at EU level that link to the CLP Regulation and which therefore would come into play if a harmonised classification of Carc Cat 1B for $TiO_2$ were to be adopted. Annex 1 (Section 8) includes a series of tables that summarise the relevant legislation and provide information on:

- The key provisions of each piece of legislation in relation to Carc Cat 1B substances;
- Whether each legislation applies to a single industrial sector/area of application (e.g. cosmetics) or several (e.g. REACH);
- Whether the legislation and its implementation has implications primarily for industrial users (I), professional users (P) or consumers, i.e. the general public (C);
- Importantly, whether the magnitude of the impact that legislation provisions would have on the current applications of $TiO_2$ would be defined by hazard profile alone (i.e. the new hazard classification) or would take into account the risk of release and exposure, and in many situations the availability of alternatives for $TiO_2$ as well; and
- An indication of whether an impact on the use of $TiO_2$ would be 'automatic' or perhaps due process needs to be followed before the new hazard classification translates into some sort of restriction on the use of $TiO_2$ in specific applications.

The tables confirm that a wide variety of legislative instruments would be of relevance. Some of it is cross-sectoral, such as the CLP Regulation itself which will require changes to labelling of mixtures, or the Carcinogens and Mutagens Directive and the Waste Framework Directive; while other legislation focuses on specific areas of application of $TiO_2$, for example, pharmaceuticals, cosmetics, food safety, food contact materials and construction products. There is also legislation which, whilst having a specific focus, may transcend market sectors and applications; for example, biocides containing $TiO_2$ may find applications in several sectors (e.g. cosmetics, paints and coatings).

It is understood that the formal adoption of the new classification would take some time (typically 18 months or longer). Following this, impacts under other legislation would follow. In some cases, impacts would arise immediately or very soon. For instance, under the Carcinogens and Mutagens Directive, where feasible and safer alternatives for $TiO_2$ cannot be found, measures would need to be taken during manufacturing activities that involve the substance (unless already in place). These might include engineering measures aimed at group protection (improved ventilation, use of closed systems, etc.), personal protection equipment, separation of operations/personnel, medical surveillance, etc. These would cause disruption and come at a cost.

In addition, after inclusion of a carcinogen into Annex VI to the CLP Regulation, the European Commission regularly enacts restrictions for the use of these substances in consumer products. Entry 28 of REACH Annex XVII regulates the restriction in consumer products of substances classified as carcinogenic (categories 1A and 1B). As soon as a substance is included by way of a Commission Regulation in the relevant tables (Appendix 2) under this entry, the substance cannot be used for final consumer uses or placed on the market any longer if a concentration limit of 0.1% by weight is exceeded.

There are also application areas where a Carc Cat 1B hazard classification would cause major problems but where rapid, successful action by interested parties could mitigate impacts. Typical examples are the cosmetics, toys, biocidal products, food, pharmaceuticals applications where a risk assessment would need to be undertaken (for instance, by the SCCS Committees for cosmetics, and the SCHEER Committee for toys) to take into account the new classification. By way of example:

- For cosmetics, securing derogations could be a challenging task as they are granted in very exceptional cases, when a series of stringent conditions are fulfilled (safety dossier, food compliance, no alternatives, specific uses) and there are only 15 months between the CLH being added to Annex VI of the CLP and the Cosmetics Regulation annexes being updated with a review of the existing authorisations for $TiO_2$ (a preservative, colourant and UV filter) by the SCCS. Therefore, the time for obtaining an SCCS opinion on safe use is very short. It is understood that it can take up to 2 years to prepare an SCCS dossier. If cosmetics companies would be interested in safeguarding the use of $TiO_2$, they would need to prepare a dossier for the SCCS opinion as soon as possible;

- As regards biocides, any active substance must be approved at Union level if it is to be placed on the market and $TiO_2$ (more accurately, its reaction mass with silver chloride, as $TiO_2$ is not a biocide) would have to go through this process anyway. The problem lies in that Carc Cat 1A and 1B classifications are exclusion criteria for active substances and biocidal products. It is possible to get around this by proving that the risk to humans is negligible and there is no alternative but derogations are granted in exceptional circumstances. This would require significant effort and coordination by industry and the Biocidal Products Committee would have to make their decision 270 days after the receipt of the eMSCA evaluation; and

- For pharmaceuticals, a variation to marketing authorisations would be required for the continued use of $TiO_2$ as an excipient. This would not only take time (for the preparation of the applications) but would be accompanied by considerable cost, given the large number of pharmaceuticals that contain the substance.

On the other hand, there is also legislation which could play a role later, depending on the actions of certain stakeholders. For instance, if $TiO_2$ was classified as Carc Cat 1B it would become eligible for being nominated (by a Member State or by ECHA on the Commission's request) as a Substance of Very High Concern under the REACH Regulation and eventually end up on the Candidate List with associated communication and notification obligations. If $TiO_2$ is then prioritised, it is probable that it would end up on Annex XIV of the REACH Regulation thus making the continued use of the substance dependent on securing an Authorisation by a specified date. A harmonised classification of Carc Cat 1B would also open the pathway for a proposal to be submitted by a Member State or ECHA for the restriction of the use of $TiO_2$ in specific applications. When or whether this would materialise, neither can it currently be predicted and, importantly, nor can it be precluded.

It should also not be forgotten that the new classification would be accompanied by new labelling requirements. This will clearly have a cost not only due to the need to update any labels used, but also due to the differences in $TiO_2$ classification between the EU and other global regions. Significant logistical and production planning complications would arise if labelling requirements were not harmonised globally.

All lifecycle stages of $TiO_2$'s use would be affected following its classification. Where waste contains a substance known to be a Carc Cat 1B in a concentration of over 0.1% by weight, the waste needs to be classified as hazardous by HP 7. Consequently, with a classification of $TiO_2$ as carcinogenic the above-mentioned limit values would apply, and waste would need to be classified as hazardous if the relevant thresholds are exceeded. Transboundary movement of wastes containing $TiO_2$ might also be hindered under the Basel Convention and it can also be envisaged that if the use of $TiO_2$ was severely restricted, the substance would likely be added to Annex I of Regulation (EU) No 649/2012 on export and import of hazardous chemicals. Given its CLH harmonised classification, export of the substance would be hindered.

Finally, national classification (for example, national rules on the protection of worker health and consumer health (e.g. the German ordinance on the ban of chemicals (Chemikalien-Verbotsverordnung)) or the environment such as TA Luft in Germany[14]) would also come into play but these are not discussed here.

**Carcinogenicity in general vs. carcinogenicity by inhalation**

European legislation regulating the use of an exposure to carcinogens generally does not distinguish between routes of exposure. Therefore, whilst the French proposal for the classification of $TiO_2$ specifically indicates that the substance be classified as a carcinogen by inhalation, the uptake of this classification by 'consequent' legislative requirements does not give due regard to the critical route of exposure (for instance, Entry 28 of Annex XVII of the REACH Regulation is not concerned with the route of exposure of consumers to substance classified as Carc Cat 1A/1B).

Thus, also applications of the substance without any inhalation risk would nevertheless fall within the scope of restrictions arising from a multitude of legislative instruments. It should be clear that in the vast majority of cases, $TiO_2$ is used by the end user within a matrix, typically as a pigment in paints, plastics, inks, paper, rubber, construction products, ceramics, glass, etc. from which exposure to $TiO_2$ via inhalation is either impossible or highly improbable. It can be recognised that in some limited cases $TiO_2$ lend itself to inhalation exposure (examples may include cosmetic powders or the spraying of cosmetic lotions such as sunscreens), however for these specific uses in cosmetics (e.g. as a UV filter in sunscreens), relevant safety assessments by authoritative bodies (e.g. SCCS) do exist and cover the inhalation risk.

It is pertinent to note here the comments made by the International Paint and Printing Ink Council (IPPIC) to the public consultation on the French proposal. IPPIC noted,

"*Categorical assertions of a low or no exposure condition and attendant dismissal of cancer hazard listings have been issued in the United States by California Office of Environmental Health Hazard Assessment (OEHHA) under its "Prop 65" regime. OEHHA uses the specific clarifying statement: "the (hazard) listing does not cover (the material) when it remains bound within a product matrix."*

[14] In item 5.2.2 of the German TA Luft, there is a direct link between the classification of this substance according to the CLP Regulation and emission limitation in waste air, this is not based on requirements under the Industrial Emissions Directive or other European provisions. In the individual case, this link can lead to disproportionate requirements in the retrofitting of industrial installations (VCI, 2016).

*Similarly, the International Agency for Research on Cancer (IARC), in its Monographs on titanium dioxide, crystalline silica and carbon black, all widely used materials in formulated products, contain specific notes affirming that "exposure to [titanium dioxide, crystalline silica and/or carbon black] does not occur during the use of products in which [titanium dioxide, crystalline silica and/or carbon black] is bound to other materials, such as rubber, printing ink or paint*" (IPPIC, 2016).

The second driver behind the impacts that would arise from the proposed classification is the **availability of alternatives**. There are four key points under this:

1. Due to its physicochemical properties (see Section 2 above), finding a drop-in replacement for $TiO_2$ with equivalent technical performance would be impossible in the vast majority of its applications. It is important to note that $TiO_2$ was largely introduced to replace more hazardous heavy metal compounds.

2. Potential alternatives for $TiO_2$ may not be accompanied by the same body of evidence on their hazards and risks across all relevant applications, particularly for applications such as food and pharmaceuticals.

3. $TiO_2$ is currently being used in very large volumes; demand in Europe is estimated at ca. 1.2 million tonnes per year. The market available of most of its alternatives is simply nowhere near as large as $TiO_2$'s. Most of the potential alternatives cannot demonstrate $TiO_2$'s abundance that would allow for economical production.

4. The French proposal bases its arguments on carcinogenicity on the physical rather than the chemical properties of $TiO_2$. As a result, the justification for the classification, if accepted as valid, would by inference apply to all other poorly soluble powders. This not only would raise potential impacts for those powders' supply chains but it also renders many of the potential alternatives to $TiO_2$ unsuitable for its replacement as they are poorly soluble powders themselves. Therefore, their use would not reduce the (theoretical) risks to human health.

A more extensive analysis of the feasibility and availability of potential alternatives is provided in Annex 2 (Section 9) to this report.

A third driver behind the impacts arising from the proposed classification is **market developments**, which generally are difficult to predict. The potential loss of $TiO_2$, a very important component in a multitude of products, will prompt many companies to review their product portfolios when planning for the future. Several stakeholders have suggested that manufacturing outside the EEA where the carcinogenicity classification for $TiO_2$ would not apply would become more attractive.

A fourth driver would be **user and consumer perceptions** and the likely confusion that the classification could cause as well as any regulatory measures to be subsequently taken. Firstly, in the mind of consumers (and probably many users) the classification of $TiO_2$ as a carcinogen would likely be dissociated from the importance of the route of exposure and the substance would be tarnished as a carcinogen irrespective of the actual level of risk across its different applications. On the other hand, if the use of $TiO_2$ continues as a result of derogations for applications such as pharmaceuticals, food, cosmetics, etc., the consumers would find it perverse that a carcinogen could be present in such products and may avoid consuming or using them. This uncertainty and confusion might damage the confidence users and consumers have in health protection rules and government decision-making.

Finally, the classification of $TiO_2$ would pave the way to the potential classification of other poorly soluble substances in the form of respirable powders that could be considered to cause lung overload. Such classification would lead to another set of **indirect impacts**.

## 4.2 Impacts on producers of titanium dioxide

### 4.2.1 Scope of analysis

As shown in **Table 3–3**, there are 17 $TiO_2$ production facilities in the EU plus one in Norway (Fredrikstad). The majority of production is based on the sulphate process (see Section 3.1.2) and the split between sulphate and chloride process is assumed to be 55:45. In terms of production capacity, Germany clearly leads with an assumed 32% of the total EEA capacity of over 1.4 million tonnes of $TiO_2$ (see **Figure 3–2**), followed by the UK (22%), Finland (9%).

Based on the information presented in Section 3.3, in the year 2015 (which will be used as the basis of the analysis below) the following figures applied.

**Table 4–1: Key metrics of $TiO_2$ market in the EEA (2015)**

| Parameter | Volume (ktonnes/y) | Value* (€million/y, approx.) |
|---|---|---|
| Demand for $TiO_2$ | 1,100 | 2,660 |
| *EEA-made $TiO_2$ consumed in the EEA* | *740* | *1,800* |
| *Non-EEA-made $TiO_2$ consumed in the EEA* | *360* | *860* |
| EEA exports of $TiO_2$ | 360 | 860 |
| ** assumes a price of €2,400/t* | | |

### 4.2.2 Value of market and profitability of EEA-based operations

***Value of the market***

The market price for $TiO_2$ has varied significantly over the years. The relevant IPPC BREF Document documents a significant decline in prices from ca. US$7,000 per tonne in 1954 to just over US$2,000 in 2002 (European Commission, 2007). In the 2000s, the price of $TiO_2$ increased so that, in 2012, $TiO_2$ was sold on average at around €3,000 per tonne (or ca. US$4,000/t). That increase did lead some users to explore alternatives without success (as explained later in this document). The price of $TiO_2$ pigments has significantly declined since 2012. Recent price data for the Chinese market (TIZE, 2016) suggest that, at the beginning of 2016, the price per tonne was ca. US$2,350 or ca. €1,800 per tonne. In addition, in July 2016, the average price of $TiO_2$ in the North American market was ca. US$1.215 per lb or US$2,675 per tonne or ca. €2,400 per tonne with a range of US$1.18-1.25/lb (free delivered) for smaller-volume buyers (ICIS, 2016). If this average price is assumed to apply in the EEA at present[15], the value of the total market in the EEA can be estimated at 1,107,000 tonnes × €2,400 per tonne = €2.66 billion per year[16].

***Profitability of titanium dioxide manufacturers***

With regard to the profitability of the $TiO_2$ manufacturing industry, some key points can be made:

- The $TiO_2$ industry suffered a major downturn during the financial crisis in 2008-2009. It recovered sharply in 2012 but has since been in decline;
- Data on Pre-tax Operating Income for all EEA plants for the year 2013 (generated by a third party) have been supplied by consultees. These show relatively low levels of pre-tax income at the time. Out of 18 plants, five plants had a negative pre-tax operating income margin and nine plants had a single-digit pre-tax operating income margin; and
- Since 2013, the decline has continued for several of the companies concerned (although on a per plant basis, some may have shown some improvement). EBITDA data for the four largest suppliers to the EEA market have been consulted (but cannot be reproduced here) and show that, for some companies, EBITDA margin figures remain at single-digit figures[17]. Accordingly, pre-tax operating income levels are even lower or negative.

For the purposes of this analysis, it will be assumed that pre-tax operating income across the industry is nil at present but may well fluctuate in the future. This assumption is likely to be an underestimate profits of some manufacturers (particularly since market prices have been increasing or are likely to increase in the coming months[18]), while it will overestimate the profits of some others.

***Gross Value Added of titanium dioxide manufacture***

There are several ways of calculating Gross Value Added (GVA); the "income" approach to estimating GVA as this is the most straightforward. Under this approach, the definition is:

GVA = compensation of employment + gross operating surplus

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15 It has been suggested that a high price correlation can be observed between world regions. There are only minimal price differences which reflect costs of freight and duties between regions. Price differences between the EEA and North America are influenced by the Euro-Dollar exchange rate fluctuations (European Commission, 2014).

16 It is worth noting that past market research had assumed a gradual increase to the value of the market until 2020 (Market Report Company, 2015; Zion Research, 2016).

17 Publicly available information demonstrates this (Huntsman, 2016n; ICIS, 2016).

18 See for example, http://www.chemmarket.info/en/news/view/30245/, https://investors.chemours.com/investor-relations/investor-news/press-release-details/2016/Chemours-Titanium-Technologies-Announces-Global-Price-Increase/default.aspx, http://investor.tronox.com/releasedetail.cfm?releaseid=985531, http://ir.huntsman.com/phoenix.zhtml?c=186725&p=irol-newsArticle&ID=2194598 (all accessed on 31 October 2016).

This translates basically into the sum of salaries, national insurance contributions, and possibly redundancy wages plus profits. As profits are currently assumed to be nil, the focus can be shifted to the compensation of employment.

Information on wages for members of TDMA is limited. However, there is information on employment levels which has been used as follows:

- Some companies have provided employment data per plant and these have been used;
- For some companies, data have been obtained from the open electronic literature;
- For others, where only total employment is known and data on capacity per plant are available, workforce is allocated on the basis of production capacity share;
- Total employment in EEA has been estimated at ca. 8,150;
- Total labour costs for the manufacturing sector in each of the countries of interest are obtained from Eurostat[19] and are reproduced in **Table 4–2**; and
- An 8-hour day, 240 working days per year assumption is made for all workers in all countries.

The full calculations cannot be provided as they might potentially disclose sensitive information. The overall labour cost is ca. €473 million/y.

**Table 4–2: Total labour cost per hour in the manufacturing sector, 2015**

| Country | Total labour cost per hour (€/h) |
|---|---|
| Belgium | 43.3 |
| Czech Republic | 9.8 |
| Germany | 38.0 |
| Spain | 22.6 |
| France | 36.9 |
| Italy | 27.4 |
| Netherlands | 34.7* |
| Poland | 7.6 |
| Slovenia | 15.4 |
| Finland | 36.8 |
| United Kingdom | 28.3 |
| Norway | 48.2 |

*Source: Eurostat*
** Value is for 2014; a value for 2015 was not available at the time of accessing the Eurostat database*

Therefore, the GVA for the manufacture of $TiO_2$ can be calculated at €473 million and will further grow once the industry returns to profitability.



19 Labour cost levels by NACE Rev. 2 activity, available at http://ec.europa.eu/eurostat/web/labour-market/labour-costs/database (accessed on 31 October 2016).

### 4.2.3 Basis of analysis of impacts from the proposed classification

***Impacts on consumer markets from the proposed hazard classification***

Sections 4.5 and 4.6 discuss the potential impacts on the downstream users of $TiO_2$ from the proposed classification. In relation to consumer uses of $TiO_2$ and its formulations, a summary table can be generated, **Table 4–3**. The following key points can be made:

- Under the provisions of the REACH Regulation, Annex XVII Entry 28, $TiO_2$ and its formulations could no longer be placed on the market, whether these are manufactured within or outside the EEA. This requirement essentially eliminates the extensive DIY market for paints, coatings, adhesives, sealants, fillers, inks, colours, correction fluids, detergents;

- Several other applications would require industry to successfully secure a derogation or exemption, for instance in cosmetics, food/pharmaceuticals, medical devices, biocides. It is believed that in some cases (food/pharmaceuticals/medical devices) the absence of approved alternatives and the absence of any/significant inhalation exposure might favour continued use. In other cases (cosmetics/biocides), securing an exemption might be a more challenging task; and

- Beyond the impact of regulatory requirements, given the ubiquity of $TiO_2$ in all aspects of consumer, public and personal life (food, medicines, packaging, medical devices, furniture and flooring, printed material and wallpaper, ceramics and tableware, glass, to name only a few), the proposed classification would likely have a severe impact on consumer perception on the safety of products that contain $TiO_2$ and would significantly impact upon their sales in the EEA, as shown **Table 4–3**.

As a result, it can be estimated that the direct regulatory impact on consumer uses of $TiO_2$ from the proposed classification of Carc Cat 1B would be the **loss of ca. 25% of current total $TiO_2$ demand in the EEA**. If market losses through negative consumer perceptions are taken into account, as well as losses associated with the inability to meet the criteria of schemes like the Ecolabel, the overall loss would be much higher and would likely **exceed one-third of current total $TiO_2$ demand in the EEA**.

| Table 4–3: Basis for estimating consumer market losses following the implementation of the proposed classification for $TiO_2$ | | | | | | |
|---|---|---|---|---|---|---|
| **Application area** | **% of $TiO_2$ demand*** | **Consumer use** | **Consumer use of formulations or articles** | **Immediate market impacts on consumer products** | **$TiO_2$ market share loss due to regulatory requirements** | **Potential for consumer market losses as a result** |
| Paints & coatings | 53% in total<br>36%: architectural<br>17%: industrial | 56% of architectural**, i.e. 20% of total demand | Formulations | REACH Regulation → DIY paints no longer placed on market (only dark blue and black would not be impacted, 80-90% of DIY paints affected) | Up to 20% | See on the left; market would be lost |
| Plastics | 25% | 60-70%,<br>i.e. 15-18% of total demand | Articles | - | - | Significant.<br>Perceptions over the safety of packaging of cosmetics, personal care products, food, pharmaceuticals may change |
| Paper and wallcoverings | 12% | Ultimately, 100%<br>Wallcoverings: 80% | Articles | - | - | Significant.<br>Perceptions may change over the presence of a carcinogen in wallpaper, flooring, furniture, doors, walls, printed paper |
| Inks | 4% | Probably <50% in the form of consumer inks, toner, artists, recreation and school colours, correction fluids | Formulations and articles | REACH Regulation → Consumer formulations no longer placed on market.<br>EuPIA Exclusion Policy and CoE Resolution mean possible cessation of use unless exemption granted | Over 1% | See on the left; market would be lost |

| Table 4–3: Basis for estimating consumer market losses following the implementation of the proposed classification for $TiO_2$ | | | | | | |
|---|---|---|---|---|---|---|
| Application area | % of $TiO_2$ demand* | Consumer use | Consumer use of formulations or articles | Immediate market impacts on consumer products | $TiO_2$ market share loss due to regulatory requirements | Potential for consumer market losses as a result |
| Construction products | Included above | Included above | Formulations | REACH Regulation → DIY products (adhesives, sealants, fillers, etc.) no longer placed on market | Included above | See on the left; market would be lost |
| Fibres | 0-1% | Unknown; significant use in textiles | Articles | Some restrictions under Toy Safety Directive. In future, the fast-track REACH restriction on textile chemicals may play a role | Far less than 1% | Significant. Most man-made fibres come into contact with consumers in everyday life (this includes clothing, underwear, sports clothing, etc.) |
| Catalysts | 1% | No | - | - | - | N/A |
| Food, feed and packaging | 0-1% | 100% | N/A; food | Use of $TiO_2$ would be challenged but an exemption could probably be secured (on basis of lack of alternatives and low inhalation exposure) | Assumed impact avoidance would be possible | Significant. Ingestion of a carcinogen would have very negative connotations |
| Pharmaceuticals | 0-1% | 100% | N/A; medicines | Use of $TiO_2$ would be challenged but an exemption for food would allow continued use in medicinal products too | Assumed impact avoidance would be possible | Significant. Ingestion of a carcinogen would have very negative connotations, particularly in the context of the use of medicines |

**Table 4–3: Basis for estimating consumer market losses following the implementation of the proposed classification for $TiO_2$**

| Application area | % of $TiO_2$ demand* | Consumer use | Consumer use of formulations or articles | Immediate market impacts on consumer products | $TiO_2$ market share loss due to regulatory requirements | Potential for consumer market losses as a result |
|---|---|---|---|---|---|---|
| Cosmetics | 0-1% | Significant, but professional uses also occur | Formulations | Cosmetics Regulation → $TiO_2$ use banned unless exemption granted | Less than 1% | Significant. Even if exemption was secured, classification would undermine safety perceptions and market shares |
| Elastomers | 0-1% | Unknown but exists (general rubber goods, e.g. erasers) | Articles | - | - | Considerable |
| Pigments | 0-1% | No | - | - | - | N/A |
| Ceramics | 0-1% | Industrial use of $TiO_2$. Ultimately some ceramic products are sold to consumers | Articles | - | - | Considerable. Food containing materials (ceramics, enamelled pots, etc.) that contain $TiO_2$ could be stigmatised |
| Glass | 0-1% | No. Glass articles do not contain $TiO_2$ | Articles | - | - | Relatively low compared to other applications |
| Medical devices | 0-1% | Generally nil, but used on patients | Formulations and articles | New Medical Devices Directive → $TiO_2$ use banned unless exemption granted. $TiO_2$ is the only whitening agent recognised in the EU Pharmacopeia | Less than 1% | Significant. Even if exemption was secured, classification would undermine safety perceptions |
| Detergents | 0-1% | Up to 100% | Formulations | REACH Regulation → Consumer formulations no longer placed on market | Less than 1% | See on left; market would be lost |

| Table 4–3: Basis for estimating consumer market losses following the implementation of the proposed classification for $TiO_2$ | | | | | | |
|---|---|---|---|---|---|---|
| **Application area** | **% of $TiO_2$ demand*** | **Consumer use** | **Consumer use of formulations or articles** | **Immediate market impacts on consumer products** | **$TiO_2$ market share loss due to regulatory requirements** | **Potential for consumer market losses as a result** |
| Biocides | 0-1% | Unknown; mostly used industrially | Formulations | Biocidal Products Regulation → $TiO_2$ use banned unless exemption granted | Less than 1% | Significant. Even if exemption was secured, classification would undermine safety perceptions |

** in literature sources, some of the minor applications have been identified as accounting for 1% or more of total demand. These include catalysts, textiles, enamel and rubber. There is no concrete information that would allow such a distinction to be made so all minor applications are assumed to account for up to 1% of total EEA demand.*
*** this is based on the estimate that DIY uses account for €3.5 billion/y out of €6.2 billion of the total architectural coatings market (based on CEPE data)*

***Impacts on professional and industrial markets from the proposed hazard classification***

Quantifying the impacts arising for professional and industrial downstream users is not as straightforward because for most applications there are no specific regulatory requirements that would restrict the use of the substance. However, Sections 4.5 and 4.6 explain that impacts may arise in a number of ways:

- Compliance with worker health protection legislation and waste disposal legislation would significantly increase manufacturing costs;
- Loss of consumer markets would more generally affect economies of scale (particularly for paints and coatings manufacture);
- For printing inks, the Exclusion Policy of the key EU trade association (EuPIA) would mean the de facto restriction on the use of $TiO_2$ unless an exemption could be justified;
- Many companies using $TiO_2$ may have their own internal policies that prevent them from using CMR Cat 1A/1B substances; and
- Similar to consumers, the supply chain may be reluctant to use a Carc Cat 1B substance even where legislation itself does not prohibit its use.

In general, the manufacture of $TiO_2$-containing articles and formulations and the use of $TiO_2$-containing formulations in the EEA would become more complex and more costly. This would impact upon the competitiveness of supply chains based in the EEA. Some activities would not be possible to relocate, i.e. re-painting of structures needs to happen in situ. However, the relocation of manufacturing processes (of $TiO_2$-based formulations and $TiO_2$-containing articles) could become more attractive.

It would be difficult to argue that relocation to non-EEA countries would happen across the board, both because of the very large number of SME users of the pigment who could not afford the cost of relocation, as well as the sheer scale of such undertaking. Architectural paints, for instance, are typically manufactured in the country where they are used by consumers and professional decorators. Whilst it is possible to produce and supply architectural paints for professional use (which would replace DIY use) from outside the EEA, the costs would be high; the industry infrastructure in the EEA is vast and relocating this would be unrealistic. Still, their capacity utilisation in Europe would dangerously decline.

On the other hand, manufacturing articles without the burden of the additional requirements of the EU worker protection legislation would become an option to consider. Plastics would be a good example; masterbatch manufacture and article manufacture (e.g. white PVC window profiles, etc.) could become good candidates for relocation with the end products ultimately imported into the EEA, thus decimating the EEA-based supply chain. Another example is painted articles; Original Equipment Manufacturer (OEM) production has significant infrastructure whereby articles are coated in a range of colours and most contain $TiO_2$ at a level that exceeds 0.1% by weight. It would require significant write off of the assets and re-investment to move significant volumes of OEM coatings outside the EEA. However, this could become a long-term strategy for OEM applications such as automobiles, can coatings, coil coatings and powder coatings (e.g. for household appliances) where non-EEA locations would be chosen for new investment and expansion and a gradual relocation of operations outside of the EEA.

Overall, the proposed classification for $TiO_2$ would have significant repercussions on the professional and industrial use of $TiO_2$. EEA markets would likely shrink with some (parts of) supply chains becoming too uncompetitive vis-à-vis their non-EEA counterparts.

Taking into account the aforementioned projected losses of consumer markets, it would be reasonable to expect that the proposed classification would mean the loss of 50%, if not more, of the current demand for $TiO_2$ in the EEA.

***The role of the REACH Regulation***

The analysis presented in this document largely disregards the impacts that would arise from a potential future listing of $TiO_2$ in the Candidate List and thereon the Annex XIV Authorisation List of the REACH Regulation, as it is uncertain whether and when such a development might occur. It should be understood, however, that the listing of the substance in the Candidate List and particularly any subsequent requirement for Authorisation would have a profound impact on a multitude of industry sectors. Although the evident lack of feasible alternatives (see rest of Section 4 and Annex 2 (Section 9) in particular) would support the submission of robust Applications for Authorisation, the implications of Authorisation would be far-reaching; the number of companies using $TiO_2$ and its formulations is very large, in their thousands. The vast majority of these would have no expertise or experience in the Authorisation process and would therefore rely on their suppliers upstream to cover their uses in their own Applications. Given the sheer number of uses of $TiO_2$, the preparation of Applications will be very challenging. This could well lead to the abandonment of some uses, either by downstream users who could not afford or cope with the Authorisation process, or by upstream suppliers for whom specific minor uses may account for a very small proportion of income and thus are of limited interest. In light of the significant cost of preparing, submitting and following through an Application for Authorisation and the extreme burden that this process would place on ECHA, its Committees and the European Commission, REACH Authorisation would stand to be one of the major threats to many current uses of $TiO_2$.

### 4.2.4 Market outcomes from the proposed classification

Based on the analysis above, the proposed classification would result in the loss of 50%, if not more, of the EEA market for $TiO_2$. Such a loss would realistically result in the loss of the EEA $TiO_2$ manufacturing base for the following reasons:

- **Capacity underutilisation**: in recent years there has been overproduction of $TiO_2$ pigment, with an average capacity utilisation within the industry of just under 80% (Roskill, 2016). Capacity utilisation rates for $TiO_2$ plants are predicted to rise in 2016, normalise in 2017 and exceed 90% by 2018 and 2019 (ICIS, 2016b). If 50% of the EEA market were lost, capacity utilisation of the EEA-based $TiO_2$ manufacturing plants would drastically decline. $TiO_2$ plants running at a capacity utilisation below 80% or less cannot be sustained economically for any prolonged period of time. These plants have very high fixed costs which must be absorbed over very high/nearly full capacity utilisation rates. $TiO_2$ production in the EEA would become economically unsustainable;

- **Opportunities for increased $TiO_2$ exports**: unless the introduction of the new hazard classification for $TiO_2$ in the EEA is emulated by other jurisdictions, the use of $TiO_2$ outside the EEA would continue as normal and indeed non-EEA manufacturing would become more competitive and thus more attractive. Thus, theoretically, EEA manufacturers of $TiO_2$ might be able to export increased volumes of $TiO_2$ to non-EEA downstream users. Still, access to overseas markets would be easier for the larger multinational producers, as opposed to the smaller ones who may have a more regional focus and less capability of becoming competitive exporters. In any case, all EEA-based $TiO_2$ producers would be disadvantaged by additional freight and duty costs, plus a more costly manufacturing base in the EEA. It is unrealistic to expect any significant increase to the currently estimated 360 ktonnes/y $TiO_2$ exports from the EEA;

- **Spare capacity outside the EEA**: as shown in Section 3.2.2, EEA demand for $TiO_2$ amounts to ca. 1.1 million tonnes per year, while global demand is at 5.9 million tonnes per year and global capacity is 7.2 million tonnes per year. Hence, a surplus capacity of around 1.3 million tonnes exists, which is similar to the current Western European capacity and exceeds current EEA demand for the pigment. As a result, non-EEA $TiO_2$ manufacturers (including multinationals currently operating in the EEA) would be in a good position to take over the EEA market for the pigment, although, logically, some additional capacity outside the EEA might need to be built up over time.

Overall, loss of 50% of the EEA market or more would probably lead to the collapse of the entire $TiO_2$ manufacturing base in the EEA with several plants shutting down and operations being consolidated across the EEA. This would have a significant knock-on effect on EEA-based supply chains but also on non-EEA users of the pigment: EEA-made $TiO_2$ is currently being exported plus some $TiO_2$ grades may only be made in European plants so these grades would no longer be available to customers outside Europe.

### 4.2.5 Impacts on ancillary operations

$TiO_2$ manufacturing plants not only produce $TiO_2$. They are capable of generating several by-products and, in some cases, may also manufacture titanium tetrachloride and other titanium substances. Whilst the manufacture of these products might continue even if $TiO_2$ production ceases, by-product generation could not continue. Such by-products include:

- Iron salts, such as copperas;
- Gypsums;
- Sulphuric and other acids;
- Aluminium substances;
- Other.

There is insufficient information to allow a quantified estimate of losses in terms of volume and value to be provided. However, given the large volumes of $TiO_2$ generated, several hundred thousand tonnes of the above by-products would no longer be possible to produce. It is worth noting that whilst, for many of these products, the EEA market is substantially large, for titanium tetrachloride and other titanium chemicals, the affected plants collectively account for the majority of the volume placed on the EEA market. Thus, downstream users of these products would likely be affected by the shortages in supply.

### 4.2.6 Employment impacts

The total employment in the 18 $TiO_2$ manufacturing plants in the EEA is estimated at ca. 8,150 workers. Specific figures per plant, company or country cannot be provided for confidentiality reasons. A rough split among EEA Member States is provided in **Table 4–4**. The table also provides the domestic employment multipliers for each country for the 'chemicals' sector, as presented in a 2012 study for the European Commission (which analysed 2005 data) (Stehrer & Ward, 2012). Using these multipliers for each Member State, it can be estimated that direct employment at $TiO_2$ manufacturing plants creates ca. 22,800 jobs in the domestic economies (overall multiplier: 2.8).

| Table 4–4: National shares of total employment in $TiO_2$ manufacturing plants | | |
|---|---|---|
| **Country** | **Share of total number of workers in the EEA** | **Domestic employment multiplier (chemicals sector)** |
| Belgium | 5-10% | 2.2 |
| Czech Republic | 5-10% | 2.3 |
| Germany | 30-40% | 2.8 |
| Spain | 1-5% | 2.7 |
| France | 5-10% | 4.9 |
| Italy | 1-5% | 3.3 |
| Netherlands | 1-5% | 3.0 |
| Poland | 1-5% | 2.7 |
| Slovenia | 10-20% | 2.0 |
| Finland | 5-10% | 2.6 |
| United Kingdom | 10-20% | 3.3 |
| Norway | 1-5% | 2.3* |
| **Total** | **8,150 workers** | |
| *Source: TDMA member information, employment data retrieved from the Internet*<br>** in the absence of data, the EU-27 average is used* | | |

If $TiO_2$ manufacturing plants were to stop production following the introduction of the proposed classification and the collapse of the EEA market for the substance, the entirety of direct employment would be lost and, with it, the indirect employment described above.

## 4.3 Impacts on upstream suppliers

### 4.3.1 Ore mining and slag production in the EEA

There is only one commercial mining operation in the EEA, the ilmenite ore deposit at Hauge i Dalane on the southwest coast of Norway operated by Titania AS (owned by Kronos)[20]. The facility was founded in 1902 and has continuously produced ilmenite ($FeTiO_3$), the most abundant titanium mineral, since 1916. Currently production is at 850,000 tonnes of ilmenite concentrate[21]. Global production of ilmenite in 2015 is estimated at ca. 5.6 million tonnes thus meaning that the Titania AS operations account for ca. 15% of global production (global production of rutile is estimated at ca. 6.1 million tonnes per year (USGS, 2016)). Titania AS employs more than 280 personnel[22], including apprentices, many of whom live in the nearby municipality of Sokndal. The company has a long

20 Note that feedstock production does take place in the periphery of the EEA, in Ukraine.

21 As indicated at http://kronostio2.com/en/manufacturing-facilities/hauge-norway and http://www.ngu.no/sites/default/files/Focus%20nr4_TITANIUM_AND_IRON_TITANIUM%20%20DEPOSITS_IN_NORWAY__v2.pdf (both accessed on 4 November 2016).

22 257 employees in 2015 according to http://www.proff.no/selskap/titania-as/hauge-i-dalane/-/Z0ITENO3/ (accessed on 4 November 2016).

history of providing employment for local people and has education programs with Universities and also has several apprentices and trainees every year[23].

In addition, the TiZir Titanium and Iron facility (located at Hardangerfjord on the west coast of Norway) is producing titanium slag and high purity pig iron (HPPI) (NB. the company has recently decided to transition from sulphate to chloride titanium slag). It is the only such facility in Europe and only one of five in the world. The current capacity is 230 ktonnes/y of titanium slag and the titanium slag is predominantly sold to pigment producers[24]. Sales of titanium slag in 2014 and 2015 were ca. 178 ktonnes and 132 ktonnes respectively[25]. Levels of employment at the plant were over 200 employees (2013 and 2014 data suggest 236 and 214 employees respectively[26]).

### 4.3.2 Impacts on suppliers of feedstock, raw materials and utilities

It is understood that both these Norwegian companies sell the majority of their output to European customers. Thus the potential collapse of the $TiO_2$ manufacturing base in the EEA would have adverse repercussions for the profitability of these mining and ore processing operations. Levels of employment would likely be affected as a result of the proposed classification for $TiO_2$.

- **Ilmenite concentrate (Titania AS)**: publicly available financial information for the company suggests a turnover of ca. €80-104 million in the period 2013-2015 with earnings before taxes in the region of €23-28 million per year[27]. The majority of profits are assumed to be derived from sales to European customers. If $TiO_2$ production in the EEA would stop, the company would naturally aim to find customers overseas. The extent to which this would be successful and what the economic impacts would be is uncertain – freight costs would make sales to overseas customers potentially uneconomic and there are not that many alternative uses of ilmenite; and

- **Titanium slag (TiZir)**: the 2015 annual reports of TiZir Titanium and Iron suggests total sales of ca. 132 ktonnes in 2015 and ca. 178 ktonnes in 2014[28]. The financial performance of the company in 2015 was worse than the previous years with negative earnings before tax in 2015 down from €4 million in 2014 and €41 million in 2013[29]. It must be noted however that the

[23] Information available at http://kronostio2.com/en/manufacturing-facilities/hauge-norway (accessed on 2 November 2016).

[24] Information available at http://www.tizir.co.uk/projects-operations/tyssedal-tio2/ (accessed on 2 November 2016).

[25] Multiple sources – Information available at http://www.tizir.co.uk/investors/news-releases/ (accessed on 2 November 2016).

[26] Information available at http://www.largestcompanies.com/company/Tizir-Titanium--Iron-AS-275252/closing-figures-and-key-ratios (accessed on 2 November 2016).

[27] Information available at http://www.largestcompanies.com/company/Titania-AS-140102/closing-figures-and-key-ratios (accessed on 4 November 2016).

[28] Information available at http://www.tizir.co.uk/wp-content/uploads/2016/04/Tizir-Ltd-Annual-Report-2015.pdf (accessed on 2 November 2016).

[29] Information available at http://www.largestcompanies.com/company/Tizir-Titanium--Iron-AS-275252/closing-figures-and-key-ratios?currency=EUR (accessed on 4 November 2016).

company produces not only titanium slag but also pig iron and the financial results reflect profits from sales of both products. As for the mining company above, if $TiO_2$ production in the EEA would stop, this company would naturally aim to find customers overseas. The extent to which this would be successful and what the economic impacts would be is uncertain.

The majority of feedstock currently used by $TiO_2$ manufacturers is sourced from non-EEA suppliers. The volumes are particularly large. For instance, the relevant IPPC BREF Document notes that sulphate plants may use on average 1.662 tonnes of ilmenite per tonne of $TiO_2$ pigment products and 0.956 tonne of slag per tonne of $TiO_2$ pigment produced. Considering that production is estimated at 1.1 million tonnes of $TiO_2$, the volumes of feedstock that would no longer be imported into the EEA would be large.

The volumes of other raw material inputs are similarly large and some calculations can be made to provide an order of magnitude of the volumes of chemicals that would no longer be consumed in the EEA. The majority of these are widely used substances and are likely to be sourced from EEA suppliers. The basis of the calculations are figures provided in the relevant IPPC BREF document (European Commission, 2007) and are reproduced in **Table 4–5**.

**Table 4–5: Raw material and energy input to $TiO_2$ pigment manufacture according to the IPPC BREF Document (excluding feedstock)**

| Input | Unit | Chloride process | Sulphate process |
|---|---|---|---|
| Chlorine | t/t pigment | 0.201 | - |
| Sulphuric acid | t/t pigment | - | 3.250 (total, new + recycled) |
| Coke | t/t pigment | 0.366 | - |
| Lime | t/t pigment | 0.137 | - |
| Coal | t/t pigment | 0.090 | - |
| Oil | t/t pigment | 0.005 | - |
| Oxygen | t/t pigment | 0.467 | - |
| Silica sand | t/t pigment | 0.049 | - |
| Rock salt | t/t pigment | 0.016 | - |
| Scrap iron | t/t pigment | - | 0.150 |
| Aluminium sulphate | t/t pigment | - | 0.021 |
| Hydrogen peroxide | t/t pigment | - | 0.012 |
| Calcium hydroxide | t/t pigment | - | 0.363 |
| Calcium chloride | t/t pigment | - | 0.015 |
| Calcium carbonate | t/t pigment | - | 1.380 |
| Aluminium hydroxide | t/t pigment | - | 0.030 |
| Caustic soda | t/t pigment | 0.104 | 0.090 |
| Energy | GJ/t pigment | 17-29 | 23-29 with sulphuric acid neutralisation<br>33-41 with sulphuric acid re-concentration* |

*Source: European Commission* (2007)

** Given different combinations of systems used across the EEA $TiO_2$ industry for acid neutralisation and/or acid reconcentration, the extreme ranges as in (a) and (b) above apply only as indicative levels for the estimation of the overall energy efficiency in the $TiO_2$ plant in question*

It is also assumed that:

- The amount of $TiO_2$ production to be lost would be ca. 1,100 ktonnes per year (comprising sales to EEA downstream users and exports to non-EEA customers); and

- The split between sulphate and chloride $TiO_2$ production capacity in the EEA is 55:45 and this is assumed to apply to the actual production volume of 1,100 ktonnes/y. Therefore, it is assumed that ca. 600 ktonnes/y are produced via the sulphate process and ca. 500 ktonnes/y are produced via the chloride process.

**Table 4–6** summarises the volumes of raw material inputs (excluding feedstock) and energy which would no longer be consumed by EEA-based $TiO_2$ manufacturers following a collapse of operations as a result of the implementation of the proposed classification for the substance. In total, the trade of ca. 4 million tonnes of raw materials would be at stake. Some of this, potentially, would be sold outside the EEA as a result of the likely increase $TiO_2$ production overseas.

**Table 4–6: Raw material and energy input to $TiO_2$ pigment manufacture that would be eliminated as a result of the proposed hazard classification for $TiO_2$**

| Input | Inputs no longer used | Unit |
|---|---|---|
| Feed - Ilmenite | 1,540,000 | t |
| Feed - Slag | 580,000 | t |
| Chlorine | 100,000 | t |
| Sulphuric acid | 1,960,000 | t |
| Coke | 180,000 | t |
| Lime | 70,000 | t |
| Coal | 40,000 | t |
| Oil | 2,490 | t |
| Oxygen | 230,000 | t |
| Silica sand | 20,000 | t |
| Rock salt | 10,000 | t |
| Scrap iron | 90,000 | t |
| Aluminium sulphate | 10,000 | t |
| Hydrogen peroxide | 10,000 | t |
| Calcium hydroxide | 220,000 | t |
| Calcium chloride | 10,000 | t |
| Calcium carbonate | 830,000 | t |
| Aluminium hydroxide | 20,000 | t |
| Caustic soda | 110,000 | t |
| Energy | 27,100,000* | GJ |

** Equivalent to ca. 7530 GWh*

By way of example, we may estimate the market values of one of these raw materials, namely sulphuric acid. A price of US$30 or ca, €26 per tonne has been reported for January 2015[30]. If this is assumed to still apply, demand for sulphuric acid in the EEA would mean a potential loss of €26 × 1,960,000 = ca. €51 million for EEA suppliers.

In conclusion, closure of $TiO_2$ manufacturing plants in the EEA would result in significant loss of turnover for the suppliers of feedstock, raw materials, consumables, utilities as well as suppliers of all purchased services required to maintain and operate those manufacturing facilities.

[30] Information available at http://www.argusmedia.jp/~/media/Files/PDFs/Regional-Specific/JP/Downloads/Sulphur-Sulphuric-Acid-Hopes-and-Fears-for-2015/Sulphur-Sulphuric-Acid-Hopes-and-Fears-for-2015.pdf/?la=en (accessed on 2 November 2016).

Beyond the economic losses, impacts may arise for feedstock suppliers from a regulatory perspective as well. According to a feedstock supplier who commented on the French proposal for the classification of $TiO_2$:

> "*Under REACH regulation, Rio Tinto Iron & Titanium is the SIEF lead registrant for the substance UGI (slags, ilmenite electrothermal smelting, EINECS: 293-671-6). The proposed ANSES classification for $TiO_2$ will affect the REACH dossier for UGI directly, since a complete read-across approach with $TiO_2$ was applied for all routes of exposure. It will also affect other titanium feedstocks (ilmenite, rutile…) that were not registered under REACH since they were considered as ores and concentrates. The proposed classification will therefore have a direct impact on the overall titanium feedstocks industry, specifically for the feedstocks entering the EU market*" (Rio Tinto Iron and Titanium, 2016).

## 4.4 Impacts on downstream users from horizontal legislation

### 4.4.1 Introduction

There are three key pieces of legislation that would generally affect the vast majority of downstream users of $TiO_2$:

- Legislation on Classification & Labelling, namely Regulation 1272/2008/EC, which creates labelling requirements for those using $TiO_2$ for incorporation into formulations and articles;

- Legislation on the control of risks to workers from carcinogenic substances, namely Council Directive 1989/391/EEC and Directive 2004/37/EC, the Carcinogens and Mutagens at Work Directive which requires that employers of users of the substance should consider the use of alternative substances. If the substance cannot be replaced, closed systems should be used. Where this is not possible exposure should be reduced. Employers also have to make certain information available to the competent authority if requested (activities, quantities, exposures, number of exposed workers, preventive measures); and

- Legislation on waste management, namely the Waste Framework Directive 2008/98/EC and associated instruments (Regulation 1357/2014, and Decision 2000/532/EC). The properties that render wastes hazardous are defined in Annex III to Directive 2008/98/EC. According to Annex III, when a waste contains a substance classified as a carcinogen under CLP and exceeds or equals one of the concentration limits shown in Table 6 to the Annex, the waste shall be classified as hazardous by HP 7. A Carc. Cat 1B classification for $TiO_2$ would mean that a concentration that exceeds 0.1% would render any $TiO_2$-containing waste hazardous.

Other, perhaps less critical horizontal legislation includes the Industrial Emissions (IPPC) Directive 2010/75/EC, Annex II of which describes in relation to polluting substances "*Substances and mixtures which have been proved to possess carcinogenic or mutagenic properties or properties which may affect reproduction via the air*". Member States shall ensure that permits issued to industrial installations falling within the remit of the Directive will include emission limit values.

## 4.4.2 New labelling requirements

There would be clearly a need for replacing existing labels on $TiO_2$ products and $TiO_2$-containing products to account for its new classification, as proposed. This would undoubtedly have cost implications:

- Part of the existing stocks of labels and packaging (i.e. those intended for use within the EEA) would need to be disposed of (or recycled, where possible);
- New labels and packaging would need to be designed, produced and supplied to interested parties; and
- Logistic complexities would arise from the new labels and packaging being selectively used when trading within the EEA.

Estimates for the cost of new labelling following the proposed classification of $TiO_2$ are not available, although some figures can easily be retrieved on line from other cases of (re-)classification of substances and products[31]. Realistically, the cost per company may not be prohibitive depending on the type and volume of packaging[32], however when aggregated across the numerous uses of the substance, the overall cost would be very substantial. Moreover, given that only inhalation exposure may result in adverse health effects (and only under conditions of extremely high exposure levels) but the probabilities for such exposure and at relevant exposure levels are extremely remote, the expense for new labels would appear entirely unjustified.

Another significant complexity would arise from the differences between the classification of the substance in the EEA and outside the EEA. Manufacturers of formulations and other products would need to hold stock of two different packaging/label types to be used when bagging their output depending on where it will be sold. It would cause a significant logistical burden for what will essentially be the exact same product needing to be labelled differently thus causing delays, giving rise to errors and requiring more manual intervention for the necessary checks to be made. Again, all this would have no discernible benefit to workers' health.

In this context, it is important to highlight a recurrent feature of stakeholder responses received to the consultation undertaken. Respondents have expressed concern over indirect market impacts of the proposed classification and labelling. Many manufacturers and their customers would prefer not to handle formulations and products that are labelled as carcinogenic. For instance, most paints are not classified today and certainly not for such a severe category such as Carc Cat 1B, hence manufacturing plants are likely not used to handling such materials and customers might not be happy to continue using them, especially if this would mean additional measures for the control of worker exposure.



[31] For instance, small changes to the hazard labelling of aerosols would cost £0.14-0.2 million per aerosol manufacturer in the UK, or ca. £150-200 per production line (BIS, 2014). In another case, the cost of changing the labelling/packaging of cement bags was estimated at €0.7-7 per 1,000 kraft paper bags (depending on whether the entire bag or only part of it changes) and a total cost of €1.4-4 million per year for the whole of Europe (Cerame-Unie, 2013).

[32] It must also be remembered that proposed classification would also affect the use of $TiO_2$ in labels and inks that would need to be used in the new packaging.

### 4.4.3 New exposure controls for titanium dioxide-related manufacture

As noted above, the driving force behind the changes on exposure controls in the workplace will be the Carcinogens and Mutagens Directive as implemented and enforced across EEA Member States.

A significant number of stakeholders have provided estimates on the likely costs of complying with the requirements of this Directive. Firstly, employers would need to investigate the possibility of replacing $TiO_2$. We discuss below the limited possibilities for doing this. In short, elimination of $TiO_2$ from the vast majority of formulations and articles is not possible and, where it could be technically achieved, the performance of the final product would be impaired.

Where exposure to dust cannot be precluded, the proposed classification would lead to lower tolerable dust limits. Many workplaces would need to be newly evaluated, including dust measurements and a variety of measures could be taken depending on the requirements of the manufacturing processes. Where there is significant and frequent handling of dry $TiO_2$ pigment (for example, paint manufacture where $TiO_2$ is widely used) there would be a need to set up a 'clean room' scenario for manufacturing products based on $TiO_2$, isolating the manufacturing process for these products, where dry $TiO_2$ pigment is being used, from the remainder of the production.

Beyond that, investments for rebuilt raw material delivery and raw material handling, installation of dust handling and air cleaning equipment and improved ventilation would be required (for instance, to bring the filtration standards to a HEPA 14 efficacy or higher). Workers directly handling $TiO_2$ would need to wear full PPE – suits, gloves, goggles and air-fed respiratory equipment as well as specific cleaning posts and procedures, as appropriate. In addition, exclusive access to rooms, changes in shift patterns, use of specific storage/warehouses, additional cleaning, additional training, additional medical surveillance, additional workplace measurements, etc. would be required. Finally, for companies selling both in the EEA and non-EEA markets, consideration might be given to separating productions units, warehousing and control for EEA and non-EEA products.

Individual companies have provided some quantified estimates of the cost of complying with the existing legislation on worker health protection from exposure to carcinogens. **Figure 4–1** shows an overview of those estimates per site. For a very small minority of respondents, measures already in place are considered adequate, as exposure to $TiO_2$ powder is assumed not to occur or be already adequately controlled. However, even in that case, additional monitoring campaigns costing a few thousand Euros per year would be required. Costs could rise to up to €20 million per site for the implementation of completely closed systems for the handling and use of $TiO_2$. If closed systems were not to be used, improvements to ventilation and air extraction would still require an investment of hundreds of thousands of Euros. It should be noted that figures provided are only the costs for Year 1 but ongoing costs would also increase as additional monitoring, operation of extraction systems, use of PPE would continue in perpetuity. Clearly, these increased costs for worker protection would have a knock on effect on manpower and time dedicated to other key parts of the business, e.g. R&D. For large companies with many sites, overall costs could be very large.

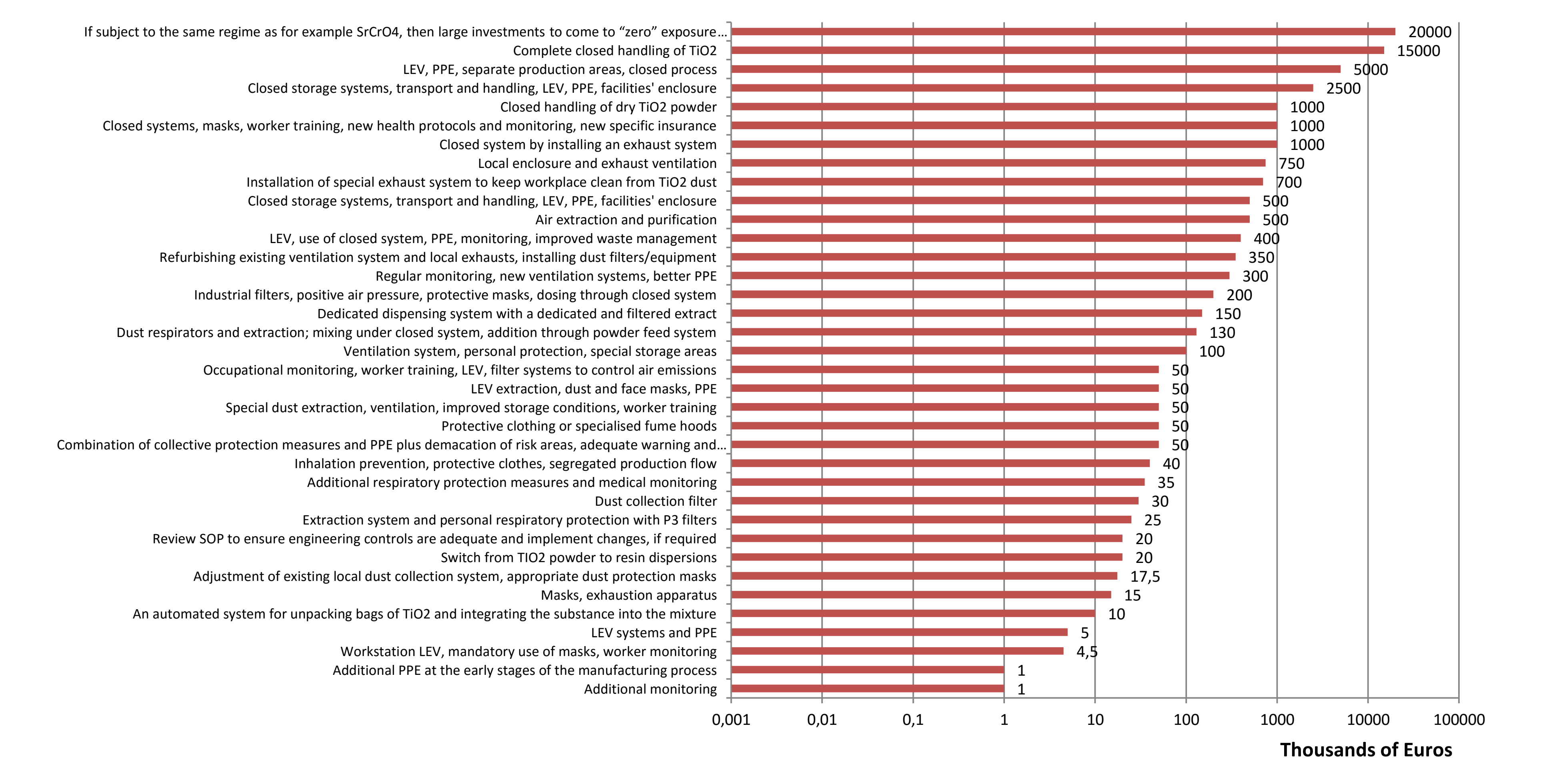



**Figure 4–1: $TiO_2$ users estimates on the cost of implementing existing worker protection legislation on carcinogens (thousands of Euros)**

*Source: consultation*

It is worth noting that in some applications, $TiO_2$ can be used in the form of a slurry (or in preparations, for instance in silicone fluid for sealants) and such use indeed takes place to a certain extent (for example, in liquid inks). This form of $TiO_2$ could eliminate exposure to powders and thus eliminate the need for additional measures for certain parts of the production lines; however, during drying processes $TiO_2$ dust might still be released to the air and thus total elimination of exposure may be difficult to achieve. Importantly, the price of slurry is €200-250/tonne higher compared to powder. This would have a profound impact on the economics of production and would further require significant investments the form of new tanks, pipes, etc., not taking into account the overall practicality of this measure (i.e. compatibility with production technologies, on-site space availability, etc.). To give an order of magnitude of the change in raw material costs, if slurry could replace 10% of the volume of $TiO_2$ currently used in Europe, the cost increase across markets would be larger than €200 × 1,107,000 × 10% = €22 million per year.

Finally, certain stakeholders have suggested that emissions to the environment might also come into focus, although the proposed classification is relevant to hazards to human health. For instance, one downstream user has advised that they are using a number of chemicals which are not classified as hazardous to the environment (but are for other endpoints) where the suppliers have still put limits on the environmental releases into extended SDS and in some cases these are stringent limits. When challenged, the suppliers argue that whilst the material does not fall under one of the classifications for environmentally hazards it still has some environmental impact and therefore the controls listed are relevant. If the suppliers of $TiO_2$ and $TiO_2$-based formulations would include in SDS release limits which are more stringent than the current ones, downstream users would need to assess this and potentially introduce more stringent measures (e.g. on wastewater controls).

### 4.4.4 New waste management requirements

***Impacts on waste management during manufacturing operations***

Additional impacts may arise in relation to waste regulations. To start with, waste regulations would affect the disposal, transport and removal of packaging that contained $TiO_2$ (paper sacks or big bags). Thereafter, waste containing $TiO_2$ at a concentration above 0.1% by weight could be classified as hazardous and would require to be disposed of accordingly. Improved waste management processes would have to also encompass the management of water effluents where $TiO_2$ is present. Manufacturers of $TiO_2$ generate significant volumes of $TiO_2$-containing waste and would clearly be impacted by a change to the hazard classification of such waste. Downstream users of the substance would also be impacted and some examples relevant to specific application areas of $TiO_2$ are provided hereunder.

In the field of **paint manufacture**, process washings are recycled and/or fully treated before leaving the site, and sub-standard product is usually reworked into production thus the volumes of hazardous paint waste would likely be small. However, the arising of hazardous waste would require segregation of wastes, collection of hazardous waste by a specialised disposal company and a significant relative increase in the cost of waste treatment.

In **ink manufacture**, depending on the formulations generated, waste may already be treated as hazardous; hence there would be no impact from the proposed classification for $TiO_2$. However, this does not apply to all manufacturers (for example, those producing recreational/school products which are non-toxic) and one such manufacturer provided an indicative additional cost of €0.1 million per year for the treatment of waste.

In the manufacture of **construction products** (adhesives, sealants, etc.) several consultees have suggested that waste that contains $TiO_2$ is already classified as hazardous so the proposed classification would not have a discernible impact. For some companies where the classification of waste would change, the additional annual cost would be less than €0.1 million per manufacturing site per year for waste segregation and treatment.

In the field of **paper manufacture**, production is currently set up to handle production waste that is classified as non-hazardous and therefore the proposed classification would cause increased processing complexity and costs. Some paper producers who use $TiO_2$ exemplified this by noting that when $TiO_2$-containing grades are manufactured, despite good internal recycling and good manufacturing practices, $TiO_2$-containing waste paper (broke) and $TiO_2$-containing sludge from water purification are generated; these waste streams could exceed the 0.1% by weight limit for $TiO_2$ and therefore could not be disposed of via the current routes (for instance, paper "crumble" may be directed to land spreading or energy recovery in an incinerator). If these $TiO_2$-containing wastes are classified as hazardous:

- Their handling and disposal would become more costly (NB. sludge and waste paper are generated in volumes of thousands of tonnes each year); and
- Waste paper feedstock for incinerators would need to be replaced by fossil fuel thus increasing the operating costs of the recipient incinerators.

Similarly, the cost of disposal for manufacturers of **glass products**, requiring the identification of new disposal (recycling) outlets, as well as the adaptation of existing waste storage areas. Elsewhere, a company involved in the production of **food for human consumption** estimated that segregation of solid and water waste plus installation of a water purification station would cost an estimated €0.3 million.

***Impacts on recycling of titanium dioxide-containing products***

End-of-life recycling of formulations and articles would also be affected. For instance, it has been suggested that it is very likely that steel and aluminium recyclability would be damaged in the case of a change of classification of $TiO_2$. Currently, **coil-coated products** (primary waste, downgraded products, but also end-of-life products) are recycled either internally in the case of integrated plants or via scrap processing companies. The flows would become seriously constrained or even impossible following the classification of the substance as Carc Cat 1B.

If **plastic waste** were to be classified as hazardous, the cost of handling could increase significantly leading to a decrease in recycling. For the production of masterbatches, compounds and conversion, there would be the risk of the substance eventually being subject to restriction and authorisation under REACH. According to estimates available to EuPC[33], between 600 and 700 ktonnes of plastics from long life applications (construction, automotive, electric and electronic, excluding packaging) are recycled. Over time recycling may increase to at least 1,000 ktonnes/y. All of those streams could be potentially affected since it is not feasible to segregate materials containing $TiO_2$ (the large majority) from others. For $TiO_2$ used in packaging, due to their short lifecycle, the $TiO_2$ will remain in the packaging recycling stream for a short time once replaced by an alternative (except for longer life packaging such as crates and pallets (which represent ca. 250 ktonnes/year).

[33] Based on a 2012 report by Consultic.

Similarly, in the field of **paper** manufacture, users of $TiO_2$ who have made a contribution to this analysis generally agreed that the proposed classification for $TiO_2$ would have an adverse effect on the recycling of paper products. Paper and board are normally recovered (recycling or energy recovery). Since the paper/board may contain $TiO_2$, there could be a risk of dust release during the recycling process and also a risk that paper/board containing $TiO_2$ could be an unwanted grade in the recycling system.

In relation to the use of $TiO_2$ in **fibre manufacture**, in the spinning process of polyamide yarns, there is always some amount of $TiO_2$-containing waste generated (spinning processes generate on average an equivalent of 10% waste for each kg of yarn production). This type of waste is largely used in EU (and globally) as an input material for engineering plastics and finally applied in the automotive industry, machinery, household appliances, etc. At present, even if in the EU these pre-consumers scraps are classified as waste, they can be considered as a very homogeneous waste (chemically it is a polyamide polymer in a physical status of fibre instead of granule), containing a minor amount of additives, such as stabilisers and pigments, including $TiO_2$ at a level that exceeds 0.1%. For this reason the generator of the waste is paid for supplying the waste material, instead of paying for its disposal. The classification of $TiO_2$ as Carc Cat 1B would change the classification of this waste to hazardous (HP7) and make its direct use 'as is' as raw material for engineering plastics manufacture impossible. Moreover, the final product/article will also acquire the same hazard classification. Options available to the waste generator would be:

- Pay to have the waste disposed of as hazardous (by incineration with disposal of final ashes containing $TiO_2$); or

- Install systems that would allow the "separation" of the polyamide from $TiO_2$ and then recycle the polyamide resin. This is not a simple or common industrial process[34].

More generally, for fibres that contain $TiO_2$, the hazardous waste classification of any post-consumer (or pre-consumer) waste would seriously hinder recycling activities and therefore circular economy policy implementation due to:

- The additional significant administrative and financial burdens of hazardous waste managing and transporting through EEA Member States; and

- Limited national/regional authorisations of hazardous waste recycling activities, which possibly could not be additionally extended, due to national/local legislation. This means, that the EEA portfolio of available end-of-life/recycling solutions for waste containing $TiO_2$, would diminish.

Consequently, this might bring to the situation where (a) the generator of waste would no longer have available the best available end-of-life/recycling solutions, (b) instead of making a profit from sale of the waste they would need to pay for its disposal, and (c) waste might be sold to non-EEA customers at a lower value.

A quick estimate of the increase in waste treatment costs from the proposed classification of $TiO_2$ on fibre manufacturers can be provided here:

[34] According to EU regulations, it is forbidden to go below the established limits by diluting hazardous waste with other not hazardous or pure product, thus it would be legally almost impossible to recycle the waste generated by fibre spinning operations.

- For **polyamide fibres**, considering an average waste equivalent of 10% for each kg of yarn production, the economic loss can be evaluated as follows:

  - Loss of income from the sale of waste: 10% × €1 = €0.1/kg yarn produced (where €1 is the unit minimum price for the sale of 1 Kg of PA6 waste);
  - Cost of disposal of the – now – hazardous waste: 0.1 × €0.15 = €0.015/kg of yarn produced (where €0.15 is the average cost of the "waste to energy" (incineration) disposal of 1 Kg of PA6 waste); and
  - Total minimum loss estimate would therefore be €0.115/kg yarn produced; in view of the often very limited contribution margin generated by nylon yarn, this loss might offset most if not all of the profit.

- For **polyester fibres** with a typical $TiO_2$ content in some fibre products of >0.2% by weight, production waste is nowadays used as secondary raw material and has a certain market value. Therefore, losses per typical site can be calculated as follows:

  - Loss of revenue: since amounts between 500 and 1000 t/y are relevant, typical revenues of €0.15-0.3 million/y per company would be lost;
  - Cost of disposal of the hazardous waste: typical disposal costs are in the range of €250-350/t, therefore €0.125-0.35 million/y additional costs; and
  - In total, the negative cost impact is estimated between ca. €0.3-0.65 million/y.

***Possibilities for exemptions***

It is worth noting, however, that the proposed hazard classification specifically relates to inhalation exposure. Under Article 7(3) or Directive 2008/98/EC (the Waste Framework Directive), where a Member State has evidence to show that specific waste that appears on the list as hazardous waste does not display any of the properties listed in Annex III of said Directive, it may consider that waste as non-hazardous waste.

Generally, inhalation exposure to $TiO_2$ from end products is very unlikely to arise as the pigment is embedded in a matrix (paints, plastics, coatings, inks, etc.), and migration is nearly zero. Even if some activities would generate some dust (i.e. removal of paints might generate dust), $TiO_2$ would still not be released free but would remain embedded in a matrix in the majority of cases.

Hence, industry would likely petition Member States to invoke Article 7(3) of the Waste Framework Directive and thus classify such waste as non-hazardous[35]. This could alleviate the impact of waste regulations on the users of $TiO_2$ in Europe, although empty containers of $TiO_2$ powders could be regarded as posing a hazard and are likely to be required to be handled as hazardous waste anyway.

Overall, the complexity and cost of compliance with existing regulation on protection of worker health and waste disposal would place a very significant burden on the EEA manufacturing base. Comments received by several stakeholders suggest that the costs involved could have an impact on the economics of production leading to scaling down of operations and the loss of jobs.

[35] In addition, a mirror entry on the European Waste Catalogue could render $TiO_2$-containing waste non-hazardous unless the content of the pigment exceeded a certain threshold.

# 4.5 Specific impacts on downstream users of mass applications of titanium dioxide

## 4.5.1 Paints and coatings

***Key market descriptors***

The key economic parameters of the use of $TiO_2$ are summarised below.

Importance of the application

The majority of paints/shades would be affected if $TiO_2$ was no longer available; only dark blue and black would not be impacted. All of the applications for $TiO_2$ have a socio-economic value, as the paints/coatings/inks industry is essential for the continued activity in virtually every downstream industry, from wall paints in construction and public buildings, through corrosion-preventing coatings for metal (aerospace, cars, bridges, heavy machinery), to high tech coatings for electronics (mobile phones, laptops) and printing inks for food packaging and magazines. Thus, the potential loss of $TiO_2$ from the industry's toolbox would impact everyday life for everyone.

Estimated $TiO_2$ tonnage used

Based on available information, paints, coatings and inks represent ca. 57% of total demand for $TiO_2$. Based on past data on market shares, we will assume that the split between DIY architectural paints and coatings, industrial coatings and inks is: 36% : 17% : 4%. This would translate into a total of ca. 630 ktonnes of $TiO_2$ consumed which an assumed 400 ktonnes used in architectural paints and construction products, ca. 190 ktonnes in industrial and functional coatings and ca. 40 ktonnes in inks.

Estimated tonnage of products that contain $TiO_2$

| Application | EEA production |
|---|---|
| Architectural coatings | 3.3 million tonnes/y |
| Industrial coatings for automotive, aerospace, marine, etc. uses including coil coatings, can coatings, road marking paints, flooring coatings and functional coatings | 2.4 million tonnes/y |
| Construction materials (plasters, caulks, fillers, mortars) | 0.3 million tonnes/y |

Estimated value of markets

| Application | EEA market value |
|---|---|
| Architectural coatings | €6.2 billion/y |
| Industrial coatings | €8.2 billion/y |
| Construction materials | €0.55 billion/y |

The value of painted/coated/printed/bonded end products equal many times the actual value of the paint; for instance, for a new car the paint represents an estimated 2% of the manufacturing costs. The value of the end industries that depend on paints and coatings is a high multiple of the value of the paints/coatings (e.g. the value of the printed material would easily be a 100-fold of the printing ink

| | |
|---|---|
| | value). In the UK for instance, the British Coatings Federation has estimated that £180 billion of the UK's GDP (produced by 300,000 employees) is directly dependent on the UK coatings, inks and wallcoverings industry which itself has a turnover of £3 billion. Therefore, with a paints/coatings/inks value of ca. €15 billion, the value of downstream markets could well exceed €750 billion. |
| Estimates of Gross Value Added | The Gross Value Added for paints, varnishes and printing inks across EU-28 is €5 billion/y. |
| Number of users of $TiO_2$ | The main EU trade association is CEPE. CEPE represents about 800 paint producers (plus 75 ink producers and 20 artist colour producers across Europe). |
| Presence of SMEs | Significant. It can be estimated that among CEPE's membership of paint and ink manufacturers more than 85% are SMEs[36]. |
| Number of stakeholders that participated in consultation | Several associations and individual companies have submitted completed questionnaires (25-50 companies with a combined production of ca. 0.6 million tonnes of paints, coatings, inks, recreational and artists' colours and stationery products (e.g. correction fluids) and a combined associated turnover of over €1.1 billion). Through CEPE's questionnaire response (plus several from national associations-members of CEPE), the vast majority of the EEA paints and coatings market has been captured. |
| Locations of stakeholders that participated in consultation | Large paint/ink manufacturers are scattered across the EEA but the following countries are particularly important: Germany, UK, France, Italy, Spain, Poland, Finland, Norway, the Netherlands (NB. the last three countries host specific dominant manufacturers who are key players across the whole of the EEA). |
| Employment in the sector | 110,000 workers are employed by paint, coating and ink manufacturers in the EEA. An estimated 15-20% of these would have regular (daily/weekly) contact with $TiO_2$ and/or $TiO_2$-containing products. An estimated 1,000,000 workers are involved in the application of paints/coatings/inks and 30,000 workers are employed in the DIY retail trade. |

***Relevant legislation***

**Table 4–7** (overleaf) summarises the relevance of different legislative instruments to the use of $TiO_2$ in paints and coatings after the adoption of the proposed hazard classification. Additional detail is available in Annex 1.

36 Notably, this may vary by sub-sector. For coil coatings, for instance, SMEs may represent 33% of members of the relevant trade association ECCA (European Coil Coating Association).

**Table 4–7: Relevance of different regulatory instruments to paints and coatings applications of $TiO_2$ following a harmonised classification of Carc Cat 1B**

| Relevant legislation | Type | Number | Relevant to paints and coatings |
|---|---|---|---|
| CLP | Regulation | 1272/2008/EC | Yes |
| Carcinogens and Mutagens at Work | Directive | 1989/391/EEC | Yes |
| | Directive | 2004/37/EC | |
| Waste Framework | Directive | 2008/98/EC | Potentially |
| | Regulation | 1357/2014 | |
| | Decision | 2000/532/EC | |
| Industrial Emissions | Directive | 2010/75/EC | Potentially |
| REACH | Regulation Annex XVII | 1907/2006/EC | Yes – Consumer products |
| | Regulation Annex XIV | 1907/2006/EC | Potentially |
| Cosmetics | Regulation | 1223/2009/EC | No |
| | Regulation | (EU) 2016/1143 | |
| Toy Safety | Directive | 2009/48/EC | Potentially |
| | European Standard | EN71-3:2013 | |
| Food Contact Materials | Regulation | 1935/2004 | Yes.<br>For can coatings there is no specific EU wide legislation but reference is made to the Plastics Regulation and CEPE's Code of Practice |
| | Regulation Plastics in Materials and Articles | EU/10/2011 | |
| | Regulation Recycled Plastic Materials and Articles | 282/2008/EC | |
| | Regulation | (EC) No 450/2009 | |
| Food Additives | Regulation | 1333/2008/EC | No |
| | Directive | 94/36/EEC | |
| | Regulation | 231/2102 | |
| | Regulation | 1831/2003/EC | |

| Table 4–7: Relevance of different regulatory instruments to paints and coatings applications of $TiO_2$ following a harmonised classification of Carc Cat 1B | | | |
|---|---|---|---|
| **Relevant legislation** | **Type** | **Number** | **Relevant to paints and coatings** |
| Medicinal Products | Directive | 2001/83/EC | No |
| | Regulation | 1901/2006 | |
| | Directive | 2009/35/EC | |
| | Directive | 94/36/EC | |
| Construction Products | Regulation | 305/2011 | Potentially.<br>The Construction Products Regulation 305/2011 is already defining some rules about the declaration of performance. The proposed hazard classification for $TiO_2$ would make it necessary to communicate the relevant information in the declaration of performance. The identification of $TiO_2$ as a carcinogen could make users more reluctant to use constriction products that contain it. Moreover, this regulatory framework is under evolution, towards stronger constraints |
| Biocides | Regulation | EU/528/2012 | Yes – selected products (in-can preservatives) |
| Medical devices | Directive | 93/42/EEC (amendment agreed in June 2016) | No |
| Restriction of hazardous substances in electrical & electronic equipment (RoHS) | Directive | 2011/65/EU | Potentially.<br>It is relevant but impact not automatic. The list of restricted substances would have to be updated following a risk assessment |
| | Directive | 2012/19/EU | |
| Tobacco additives | Directive | 2014/40/EU | No |
| | Decision | (EU) 2016/787 | |

| Table 4–7: Relevance of different regulatory instruments to paints and coatings applications of $TiO_2$ following a harmonised classification of Carc Cat 1B | | | |
|---|---|---|---|
| **Relevant legislation** | **Type** | **Number** | **Relevant to paints and coatings** |
| Other | - National Health and Safety at Work Legislation; and<br>- Ecolabel provisions<br>- The Global Automotive Declarable Substance List (GADSL) would also have a role to play. The GADSL covers substances that are expected to be present in a material or part that remains in a vehicle at point of sale and shows which substances are regulated. This is a voluntary industry initiative designed to ensure integrated, responsible and sustainable product development by automobile manufacturers and their supply chain. Its purpose is to minimise individual requirements and ensure cost effective management of declaration practice along the large and complex global supply chain[37] | | |



[37] Additional information is available at http://www.gadsl.org/.

***Impacts on the marketing and use of titanium dioxide-containing products***

*Possibilities and cost of reformulation*

Firstly, reformulation of paint products so that the concentration of $TiO_2$ could be kept below 0.1% by weight would not be possible. The substance needs to be present in tonnages at much higher concentrations to deliver its desired functionality. A well-known paint manufacturer has asserted that when less than about 15-20% $TiO_2$ is present in the formulation, only translucent paintings/coatings can be formulated.

Secondly, replacement of $TiO_2$ by alternative pigments is not possible in the vast majority of products. Other raw materials (e.g. calcium carbonate, zinc oxide and zinc sulphide, which are widely known white pigments) are usually of inferior quality regarding stability and opacity, brightness (gloss) and abrasion resistance. Often, replacement substances are critical in ecological and toxicological terms, especially if they contain heavy metals like e.g. lead carbonate. As the carcinogenic effect in animal testing is not substance-specific but characteristic of dusts and as dust exposure can be expected also in the processing of potential replacement substances, a substitution of substances would not change the given situation (VCI, 2016). Annex 2 to this report provides an extensive analysis of available alternative white pigments and the issues surrounding their technical performance compared to $TiO_2$.

Trade associations have supported this view by noting that, in the past, there have been issues with reduced $TiO_2$ production capacity resulting in a worldwide shortage of $TiO_2$ and significant price increase[38]. This incentivised paint manufacturers to seek substitutes, but efforts were met by very limited success. It was confirmed that it is not technically possible to fully match the overall performance of the reformulated products to the originals based on $TiO_2$. In any case, reformulation of paint products would be a lengthy and costly process. Consultation has revealed the following:

- **Consumer formulations**: it could take between 5 and 10 years to successfully reformulate and qualify a suitable alternative to $TiO_2$ in architectural (decorative) coatings, depending on the application and test protocols required. Given that there are many (thousands) of decorative coatings formulations already on the market, even once an alternative white pigment is identified, the cost and time required to reproduce colour formulations and technical specifications (i.e. testing to try matching the existing colour range, compatibility and stability) would be vast and, for many SMEs, unachievable, resulting in withdrawal of the smaller players from the marketplace, or relocation out of the EEA; and

- **Industrial formulations**: it could take between 5 and 20 years to successfully reformulate and qualify a suitable alternative to $TiO_2$ in industrial paints, coatings, printing inks and adhesives, depending on the application and test protocols required. Some products (once they have been successfully reformulated) require at least 5 years of testing and piloting before they can be approved for safe use in e.g. automotive or aerospace applications, or on infrastructure projects. As above for consumer formulations, the sheer number of products that would require reformulation would mean that the time required and the cost involved would be very large and,

[38] AkzoNobel also provides an indication of what percentage of variable costs is represented by the cost of $TiO_2$ for manufacturers of paints and coatings. In 2015, this was estimated at 7% of raw material costs (AkzoNobel, 2016). By comparison, all other pigments combined accounted for only 4% of raw material costs (AkzoNobel, 2013).

for many SMEs, unachievable, resulting in withdrawal of companies from the marketplace or relocation out of the EEA. It would also result in many downstream applicators of paints, coatings, inks and adhesives, relocating outside the EEA, as it would still be possible to import finished articles into Europe.

**Box 4-1: Case study – The challenges of reformulating coil coatings to eliminate $TiO_2$**

The paints used for coil-coating are probably among the most sophisticated paints. In the case of coil-coating, the liquid paint must have a rather low viscosity to make it possible to coat wet thickness sometimes below 10 µm and at the same time be curable within 8-20 seconds in hot air ovens (250 °C). The liquid paint is then a complex mixture that has specific physical properties (rheology) and chemical properties (to have the correct crosslinking rate in the curing step). Some coil-coating lines use powder coating. In this case, there is also a difficult compromise between the rather short curing time and the kinetics for melting, flowing and crosslinking.

Moreover, the coil-coated products are asked to reach a compromise between hardness and flexibility that is unique in the world of paints. Coil-coated products are bent, stamped, folded, etc. after being painted. The paint needs to avoid any cracking or loss of adhesion in this machining step, so it must be very flexible. However, at the same time the surface must resist scratches in the machining process and its appearance cannot be altered, so it must be very hard. This balance of hardness/flexibility is the result of a very complicated formulation, even more complicated if you consider that the paint thickness usually cannot exceed 25 µm.

Because of the balance between flexibility and hardness on the one hand, and the relatively low thickness on the other hand, coil coating is such a technically demanding sector that the probability of finding alternative solutions is quite low. When $TiO_2$ became too expensive and appeared to be unaffordable (after its price moved from US$2500 to over US$4000 per tonne between 2010 and 2012), major paint companies tried to replace it in all types of paints, including paints for coil-coating. In some paint applications it was possible to partly replace $TiO_2$ with some extenders, where it is mainly asked to cover and where there is no requirement about mechanical properties (for example some latex paints used in DIY as indoor paints). But in the case of coil-coating, this is simply not possible: after intensive R&D development, in the very best case some companies could find lab alternatives to replace only 2-3% of the $TiO_2$ loading, which is rather insignificant. The main reason for this is that any substitution of the $TiO_2$ makes it necessary to either increase the thickness of the paint layer or to increase the concentration of the pigment (because no other compound has the same hiding power and white intensity as $TiO_2$). In both cases (higher thickness or higher pigment concentration), the balance between flexibility and hardness of the coil-coated product would not be assured anymore and this compromise is a *sine qua non* condition for a product to be painted before being machined. A higher thickness would also have serious consequences on the coil-coating line, because of limitations in the ovens capacity (solvent concentration would increase and there would be a flammability concern) and because of winding problems (tension should be increased to avoid coil-collapsing and this increase would damage the paint layer).

In summary, in the case of coil-coating, the experts have identified $TiO_2$ as the only option for white pigmentation and as opacifier from all the known available materials both in terms of technical performance and from a health, safety and environmental perspective. Hence, there are no known options for improvement in this respect. If one could imagine that in spite of these technical hurdles some acceptable alternatives are finally discovered one day, the time needed for becoming able to use these alternatives would be very long. There are thousands of different products with a technical compromise as described above that would need to be reformulated and validated through a 2-4 years outdoor exposure. So the consequences of the proposed classification for $TiO_2$ for the paint suppliers and for the availability of coil-coated products on the market would be very significant.

*Source: information submitted by the European Coil Coatings Association*

Among all individual companies that have responded to the questionnaire, only two indicated that some reformulation of some industrial paint formulations could theoretically be possible. One of those indicated that reformulation would take longer than two years, while the other indicated an estimated reformulation cost of €60 million.

*Product availability post-classification*

The first and foremost impact from the proposed classification of Carc Cat 1B would be the loss of the architectural paint markets and of any other product that is sold to the consumer and contains more than 0.1% by weight $TiO_2$. This would arise as a result of the provisions of Entry 28 in Annex XVII of the REACH Regulation. As such, a significant proportion of the 3.3 million tonnes/y of architectural coatings that are produced in the EEA and placed on the EEA market would no longer be possible to be sold to consumers because there would be no feasible alternative to $TiO_2$ and even if one could be found its development would require a very long reformulation effort. Alternatively, architectural paints could only be used by professional users (i.e. professional decorators) and this will be the only lawful means of decorating homes in the future (this is discussed in more detail later in this document).

Apart from DIY use of paints in the EEA being effectively banned, from a technical perspective, it must be remembered that $TiO_2$ has an excellent brightening capacity vis-à-vis coloured media. A contributor to the public consultation on the French CLH proposal have noted that being forced to eliminate the use of $TiO_2$ would have a serious impact on the colour variety in particular for high quality decorative products, both interior and exterior.

**Figure 4–2** illustrates colour areas that can be theoretically reached with $TiO_2$ (light + dark area) and without $TiO_2$ (dark area only) as a component. The area of theoretically possible colours is reduced considerably. If one takes the NCS catalogue as an example, out of the 1950 NCS colours, in total only 125 are currently produced without $TiO_2$. In **Figure 4–3,** the top row shows the distribution of all NCS colours in the three-dimensional CIELab colour space. The lower row shows the remaining NCS colours when $TiO_2$ would be not available. That means without $TiO_2$ the practically achievable colour space would lack:

- All blue and violet colour shades;
- Bright colours; and
- Almost all grey shades.

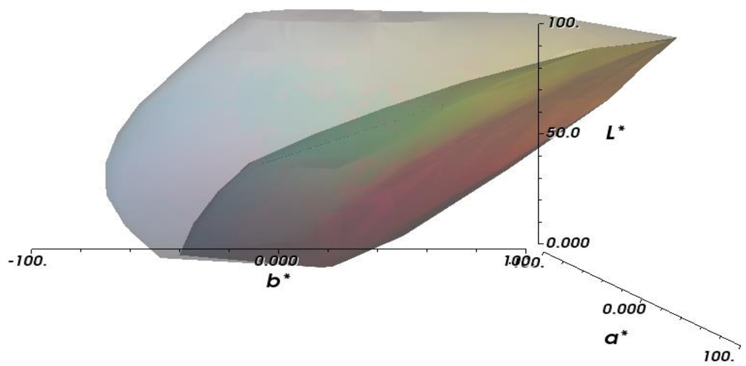



**Figure 4–2: Colours that can be achieved with (light + grey area) and without (grey area) $TiO_2$**
*Source: Jotun (https://echa.europa.eu/documents/10162/48252319-d727-42aa-8b3e-bb97cb218f0e)*

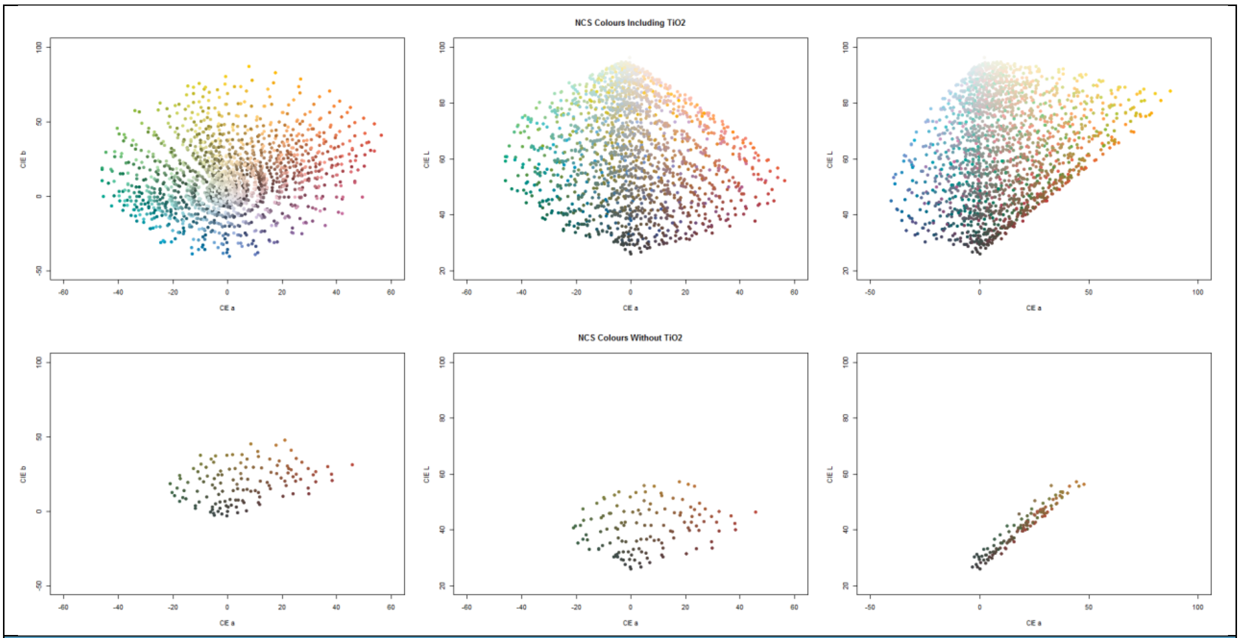



**Figure 4–3: NCS colours that can be achieved with (top) and without (bottom) $TiO_2$**
*Source: Jotun (https://echa.europa.eu/documents/10162/48252319-d727-42aa-8b3e-bb97cb218f0e)*

Trade associations and individual companies estimate that a very large percentage of paints manufactured in the EEA would be affected by the proposed classification. More specifically, **it is estimated that the proposed classification would affect 80-90% of the product range of EEA-based paint and coating manufacturers**.

*Market and economic losses*

As explained above the entire DIY market for $TiO_2$-containing paints, worth **€3.5 billion per year** will be lost. Part of this could be replaced by additional sales to professional users who would be the only persons legally allowed to use $TiO_2$-based paints in the domestic context, but as will be discussed below, the frequency of re-decoration would be impacted, thus only a fraction of the existing market would ultimately be preserved.

In any case, the prospects of EEA manufacture of architectural paints would be very poor:

- There would be a major impact on buying power related to raw materials, and to production set-ups and volumes. Companies would no longer have the production volumes running through their factories to cover their overheads;
- In addition, due to the requirements for manufacture (i.e. clean room production facilities), it would not be feasible to continue manufacture for sales outside the EEA as a result of the loss of competitiveness;
- For manufacturers whose consumer products (DIY paints, etc.) are a major part of their portfolio, the removal of these products from the EEA market would lead to a fundamental shift in the cost/benefit base of each company; and

- Finally, one might envisage that following the implementation of the proposed classification in the EEA, other regions might consider adopting similar classifications. This would lead to further restrictions on the marketing of architectural (decorative) paints and other consumer products.

In relation to industrial paints, as noted above, it is expected that 80-90% of production is likely to be affected by the proposed classification. The market value of these products is **€11.5 billion per year**. The extent to which this market would be affected would depend on many parameters which are difficult to quantify at present:

- **Compliance cost and competition with non-EEA manufacturers**: the cost of implementing measures for the protection of workers would place a significant burden on paint manufacturers. Some of them, particularly companies with production facilities outside the EEA may consider relocating production and thereafter importing the finished industrial paint product into the EEA. In addition, an increase in the manufacturing cost in Europe would hinder the export of EEA-made paints but potentially also painted products;

- **Economies of scale**: a potential loss of the DIY market would make the production of paints overall more expensive and thus EEA-made industrial paints less competitive;

- **Impact of certain regulations**: the marketing of paints regulated under the Biocidal products Regulation would be restricted. In addition, there would also be an impact on the industrial use of paints (and inks) under the Toy Safety Directive. Manufacturers who are currently placing on the market products that have been awarded an Ecolabel (or a Blue Angel label in Germany) would no longer be able to retain this, if $TiO_2$ remained in the formulations;

- **Follow-up regulatory action**: any subsequent actions by Member State Authorities or ECHA under the REACH Regulation would be of most concern, especially if $TiO_2$ then became classified as a Substance of Very High Concern (SVHC) and a subsequent restriction or requirement for Authorisation would ensue. The administrative burden, costs, resources and timescales required could lead many EEA-based paint and coating manufacturers to reconsider their portfolios and manufacturing locations; and

- **Setting precedence and an example for action by other jurisdictions**: as noted above, similar regulatory action in other global regions could follow. This would further impact upon exports of EEA-made products.

*Impacts on downstream users (industrial and professional)*

Users of paints and other coatings and related products would certainly be impacted too:

- **Continued use of $TiO_2$-based paints**: downstream users' use of these products, especially transport, handling and application, would have to be revised to meet the legislation requirements related to Carc Cat 1B-containing mixtures. This would undoubtedly involve additional costs and resources, and may impose limitations on production rates and capabilities. New equipment may be required to be installed, new storage systems and disposal procedures would have to be put in place – waste packaging that contained $TiO_2$-based mixtures would be automatically classed as hazardous and would need to be disposed of accordingly, for example.

  Companies using $TiO_2$-based products may be required by their customers to state that they are using a product that contains a Carc Cat 1B substance in the production of the article. This would potentially not be acceptable to many users further downstream in many sectors that produce finished items, articles or components or, for example, food packaging. Brand owners are likely to therefore put significant pressure on the supply chain to replace $TiO_2$. This would also attract negative publicity and undue attention from the media, NGOs, professional users (e.g. decorators) and the end consumer, even where the $TiO_2$ inhalation risk is close to zero (labels, food packaging, adhesives, painted objects, etc.) adding further pressure towards avoiding the use of $TiO_2$-based products even where the risk (or rather the lack of it) does not warrant such action;

- **Impacts from a switch to alternative pigments**: as noted above, feasible alternative pigments are not available. Any attempt to use alternatives on a large scale would cause severe technical and performance difficulties and would damage the image of EEA-based manufacturers, especially vis-à-vis their non-EEA competitors who would be able to continue using $TiO_2$ in their formulations.

  At a more basic level, the availability of many of the potential alternatives is far lower than $TiO_2$'s therefore with the exception of abundant minerals such as calcium carbonate or kaolin, sourcing the required volumes of pigments would be very challenging and would lead to production problems and increased raw material costs. Even where reformulation would be practicable, the results would not be acceptable, for instance:

  - Inks are applied at low film weights and $TiO_2$ substitutes would not be able to achieve the same opacity through the current standard printing procedures;
  - The durability of replacement exterior white coatings would be considerably inferior, so e.g. the finish on aeroplanes and cars would not be acceptable, if no longer based on $TiO_2$; and
  - White colour represents 80% of the production of coil coated galvanised steel. In order to preserve corrosion resistance without $TiO_2$, the industry could use more zinc but this would increase the cost for the customer (and impact upon the final thickness of the product).

A particular mention must be made to DIY stores across the EEA. The DIY retail sector would suffer an extensive setback with many key products no longer being available to the consumer. The footfall in DIY stores would significantly decline and sales would greatly suffer.

Impacts on the consumer use of paints, coatings and painted/coated objects are discussed further below.

***Social impacts***

*Employment impacts*

The estimated level of employment associated with the use of $TiO_2$ in paint and printing inks manufacture is 110,000 workers and many more are employed in downstream user sectors. Paint and printing inks are widely used and there is a very large number of people using/applying paint in Europe. The number of workers involved in the application of paints (at construction sites, industrial production lines, etc.) is estimated to be around 1 million.

Stakeholders have asserted that the proposed classification of $TiO_2$ might lead to the loss of thousands of jobs in paint/coating/ink manufacture[39] and among downstream users. By way of example, a threat on coil-coating would be seen as a wider threat for the activity in those integrated steel or aluminium making plants, leading to potentially accelerated decline of the European steel and aluminium making industry employing hundreds of thousands of workers. Related industries such as panel manufacturers and profilers, the construction industry, and domestic appliance manufacturers could also potentially be affected.

Jobs involved in the distribution of paints to the DIY user (estimated at 30,000 employees) could also be impacted.

*Impacts on the welfare of consumers*

The proposed classification for $TiO_2$ would have a profound impact on consumer choice and welfare. The following impacts should be noted:

- **Consumer choice and product availability**: irrespective of where DIY paints, adhesives, sealants and other formulations are made, they would be removed from the consumer market to a very great extent. Only black and very dark colours would remain and even these contain other poorly soluble particulate materials such as carbon black. No more DIY glossy paints would be available. Therefore, DIY activities as we know them would be severely curtailed. The only realistic option available would be the hiring of professional decorators, plumbers and builders to undertake work around homes that often is done by homeowners and tenants[40]. In certain countries where the use of pre-painted steel for cladding and roofing is widespread in residential buildings, the urban landscape and residential aspect would be changed;

- **Cost implications**: as professional decorators would be the only ones who would be permitted to work with $TiO_2$-based mixtures, consumers' costs would increase significantly, as they would have to pay more for materials and labour. By way of example, a member of the public may currently purchase the DIY paint needed for painting the walls and ceiling of a 120-130 $m^2$ apartment for, say, €50. A professional painter would charge more than €500, if not more. The cost of hiring a professional painter is already prohibitive for a large percentage of the population. Following the implementation of the proposed hazard classification for $TiO_2$, the fees of professional decorators might even rise if demand for their services was to grow disproportionately, thus making simple redecoration more costly, even for medium income families. Beyond the DIY uses of paints, reduced durability and increased frequency of paint/coating application would increase costs for the public sector, local authorities, housing associations, etc.;



[39] 11 individual companies who provided both their current level of employment (with a combined number of jobs of over 13,200) have estimated that the number of jobs lost would exceed 15,000, as non-TiO2 operations would also be impacted by the proposed classification.

[40] It is plausible that dust creation from the refurbishment of existing painted objects (walls, ceilings, wood trim in private houses) would also come under the spotlight for risk management – the public would no longer be able to strip paint from their houses or use abrading tools, due to concerns over their exposure to $TiO_2$-containing dust.

- **Loss of consumer satisfaction and welfare**: $TiO_2$-free alternative DIY paints and coatings would have neither the durability nor the 'brilliant white' appearance of existing paints. Higher paint thicknesses would be required to achieve the same opacity / hide the paint that is being overcoated. In addition, paint would probably need to be applied in three or four layers, not the current one to two applications. Painted walls would need to be refurbished more regularly due to damage and discolouration. Thus, painting jobs would take longer, would need to be done more often, and homeowners and tenants would be disappointed with the final results compared with what can currently be achieved with $TiO_2$-based paints. Thus:

  - It could be envisaged that paints intended for use by professional users would still be sourced and used by members of the public who value the aesthetics and durability of white and bright coloured paints and coatings. Such disregard for legislation aimed at consumer protection in combination with the clearly very limited scope for inhalation protection could undermine the public's trust in the appropriateness and validity of restrictions on consumer products;
  - Where members of the public would not wish to engage in DIY work anymore, due to the cost associated with hiring a professional decorator, they might then choose to decorate less often, which would have an impact on quality of life / standard of decoration in homes across the EEA (e.g. due to growth of mould in bathrooms). This would mostly affect people on low incomes.

  DIY work is a popular activity for the public in many countries. It offers satisfaction, a sense of ownership and achievement once the job is completed. It is a talking point and something people take pride in. Painting one's home or community centre can bring groups of people and families together, and strengthens a community and hence society. The message that the classification of $TiO_2$ would convey is that such activities are potentially harmful and thus should be avoided.

  Consumer satisfaction with articles that require painting, coating, printing and bonding may well be affected if there were subsequent impacts on $TiO_2$ use in numerous industrial sectors (due to the reclassification and loss of consumer products) e.g. for cars, aeroplanes, 'white' goods, furniture etc.

  Recycling of paint, although still relatively in its infancy, is a major part of Third Sector/charity activities, with paint helping to reintegrate members of the public with difficulties back into the community, and providing a focus for care and rehabilitation. These activities would likely be curtailed or prohibited.

- **Adverse effects on public health**: as the $TiO_2$ is not available as powder to the consumers/professionals when within a paint (a $TiO_2$ suspension), using the paint cannot realistically give rise to exposure to $TiO_2$ particles. On this basis, the proposed classification would not ensure better consumer health protection. Conversely, the proposed classification could, in an extreme scenario, result in adverse impacts on public health. $TiO_2$ is used extensively in the road marking industry to create bright safety coatings, the vast majority of which are used to keep members of the public safe on the road network. If the proposed classification would impact upon the market availability of $TiO_2$-based road marking paints (which are used by professional users rather than consumers), adverse effects on public health would arise. An increased incidence of traffic accidents due to poorer visual performance of alternative coatings could result in a higher incidence of death and injury[41], increased cost to emergency services in responding to an inevitably higher number of accidents, and increased congestion which would have a negative environmental impact as more vehicles would be running for longer therefore creating more potentially harmful emissions into the atmosphere than would otherwise be produced. Nevertheless, realistically, such adverse effects are unlikely to arise.

***Competitiveness impacts***

As explained above, the legal obligations arising from a Carc Cat 1B classification would have significant cost repercussions for the EEA industry both at the paint/coating/ink manufacture level but also downstream. Increased manufacturing costs would harm the competitiveness of EEA companies vis-à-vis their non-EEA competitors who would not need to comply with similar legislation (at least not until other jurisdictions potentially decide to follow the EU example on the hazard classification of $TiO_2$).

**Box 4-2: Case study – Loss of $TiO_2$ could mean more than the loss of white paints for EEA manufacturers**

Although $TiO_2$ is mainly used as a white pigment, the substance is used in approximately 100% of the order book of the pre-painted metal manufacturers since this pigment is used not only for the whites but also as a base pigment (along with black) to which other pigments are added to gain the final colour and obtain the correct colour saturation. Many of their customers buy a range of colours in pre-painted metal from one supplier. Even if loss of $TiO_2$ only affected the whiter colours, to remove the most common colour which is white, would affect not only the cost price of the remaining colours but stimulate the end customers to buy/import the total package from alternative sources not regulated by European legislation. Without $TiO_2$, many European coil-coating lines would probably stop because this pigment would still be used out of the EEA zone and imported as an acceptable final product (a phenomenon already seen with other substances, such as anticorrosive pigments).

*Source: information submitted by the European Coil Coatings Association*

Loss of competitiveness among paint/coating/ink manufacturers could result in a variety of reactions:

- Those EEA-based companies with affiliates or branches outside the EEA might consider relocating manufacturing operations where legislation is less stringent and thus costs are lower or alternatively outsource production; or
- Others with global operations might consider the adoption of variable protection standards across operations both logistically unwelcome and reputationally risky and thus adopt measures appropriate to a Carc Cat 1B substance across their global operations.

Relocation of the production of DIY and professional architectural paints might not appeal across the board as it is mainly a regional activity, however, more severe impacts might arise in relation to painted/coated/printed articles and the location of their manufacture. For obvious reasons, the manufacture of finished articles outside the EEA would become less costly and burdensome and thus

[41] Research in the UK estimates that the cost of a fatal road accident in 2012 was £1.6 million while the cost of serious or light injury was £0.19 million and £0.015 million respectively (information from http://www.makingthelink.net/tools/costs-child-accidents/costs-road-accidents, accessed on 11 October 2016).

more appealing. Such finished articles are unlikely to contain sufficient $TiO_2$ by weight (i.e. >0.1%) to trigger the SVHC requirement to notify recipients as per Article 33 of the REACH Regulation. Thus the local supply of products to manufacture these articles would probably be preferred on economic and supply security grounds, so relocation of parts of the supply chain might occur. DIY retail chains might also face increased competition from non-EEA e-commerce retailers who might be willing to supply professional users and consumers with $TiO_2$-based formulations. A cross-border pseudo 'black' market for white DIY paint might be created.

### 4.5.2 Plastics

***Key market descriptors***

The key economic parameters of the use of $TiO_2$ are summarised below.

Importance of the application

Estimated $TiO_2$ tonnage used

The plastics converting area covers a variety of sectors where $TiO_2$ may be used such as packaging, building and construction, automotive, electric & electronic, medical, household, leisure, footwear and clothes. The major sectors are packaging, building and construction and automotive. $TiO_2$ is not only used in the production of white masterbatches, it is also used in a wide number of colour formulations to obtain the desired colour.

60% to 70% of plastics articles end up with the consumer, while between 30 and 40% of plastics articles end up in sectors such as infrastructure, commercial and industrial, agriculture, etc.

Based on available information, plastics represent 25% of total demand for $TiO_2$. In the EEA, this would translate into ca. 275 ktonnes of $TiO_2$. Of this, 165-190 ktonnes will end up in consumer products with a further 85-110 ktonnes being present in industrial products (using the percentages shown above).

Estimated tonnage of products that contain $TiO_2$

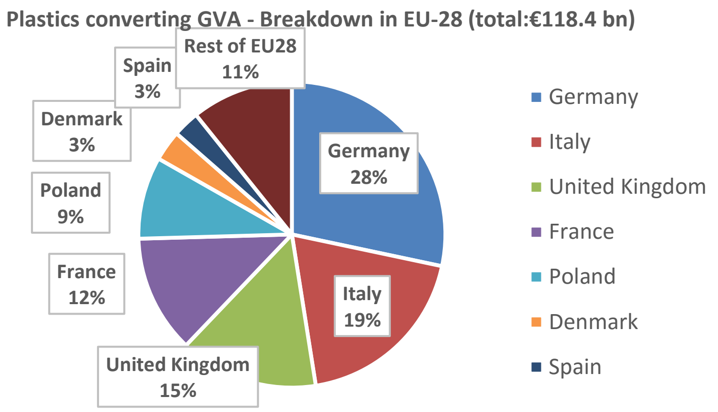
| Application | EU production |
|---|---|
| Plastic packaging (food, pharmaceuticals, other) | 15.1 million t/y |
| Plastics in construction | 8.2 million t/y |
| Plastics in automotive | 2.9 million t/y |
| Plastics in E&E | 1.4 million t/y |
| Plastics in agriculture | 0.7 million t/y |
| Plastics for consumer, household, furniture, sports clothing and footwear | 8.2 million t/y |
| **Total converted plastics** | 36.9 million t/y |
| *Source: EuPC* | |

Estimated value of markets

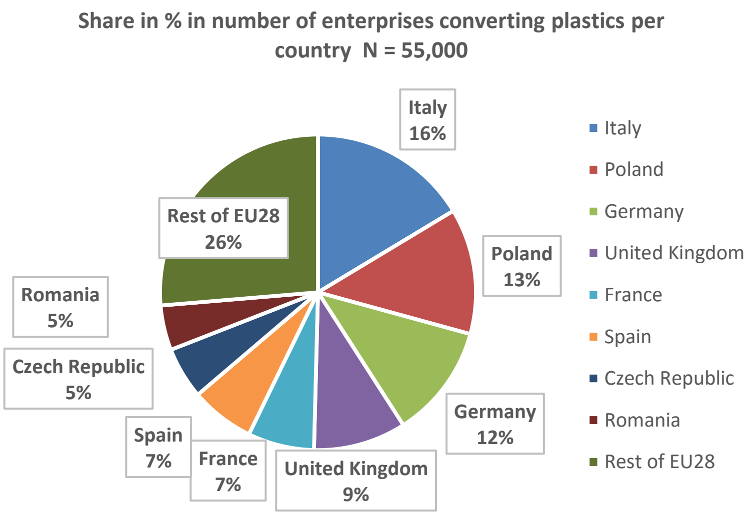
| Supply chain | EU market value |
|---|---|
| Plastics conversion | €170 billion |
| All plastics value chain (incl. polymer production and machinery) | €270 billion |
| All plastics value chain including resin manufacture (not only of $TiO_2$ relevance) | €350 billion |

According to PlasticsEurope, the multiplier effect for GDP for the plastics industry is 2.4 (PlasticsEurope, 2015). Therefore, the overall value including downstream markets can be estimated at ca. €650 billion.

| | |
|---|---|
| Estimates of Gross Value Added | The GVA of plastics converting in 2013 according to Eurostat was €118.4 billion for EU-28. Its breakdown among EU Member States is provided below (with Germany, Italy, the UK and France being the most important partners) (source: EuPC). |




| | |
|---|---|
| Number of users of $TiO_2$ | The main trade association, European Plastics Converters (EuPC) has ca. 55,000 members. The breakdown of these enterprises per Member States is given below (source: EuPC). It is estimated that almost all companies in the converting sector, mainly SMEs, may be potentially impacted should the availability of $TiO_2$ become uncertain. |




| | |
|---|---|
| Presence of SMEs | The majority of companies in the sector are SMEs. |

| | |
|---|---|
| Number of stakeholders that participated in consultation | Two key trade associations have participated, EuPC and the European PVC Window Profile and Related Building Products Association (EPPA). EuPC incorporates the European Masterbatchers and Compounders (EuMBC), an association representing more than 70% of the masterbatches and compounds manufactured in Europe.<br><br>Also an additional 10-25 individual companies active in the plastics field (masterbatch formulation, profiles, consumer products) have submitted completed questionnaires. Individual companies represent almost 1 million tonnes of $TiO_2$-containing products. |
| Locations of stakeholders that participated in consultation | EuPC spans the whole of the EU-28 plastics conversion industry while EPPA has members in Austria, Belgium, Denmark, France, Germany, Poland, Spain and the UK. The individual companies that have participated have operations in many EU Member States (some respondents own several plants). |
| Employment in the sector | Plastics conversion in Europe encompasses 1.5 million jobs (of which 25,000 work on the manufacture of profiles). According to PlasticsEurope the multiplier effect for jobs for the plastics industry is almost 3 (PlasticsEurope, 2015). Therefore, the overall employment including downstream markets can be estimated at ca. 4.5 million jobs. |

***Relevant legislation***

**Table 4–8** summarises the legislation that would be of relevance to the use of $TiO_2$ in plastics applications in the EEA, after the adoption of the proposed hazard classification. Additional detail is available in Annex 1.

**Table 4–8: Relevance of different regulatory instruments to plastic applications of $TiO_2$ following a harmonised classification of Carc Cat 1B**

| Relevant legislation | Relevant to plastics |
|---|---|
| CLP | Yes, for masterbatch & compounds and their use. Not for plastics articles |
| Carcinogens and Mutagens at Work | Yes, use in masterbatch and converting |
| Waste Framework | Potentially.<br>It depends if there is a mirror entry in the list of waste. If not then, no impact |
| Industrial Emissions | Potentially |
| REACH | **Annex XVII**: Potentially.<br>Impact not automatic. Restriction is only applicable to substances and mixtures for consumer use. This is not the case of plastics: masterbatches and compounds are mixtures for industrial use. Articles are sold to consumers.<br>$TiO_2$ could however be restricted following the submission of a specific Annex XV dossier |
| | **Annex XIV**: Potentially.<br>Relevant to availability of raw material (pigment, stabiliser or masterbatch or compound and their uses) |

| Table 4–8: Relevance of different regulatory instruments to plastic applications of $TiO_2$ following a harmonised classification of Carc Cat 1B | |
|---|---|
| **Relevant legislation** | **Relevant to plastics** |
| Cosmetics | Potentially.<br>$TiO_2$ is on the positive list of the cosmetics regulation, as a colourant as well as a UV-stabiliser used in cosmetics packaging. The regulation would have to be reviewed following a risk assessment |
| Toy Safety | Potentially.<br>Impact not automatic |
| Food Contact Materials | Potentially but unlikely.<br>$TiO_2$ is authorised in the positive list. $TiO_2$ classification does not cause an impact immediately. There could be an impact in case EFSA re-evaluates $TiO_2$. However this is unlikely since the proposed classification is carcinogen by inhalation, not relevant for food contact. Reaction by customers may differ however |
| Food Additives | No |
| Medicinal Products | No |
| Construction Products | Potentially |
| Biocides | No |
| Medical devices | Yes.<br>In the new Medical Devices Regulation producers will have to justify presence of CMRs in products if above 0.1% and label accordingly |
| RoHS | Potentially.<br>It is relevant but impact not automatic. The list of restricted substances would have to be updated following a risk assessment |
| Tobacco additives | No<br>Relevant to fibres applications of $TiO_2$ |
| Other | Global Automotive Declarable Substance List (GADSL) |

***Impacts on the marketing and use of titanium dioxide-containing products***

*Possibilities and cost of reformulation*

The unanimous view of the industry is that $TiO_2$ cannot be reformulated out of plastics in the vast majority of cases. In some limited cases, substitution of $TiO_2$ might be a practicable solution but would most likely constitute a case of regrettable substitution. Key implications would be:

- The need to use pigments in much higher loadings than $TiO_2$ in order to achieve the required whiteness;
- Additional additives would need to be included in the formulations, for instance additional UV absorbers/blockers would be required to replace $TiO_2$ functionality in supporting the weatherability of the plastic articles; and
- Some alternative pigments may carry their own adverse hazard classifications; any and all alternatives would have to be used in greater quantities to obtain a similar level of whiteness. Furthermore, such substitution would also require other non-colourant additives to be added. These non-colourant additives would primarily include UV-blockers.

In order to evaluate possible alternatives already used or evaluated, EuPC prepared a report on alternatives which incorporates the views of members that responded to a EuPC questionnaire. The report is reproduced below and whilst is specific to the plastics sector, it can be read in the wider context of Annex 2 to the present report.

**Box 4-3: Comparison of alternatives for $TiO_2$ in the plastics industry by EuPC**

The method used by EuPC was a grid questionnaire to evaluate $TiO_2$ as well as the possible alternatives. Possible alternatives were suggested based on information obtained in literature (Ruszala, et al., 2015; Zweifel, et al., 2008) and respondents (members) were invited to propose other alternatives.

Respondents were asked to rate these possible alternatives on a Likert scale (1, the worst to 5, the best) for the following properties: whiteness, food preservation, write-ability, opacity, weatherability, and chemical, colour and mechanical stability.

The proposed alternatives included in the question were: calcium carbonate ($CaCO_3$, CAS No. 471-34-1); zinc oxide (ZnO, CAS No. 1314-13-2); different clay minerals: kaolin, talc, perlite, vermiculite, calcined clays and flash calcined clays; cenospheres; and hollow spheres. Furthermore a space for other comments was added in order to give the possibility to the companies to contribute with qualitative remarks.

Sixteen (16) responses to the questionnaire were collected. All of them evaluated $TiO_2$, particularly its whiteness and colour stability. The results of $TiO_2$ are highly positive for all properties, with all scores above 4.3, and a total average of all properties of 4.6, as shown in **Table 4–9**.

The most evaluated alternative is calcium carbonate, followed by zinc oxide, kaolin, and talc. On other alternatives there were insufficient data to make general statements on the appropriateness of the alternative for the plastic converting sector. Conclusions on the most prominent alternatives are as follows:

- **Calcium carbonate**: calcium carbonate has an average score of 3.0 which is comparable to other alternatives, but low compared to $TiO_2$. The whiteness of calcium carbonate is also an issue. One respondent even suggested not considering calcium carbonate a pigment, but rather a filler additive. Furthermore, as calcium carbonate is able to react with acid ($CaCO_3 + 2\ H^+ \rightarrow Ca^{2+} + H_2O + CO_2$), it might be compromised in outdoor applications, which is reflected in the score of 2.17 for weatherability;
- **Zinc oxide**: apart from being an inferior whitening agent as determined by various scores, respondents indicated that this substance is also classified as very toxic to aquatic life and very toxic to aquatic life with long lasting effects. Thus substitution of $TiO_2$ by zinc oxide might not be a suitable option;
- **Kaolin and talc**: kaolin and talc are clay minerals which are generally considered to be fillers and not pigments. The loading levels required to obtain similar whiteness as a plastic whitened with $TiO_2$ are much higher for these substances, which can cause problems in terms of the mechanical properties of the plastic; and
- **Titanium dioxide**: several companies remarked the fact that $TiO_2$ is the only pigment that gives such a white colour with stability. Several respondents indicated that to achieve similar properties as plastics coloured with $TiO_2$, one would need to add other additives with consequent substantial cost increases for the end product. The same situation would be for UV absorbent properties. One of them stated that "*only $TiO_2$, ZnO and lithopone are white pigments, the other alternatives $CaCO_3$, clay, talc, kaolin are fillers and do not impart really opacity to a film*" and pointed out that $TiO_2$ has good weatherability. According to another respondent these alternatives are generally fillers developed for incorporation into the polymer matrix alongside $TiO_2$ in order to reduce cost. Great importance was given to $TiO_2$ for being a cost effective whitening agent. One respondent described $TiO_2$ as: "*undoubtedly the most efficient and cost-effective material to provide opacity and whiteness to plastics*." The fact of the need to add higher concentrations to achieve $TiO_2$-like properties was

indicated as well. One respondent explained: "*the best of the alternative materials would require four or five times the concentration to achieve similar levels of opacity and would not approach the whiteness provided by $TiO_2$.*" Some respondents concluded that currently, after having undertaken an extensive evaluation of alternatives, there are no suitable alternatives to this compound available on the market.

**Table 4–9: Analysis of Alternatives to $TiO_2$ in plastics (average values for each alternative's properties and the number of responses between brackets)**

| Chemical | Whiteness | Food preservation | Write-ability | Opacity | Weather-ability | Stability | | | Average score |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Chemical | Colour | Mechanical | |
| $TiO_2$ | 4.87 (16) | 4.5 (2) | 4.33 (3) | 4.71 (7) | 4.71 (7) | 4.83 (12) | 4.8 (15) | 4.36 (11) | 4.6 |
| $CaCO_3$ | 2.1 (15) | 3 (2) | 4.67 (3) | 3.17 (6) | 2.17 (6) | 3 (7) | 2.6 (10) | 3.1 (10) | 3.0 |
| ZnO | 2.75 (8) | 3.5 (3) | 3.33 (3) | 4 (4) | 2.67 (6) | 3 (6) | 3.14 (7) | 3.33 (6) | 3.2 |
| Kaolin | 2.125 (8) | 2.5 (2) | 4 (2) | 3 (4) | 2.5 (4) | 4.25 (4) | 3 (5) | 3.5 (4) | 3.1 |
| Talc | 1.92 (12) | 2.5 (2) | 4 (2) | 2.8 (5) | 2.67 (6) | 4.33 (6) | 2.86 (7) | 3.57 (7) | 3.1 |
| Perlite | 2 (1) | (0) | (0) | (0) | 1 (1) | (0) | 1 (1) | (0) | - |
| Vermiculite | 2 (1) | (0) | (0) | (0) | 1 (1) | (0) | 1 (1) | (0) | - |
| Calcined clays | 1.5 (6) | 2 (1) | 4 (1) | 2.5 (2) | 2 (3) | 4.33 (3) | 3 (3) | 3.33 (3) | 2.8 |
| Flash calcined clays | 1.33 (3) | (0) | (0) | (0) | 1 (1) | (0) | 1 (1) | (0) | - |
| Cenospheres | 2 (1) | (0) | (0) | (0) | 1 (1) | (0) | 1 (1) | (0) | - |
| Hollow spheres | 2 (3) | (0) | (0) | 3.5 (2) | 2.5 (2) | 4.5 (2) | 2.67 (3) | 2 (1) | - |
| Lithopone (ZnS + $BaSO_4$) | 4 (1) | 4 (1) | 5 (1) | 4 (1) | 3 (1) | 3 (1) | 3 (1) | 3 (1) | 3.6 |
| Barium sulphate | 1 (1) | (0) | (0) | (0) | (0) | 5 (1) | 4 (1) | 5 (1) | - |
| Antimony Trioxide ($Sb_2O_3$) | 4 | (0) | (0) | 4 | 3 | 3 | 3 | 3 | - |
| Zinc sulphide | 2.5 (2) | - | - | 3 (1) | 3 (1) | 4.5 (2) | 4 (2) | 5 (2) | - |

*Source: EuPC*

Even if the technical shortcomings of the alternatives could be disregarded, the cost of reformulation would be significant. An individual masterbatch manufacturer has noted that they would need to change 10,000 different formulations, the customers would have to review their processes and all new products would have to be tested and re-certified. Other stakeholders have suggested a reformulation cost as high as €4-10 million and a possible timeframe for reformulation of several years.

As noted above, loadings of alternatives would be higher and new additives would be required; organic UV stabilisers are relatively more expensive than $TiO_2$. Expert judgment within the EuPC indicates that the typical estimated costs for reformulation would be 5% of turnover and dedicated production for niche products would account for a further 5%, as companies would need to plan and organise detailed production campaigns to allow for the production of dedicated $TIO_2$-free products.

*Market and economic losses*

In relation to consumer-related products (**60-70% of plastics containing $TiO_2$**), as no mixture is sold to the public, the proposed classification would not mean an immediate loss of markets (cf. DIY paints discussed earlier)[42]. However the classification would have repercussions which could affect the marketing of consumer plastics:

- **Impact of waste regulations**: if waste was to be classified as hazardous, the cost of handling could increase significantly leading to a decrease in recycling making this operation uneconomical;

- **Perception and supply chain reaction**: consumer views on the presence of a carcinogen in plastic products might have an adverse effect on the market. The end users' perception of buying products that contain, or are packed or stored in materials that contain a potential carcinogen would affect their buying behaviour (for instance, when considering cosmetics, personal care products, food, food contact, pharmaceuticals). EuPC can further recount past examples where a change in hazard classification has resulted in reformulation in the short (additives for use in contact with food) to medium term (phthalate plasticisers). In the case of $TiO_2$, identifying a feasible alternative is currently impossible; and

- **Subsequent regulatory initiatives**: if $TiO_2$ were to be subject to REACH Authorisation and this Authorization were not to be granted, this could create a major disadvantage for the EEA plastics manufacturers who would see their exports impacted. At the same time, the volumes of imported better quality articles containing $TiO_2$ would increase, while EEA-made products would display worse quality, durability and aesthetics. Lifetime guarantees could not be met thus long-life applications (e.g. profiles) would be negatively impacted.

For industrial products, the above concerns would also apply. Classification as a Carc Cat 1B substance, and particularly inclusion in the REACH Candidate List, would trigger substitution especially from public procurement (infrastructure, public building, supplies for public administration) but also from some commercial sectors (outlets, shopping malls, etc.). Pressure

[42] It is worth noting the linkages between different applications of $TiO_2$, here between plastics, paper and printing inks. EuPC assumes that the majority of plastic packaging cannot be sold without a label as this would not be a functional unit. This means also a transparent PET bottle or tray cannot be sold without use of $TiO_2$ as the packaging will be unable to perform its function. $TIO_2$ pigment is used as a base colour on the label in order to enable the printed text to be seen. It is the only pigment that allows adequate legibility. For the time being the assumption is that 95% of packaging would be impacted.

from customers might lead to the need to reformulate products which would more specifically impose constraints on production organisation and significant R&D costs as well as the replacement of plastic with alternative materials (metal, wood, cement, for example).

Masterbatchers and compounders could expect serious negative effects on their business if the proposed classification were adopted, ranging from a significant reduction to a total loss of business in Europe, as the majority are SMEs. Again this would be driven both by regulatory requirements and customer buying behaviour. $TiO_2$ would be stigmatised and, thus, even if it legally could be used it could be de facto banned in consumer applications/products.

As indicated above, the typical estimated costs for reformulation would be 5% of turnover and dedicated production for niche products would account for a further 5%. Whilst part of this cost would be passed to the customers, other important costs would arise in relation to reduced performance of products (energy saving, durability) and shorter service life (more frequent replacement).

Elsewhere, under the newly agreed Medical Devices Regulation, the presence of $TiO_2$ would have to be justified. This would result in compliance costs, but is ultimately manageable as $TiO_2$ is the only whitening agent recognised in the EU Pharmacopeia and the particles are firmly embedded in a polymer matrix. Furthermore, the medical devices would have to be labelled as containing $TiO_2$, which again would create significant costs, but is ultimately manageable as the cost would be similar for all industry participants and there is a high willingness to pay, meaning that costs would be possible to transfer to consumers. This would, due to national health care system's collectivisation of risk, lead to increase costs for society.

***Social impacts***

*Employment impacts*

Estimating employment impact without clarity on what economic and market impacts would arise is difficult. Pressure from the supply chain to reformulate and increased regulatory burden at the manufacturing step would put pressure on employment levels. Given the very large number of workers in the sector, even a small percentage effect would result in a large number of job losses (loss of 1% of EEA-based jobs would mean redundancy for 15,000 workers).

*Impacts on the welfare of consumers*

The proposed classification for $TiO_2$ could have significant impacts on consumer choice and welfare. The following impacts should be noted:

- **Loss of certain types of consumer products from the market**: a major impact on brands and their ability to commercialise their products could be expected as a result of the business cost and negative perceptions associated with a carcinogenicity hazard classification;

- **Loss of performance**: without $TiO_2$, the durability of all materials exposed to light in long life applications (windows, gutters, furniture, automotive interiors) would be significantly reduced. Alternative materials (such as wooden windows) would require periodic re-painting; however, durable exterior architectural paints typically contain $TiO_2$. Such maintenance would therefore not be possible to be undertaken by members of the public. In addition, if certain plastic packaging solutions for food or agricultural feedstock lost their capability of protecting the goods from decomposition by radiation, spoilage might occur faster and the quality of packed goods might be affected. Worsening of the physicochemical characteristics of the polymeric matrices used, could in some cases result in a push towards the use of more expensive polymers for the same application;

- **Loss of consumer satisfaction**: loss of $TiO_2$ would mean loss of design capability (dull, unstable colours); and

- **Adverse impacts on public health**: loss of $TiO_2$ would make it very difficult to display information important to the consumer (e.g. food ingredients, safety). $TiO_2$ is the only opacifying agent for plastic containers recognised by the European Pharmacopoeia's Section 3.1. Its presence is necessary for the absorption of UV radiation and thus the protection of the shelf-life of a large number of light-sensitive pharmaceuticals. Similarly, $TiO_2$ supports longer shelf-lives for foodstuffs and cosmetics when used in packaging materials.

***Competitiveness and competition impacts***

The increase in manufacturing costs and the supply chain pressure for elimination of $TiO_2$ from products would cause loss of turnover and worsening of quality/performance of EEA-made plastic products. Therefore, EEA-based plastics converters would be disadvantaged vis-à-vis their non-EEA competitors who could import cheaper to make, better quality $TiO_2$-based articles into the EEA.

The $TiO_2$ business is a very global one: raw materials are easily sourced on global market because of the quantities involved (the savings on cheaper raw materials exceed the transportation costs). Similarly, for the rest of the value chain, from powder to intermediate articles, it is reasonable to expect that non-EEA players would have a competitive advantage to offer items such as films, sheets, extruded parts, etc. to finished article producers. Over time, under the constant pressure of market needs, a shift of the value chain to outside of EEA could be expected, for reasons of proximity and integration with suppliers of masterbatches and other preparations based on $TiO_2$.

Within the EEA, the plastics industry might lose the performance advantage it has versus the manufacturers of alternative products (e.g. wooden window frames). An increased regulatory burden could also drive consolidation in the industry, leading to less competition and SMEs would be most vulnerable in the face of such a trend.

## 4.5.3 Paper

***Key market descriptors***

The key economic parameters of the use of $TiO_2$ are summarised below.

| | |
|---|---|
| Importance of the application | There are three key areas for $TiO_2$ applications in the paper sector:<br>• Décor paper for laminate flooring and furniture and laminates for packaging;<br>• Wallpapers; and<br>• Unlaminated paper for packaging and printing/writing.<br>The importance of $TiO_2$ would appear to be higher for the first two areas, although specific areas of packaging and printing also show a dependence on the unique physicochemical properties of $TiO_2$. |

**Estimated $TiO_2$ tonnage used**

It is estimated that the paper sector accounts for 12% of $TiO_2$ consumption. This would be equivalent to ca. 130 ktonnes/y. Based on data available to Cefic (for the year 2013), laminates is the most prominent area of use and accounts for ca. 80% of total paper consumption, i.e. ca. 105 ktonnes/y.

**Estimated tonnage of products that contain $TiO_2$**

| Application | EEA production |
|---|---|
| Paper laminates (data for respondents only) | 250-500 ktonnes/y |
| Wallcoverings | 244 ktonnes/y |
| Packaging and printing/writing paper (data for respondents only) | 40-50 ktonnes/y |
| *NB. data are incomplete. By way of comparison, CEPI statistics indicate the production of 35 million tonnes of graphic papers, 44.5 million tonnes of packaging papers and 3.9 million tonnes of other papers in Europe* (CEPI, 2016) | |

**Estimated value of markets**

| Application | EEA market value |
|---|---|
| Paper laminates (data for respondents only) | €500-750 million/y |
| Wallcoverings (IGI membership) | €1.2 billion/y |
| Packaging and printing/writing paper (data for respondents only) | €25-50 million/y |
| *NB. data are incomplete*<br>A calculation can be made on the value of laminated board:<br>- Value of décor paper in laminate on average: €0.30/m² of coated board<br>- Value of laminate: €5-15/m² of coated board<br>- Volume of laminated board consumed in Eurozone: 3 billion m²<br>- As both sides of board are coated $1.5 \times 10^9$ $m^2$ × €10/m² = €15 billion in value | |

**Estimates of Gross Value Added**

Information on the specific applications of concern is not available. The entire paper industry in Europe has a turnover of €75 billion with a value added of €15 billion, according to CEPI[43]. If the same % of value added (20% = 15 ÷ 75) were to be used, the value added of the wallcoverings industry would be €0.24 billion and for the laminated paper products €100-150 million.

A 2011 report estimated that for every €1 of turnover made by pulp, paper and board mills, €1.05 was being made upstream and €2.88 was being made downstream (Poyry, 2011). It is uncertain whether the same ratios would apply for the products of interest here.



[43] Data available at: http://www.cepi.org/system/files/public/static-pages/CEPI_in_brief_infographic.jpg (accessed on 13 October 2016).

| | |
|---|---|
| Number of users of $TiO_2$ | The number of users is uncertain. 54 EU-based wallcovering manufacturers are members of the IGI trade association. CEPI, the Confederation of European Paper Industries indicates that there are 515 pulp, paper and board producing companies in the EU[44]. |
| Presence of SMEs | In the wider paper sector there is a large number of SMEs, however, several are part of or owned by large enterprises. Within the wallcoverings sector, the majority of companies are SMEs, but for laminates, SMEs might be in the minority. |
| Number of stakeholders that participated in consultation | 10-25 companies and <5 trade associations have submitted completed questionnaires. |
| Locations of stakeholders that participated in consultation | Germany, Sweden and the UK are the countries where most stakeholders who made a contribution are located in. With regard to laminate production, France, Germany, and Spain appear to be important contributors to EEA production. Among wallcovering producers Germany, the UK, the Netherlands and Italy host the largest number of companies. |
| Employment in the sector | According to a 2011 report (using data for the year 2008), the level of employment in the pulp, paper and board industry in Europe was ca. 208,000 (Poyry, 2011). In the same year, the number of employees upstream was estimated at 337,300 and downstream at 1,051,700. |

***Relevant legislation***

**Table 4–10** summarises the legislation that would be of relevance to the use of $TiO_2$ in plastics applications in the EEA, after the adoption of the proposed hazard classification. Additional detail is available in Annex 1.

**Table 4–10: Relevance of different regulatory instruments to paper applications of $TiO_2$ following a harmonised classification of Carc Cat 1B**

| Relevant legislation | Relevant to paper |
|---|---|
| CLP | Yes |
| Carcinogens and Mutagens at Work | Yes |
| Waste Framework | Potentially |
| Industrial Emissions | Potentially |
| REACH | **Annex XVII**: Potentially |
| | **Annex XIV**: Potentially |
| Cosmetics | No |
| Toy Safety | Potentially |
| Food Contact Materials | Yes |
| Food Additives | No |
| Medicinal Products | No |
| Construction Products | Potentially |

44 Data available at: http://www.cepi.org/node/20504 (accessed on 13 October 2016).

| Table 4–10: Relevance of different regulatory instruments to paper applications of $TiO_2$ following a harmonised classification of Carc Cat 1B | |
|---|---|
| **Relevant legislation** | **Relevant to paper** |
| Biocides | No |
| Medical devices | No |
| RoHS | Potentially (but unlikely)<br>Self-adhesive labels may be used in packaging of electronic devices and they may also be attached directly to the devices. Customers require that the paper has to meet the demands of RoHS concerning restricted substances |
| Tobacco additives | No |

***Impacts on the marketing and use of titanium dioxide-containing products***

*Possibilities and cost of reformulation*

A concentration of $TiO_2$ as low as 0.1% by weight would not confer the desired properties to the end products. For products where aesthetics, durability, wet opacity control and light-weightness are important, namely laminates and wallcoverings, there are no feasible alternatives that could be used to replace $TiO_2$. $TiO_2$'s high refractive index cannot be matched by other pigments. Zinc sulphide might come close but it has to be added at higher loadings, around 20-50% higher. There may be limited opportunities for partly replacing $TiO_2$ with some spherical plastic pigments which could contribute to a certain extent to shade and opacity, but this would only be limited to some final applications, due to conversion conditions and final product requirements[45]. As a result, estimates for the cost of reformulation cannot be provided with confidence, although a figure of €0.4 million per company has been suggested in the field of wallcoverings. In any case, lengthy trials would be required for any alternative to be tested. Estimates for the length of such efforts range between 2 and 5 years without a guarantee of success.

On the other hand, some current users of $TiO_2$ have noted that in some limited cases, where performance requirements are low, $TiO_2$'s use may not be critical and could be replaced either in part (for instance, by a composite pigment of calcium carbonate and $TiO_2$ (but this too contains $TiO_2$)) or potentially in full (by aluminosilicate and magnesium aluminosilicate or higher loadings of calcined clay and precipitated calcium carbonate). Again, reformulation would be accompanied by considerable cost.

*Market and economic losses*

In light of the absence of feasible alternatives in the vast majority of $TiO_2$'s applications, current users of $TiO_2$ would aim at continuing the use of the substance under more stringent conditions of worker exposure controls and waste management. However, compliance with the relevant legislation (which would come at an additional cost) could not necessarily ensure that market losses might not occur.

Customers and consumers may be confused about the implications of the carcinogenicity classification of $TiO_2$ and develop a negative perception on the products that contain it, even if the $TiO_2$ in the final product is within a matrix and it is not volatile or directly accessible. Customers may not wish to handle products that contain a carcinogen. In addition, decor paper is used to manufacture articles that are present in consumers' daily lives such as flooring, furniture, doors,

45 Conversion of laminate paper and covering of wooden panels requires several process steps such as printing, impregnating and pressing.

walls, facades and the widespread presence of a hazardous substance in bedrooms, living rooms, kitchens, workplaces could have an adverse impact on the decor paper industry as well as the ready-to-assemble furniture and flooring sector. Similar effects could be envisaged with other consumer-facing applications such as paper for food packaging paper.

***Social impacts***

*Employment impacts*

Employment impacts may vary depending on whether $TiO_2$-based products are critical to any one company or not. The Global Wallcoverings Association (IGI) has suggested that all 26,000 jobs in the sector would be at risk following the adoption of the proposed classification. Among the individual companies that have made an input to this analysis, the vast majority noted that jobs would be lost but that the scale of losses would vary[46].

Impacts downstream should also be taken into account, even though they cannot be quantified. The proposed classification for $TiO_2$ would affect the whole supply chain in the laminate industry, including the décor paper producer, the laminate decor printer, the laminating companies, as well as the wood based industry (furniture and flooring as well as wood board and panel producers, since the demand for their products would decline).

*Impacts on the welfare of consumers*

The proposed classification for $TiO_2$ could have notable impacts on consumer choice and welfare. The following impacts should be noted:

- **Loss of certain types of consumer products from the market**: some consumer products would become more costly to manufacture in the EEA with an impact on their competitiveness and therefore their production may be affected, scaled back, relocated outside the EEA or discontinued. Relevant products include wallcoverings with adequate opacity and lightfastness, a variety of paper-based packaging and laminated products (flooring, furniture, etc.). Wallcoverings are primarily sold on design and colour to make the products aesthetically pleasing to the eye. White inks and coatings are used and manufacturers also blend white with other colours to change the opacity levels to create pastel shades and increase the colour gamut. Abandonment of $TiO_2$ would reduce the product options available to the consumer and would make products duller and unexciting;

- **Increased cost and loss of performance**: the use of alternatives in the place of $TiO_2$ would certainly increase production costs and impact upon the performance of paper products. Surface treatment using decor paper, especially wood-based board product, delivers a high performance, low cost, resistant and easily maintained surface at a very competitive cost. Alternative surfaces are generally either less resistant or significantly more expensive (paint/lacquers or veneer). Solid wood furniture requires the use of comparatively much more wood and also more expensive wood to manufacture one unit of furniture or flooring. The combination of low cost and high performance provides the consumers with an affordable, high quality product.

[46] The total employment of the respondents is ca. 3,600 workers of which at least 1,270 would likely lose their jobs.

Wallcoverings that do not contain $TiO_2$ would be less durable to weathering, available in a narrower variety of colours and would need to be replaced more frequently; and

- **Loss of consumer satisfaction**: $TiO_2$-based products would suffer a loss of consumer confidence with $TiO_2$-free products, such as wallcoverings, would be of inferior quality, offering poorer visual effects leading to a poorer home and office environment. Paper-based articles such as diaries, bibles, etc. would become bulkier with more 'show through' from page to page.

***Competitiveness and competition impacts***

Paper-based products made outside the EEA could still use $TiO_2$ and then be imported into the EEA. Non-EEA products would not face the administrative and cost burden of the regulatory obligations triggered by the proposed classification and thus their products could become more competitive and would also be of better quality. In addition, paper and board produced within EEA are sold globally, both intermediate paper/board as well as converted products. An increase in operating costs would make the products exported from the EEA less competitive. For bulk producers (e.g. DIY wallcoverings or laminates) price sensitivity is key and the proposed classification could severely harm competitiveness.

Relocation (outsourcing) of activities outside the EEA could be a possibility, at least for certain production steps (e.g. manufacturing of paper) and where companies already have facilities established. Less critical steps (from a worker protection perspective) such as conversion of particle boards could still remain in the EEA. Ancillary industries would also be affected, for example, the wooden substrates industry (furniture and flooring) would be affected as access to covering material would become more difficult.

In terms of intra-EEA competition, relocation of some activities outside the EEA could have an impact. Companies which are producing similar products within and outside the EEA would increase their production outside the EEA and transfer volumes and knowhow outside EEA. This would lead to repercussions for the level of competition within the EEA. A smaller market within the EEA would result in companies striving for business. In addition, competing products would become more competitive vis-à-vis paper products that rely on $TiO_2$ (e.g. wooden flooring and furniture).

## 4.5.4 Inks, toners, artists' colours and stationery products

***Key market descriptors***

The key economic parameters of the use of $TiO_2$ are summarised below.

| | |
|---|---|
| Importance of the application | See discussion above on paints and coatings which are products closely related to printing inks. About 50% of screen and pad inks are white, of which about 95% is manufactured using $TiO_2$.<br><br>Toner and materials relevant to digital printing are similarly important to everyday life, primarily in a business/office environment, but also for consumers at home. |

**Estimated $TiO_2$ tonnage used**

As noted above, we assume that printing inks (but not digital printing inks, i.e. toner) account for ca. 4% of total $TiO_2$ consumption, i.e. ca. 40 ktonnes/y. The consumption of $TiO_2$ in toner is considerably lower (toner contains 1-5% $TiO_2$).

**Estimated tonnage of products that contain $TiO_2$**

| Application | EEA production |
| --- | --- |
| Printing inks | 0.6 million tonnes/y |
| Toner | Unknown<br>The total quantity placed on the EEA market is >3,000 tonnes/y |
| Artists, recreation and school colours | Unknown<br>>1,000 tonnes/y based on consultation results |
| Stationery and correction fluids | Unknown<br>>20,000 t/y based on consultation results |
| *Members of the I&P Europe Association also place on the market ancillary products such as:*<br>- *A small tonnage of industrial coatings (imported from outside the EEA);*<br>- *Paper for printing and writing;*<br>- *Special camera film (containing $TiO_2$ as a whitener); and*<br>- *Plastic foils, special films and security cards* | |

**Estimated value of markets**

| Application | EEA market value |
| --- | --- |
| Printing inks | €2.1 billion/y |
| Toner | >€1 billion/y |
| Artists, recreation and school colours | Unknown<br>>€0.1 billion/y based on consultation results |
| Stationery and correction fluids | Unknown<br>>0.1 billion t/y based on consultation results |

As regards printing inks, the value of the printed material would easily be 100-fold of the printing ink value, i.e. over €200 billion/y.

The market for toner related products is much larger and needs to include electronic equipment that relies on the toner, i.e. printers and copiers. This is estimated at over €10 billion/y.

**Estimates of Gross Value Added**

The GVA of the EU paints, coatings and printing inks has been provided above (€5 billion/y).

**Number of users of $TiO_2$**

There are ca. 75 ink producers (members of the European Printing Inks Association) and 20 artist colour producers across Europe. In addition, there are at least 58 members of the European Writing Instrument Manufacturers Association who use $TiO_2$. Europe Imaging & Printing Association (I&P Europe) has 32 member companies.

| | |
|---|---|
| Presence of SMEs | As noted earlier, among CEPE's membership of paint and ink manufacturers more than 85% are SMEs. EWIMA also confirmed this percentage noting that in the writing instruments industry most companies are family-owned SMEs. |
| Number of stakeholders that participated in consultation | 10-25 organisations, including trade associations. |
| Locations of stakeholders that participated in consultation | The key trade associations have members across the EEA. Individual respondents are based in Austria, Denmark, France, Germany, Italy, the Netherlands, Spain, Sweden and the UK. |
| Employment in the sector | As noted above, 110,000 workers are employed by paint, coating and ink manufacturers in the EEA. Printing inks that contain $TiO_2$ are in use in the segment of printed packaging and are applied in small and large print-shops. The employment in this segment of the graphic industry in EEA is estimated at 50,000. |

***Relevant legislation***

**Table 4–11** summarises the relevance of different legislative instruments to the use of $TiO_2$ in printing inks, toner and associated products after the adoption of the proposed hazard classification. Additional detail is available in Annex 1.

**Table 4–11: Relevance of different regulatory instruments to printing inks and toner applications of $TiO_2$ following a harmonised classification of Carc Cat 1B**

| Relevant legislation | Relevant to paints, coatings and inks |
|---|---|
| CLP | Yes |
| Carcinogens and Mutagens at Work | Yes |
| Waste Framework | Potentially |
| Industrial Emissions | Potentially |
| REACH | **Annex XVII**: Yes – Consumer products |
| | **Annex XIV**: Potentially |
| Cosmetics | Yes.<br>Some pencil manufacturers may also produce cosmetic pencils (e.g. lipliners and eyeliners). Also, printing inks may be used in applications such as "tattoo stickers" or nappies. In addition, the cosmetic industry asks the packaging manufacturer to comply with the Cosmetic Products Regulation, and the packaging manufacturer/printer, to cover himself, asks to the ink manufacturer to comply with the Cosmetic Products Regulation, so to not use prohibited substances listed in Annex II of the Regulation |
| Toy Safety | Potentially.<br>Might no longer be allowed to be printed with white or high-covering inks (exemptions are a possibility). |
| Food Contact Materials | Yes.<br>There is also a ban of use of CMR 1A/1B in printing inks |
| Food Additives | No |
| Medicinal Products | No |
| Construction Products | No |

| Table 4–11: Relevance of different regulatory instruments to printing inks and toner applications of $TiO_2$ following a harmonised classification of Carc Cat 1B | |
|---|---|
| **Relevant legislation** | **Relevant to paints, coatings and inks** |
| Biocides | Yes - In-can preservatives, but $TiO_2$ does not provide the biocidal effect |
| Medical devices | No |
| RoHS | Potentially.<br>It is relevant but impact not automatic. The list of restricted substances would have to be updated following a risk assessment |
| Tobacco additives | No |
| Other | - There is a EuPIA (European Printing Ink Association) Exclusion Policy which would require ink manufacturers to cease the use of $TiO_2$, unless an exemption were provided. The Policy includes carcinogenicity classification of 1B (and 1A) under the Group A exclusion criteria (see Section 8.2.2);<br>- Ecolabel provisions |

***Impacts on the marketing and use of titanium dioxide-containing products***

*Possibilities and cost of reformulation*

Information available from consultation shows a mixed picture over the perceived ability of $TiO_2$ users to reformulate their products in order to remove $TiO_2$:

- **Consumer ink formulations**: some users of $TiO_2$ claim that reformulation of consumer inks and associated products is not possible. One company in particular has recounted past research on alternatives (such as barium sulphate, lithopone, chalk) which has confirmed that only $TiO_2$ can deliver the quality required. Yet, if lower quality products would be acceptable, reformulation might be considered. The estimated costs of reformulation range between €50,000 and over €5 million (notably, the highest estimates are from companies that have indicated that reformulation would be a theoretical possibility). The time required for reformulation would be between 2 and 5 years;

- **Consumer/industrial toner mixtures**: identifying a feasible alternative for $TiO_2$ in toner is very challenging. $TiO_2$ has been used as a charge control agent in toners for many years. It stabilizes the electrostatic charge and improves the flowability of toner powders in ambient conditions. It leads to high-definition print and promotes the stable operation of the printers and copiers. In addition, it is not possible to use a coloured particle for colour toner. No other materials meet such requirements at an acceptable performance level. Any alternative would have to pass many tests concerning the print quality and stable operation of the printers or copiers at the various printing environments (temperature, humidity, paper type, preservation conditions, etc.) before it could substitute $TiO_2$. It is of note that toners are customised for every model of the printer or the copier, and there many types of both. Hence, there would be a need to test each combination of toner-printer/copier. An estimate of the potential cost of a theoretical reformulation would be in the tens of millions of euros (including the cost of scrapping existing inventories) and the time required could range from 2 to over 10 years. Each time a reformulated product has to be introduced to a customer, this new product offer is also open to competition, meaning that a market loss is always a possibility; and

- **Industrial ink formulations**: reformulation is not possible for performance reasons in terms of opacity and ink film thickness and it is important to consider that printing inks are used for plastic/glass/metal articles in the shape of packaging, toys, medical devices, automotive products and many others. Estimates with regard to the cost and duration of a reformulation programme suggest a cost of €5 million over a period of 5 years.

*Market and economic losses*

The proposed classification for $TiO_2$ would cause loss of sales and markets for a variety of reasons:

- **Restriction on the use of Carc Cat 1B substances**: supply of inks and toners containing $TiO_2$ at a concentration above 0.1% by weight to consumers would be prohibited under Entry 28 of Annex XVII of the REACH Regulation. That would include mixtures in the form of artists'/recreation/school colouring materials, correction fluids, etc. In addition, the presence of carcinogenic components in inks used in food packaging would not be acceptable under the EuPIA Exclusion Policy and Council of Europe Resolution ResAP (2005)2; the proposed classification would therefore de facto prohibit the use of $TiO_2$-based printing inks in a consumer context;

- **Higher manufacturing costs**: the cost of manufacturing would be higher due to the need for using dedicated equipment (rather than standard equipment used for many powders) as well as the requirement to implement more stringent worker health protection measures. If products are reformulated, alternative pigments would be costlier as they would need to be used at higher loadings than $TiO_2$ (could be 5-10 times higher). In any case, new labels would be required, either to indicate that a carcinogen is contained in the formulation or to specifically indicate that $TiO_2$ is not contained in the formulation for the customers' information. Particularly, small companies could not easily absorb the costs of reformulation due to regulatory changes so would need to pass these on to customers, making products more expensive and their market position less competitive;

- **Customer requirements and perceptions**: supply chains and consumers might not be prepared to handle products that contain a carcinogen. For instance, in the case of toners, any dust seen on or around the printer (from whatever source) would be seen as potentially containing $TiO_2$ and so be treated as carcinogenic. Customers would choose $TiO_2$-free products and thus sales would be lost unless products were reformulated in which case the performance of the toner would suffer.

  In addition, as information flows globally, customers outside the EEA might be confused as to whether such mixtures still can be used safely and/or might adopt their purchasing behaviour to follow the new EU standard. In any case, reformulation, if at all possible, would result in quality loss. As white is an essential part of the colour shade range, customers located outside the EEA would prefer colours sourced from non-EEA suppliers where the white colour of the range has a better quality, compared to a white colour generated without $TiO_2$.

*Impacts on downstream users*

The protective and decorative effect obtained with white inks would no longer be obtainable. Packaging manufacturers would be forced to redesign packaging structures which are to date functional, safe and validated by tests accepted by the authorities, and trusted by the consumer. This would require significant effort in terms of new packaging development, validation, promotion to the market, leading to an increased use of different material combinations (e.g. paper labels on plastic films) which could impair established recycling processes, with foreseeable and unavoidable environmental impacts.

On the other hand, it is of note that toner preparations do not contain free $TiO_2$ particles. If the absence of exposure to $TiO_2$ particles is not taken into account and $TiO_2$ use is restricted or discontinued, there would be a significant negative impact on the laser printing business.

***Social impacts***

*Employment impacts*

See discussion above on employment impacts on the paints sector that incorporate ink manufacturers. Ink application processes would become more attractive when taking place outside the EEA. For instance, because white inks are widely used in packaging to give protection to the packaged food from light degradation, as are white plastic films for the same reason, the printing of packaging for food would move out of the EEA since the finished print would be imported as an "article" under the REACH Regulation. Relocation of economic activities outside the EEA would inevitably lead to job losses and plant closures along the supply chain (in this example, both ink manufacturers and printing plants would be affected).

Among those companies and associations that have responded to the questionnaire and which are relevant to inks, toners and ancillary products, an estimated ca. 1,500 jobs are expected to be lost (8 questionnaire responses).

*Impacts on the welfare of consumers*

The proposed classification for $TiO_2$ could have notable impacts on consumer choice and welfare. The following impacts should be noted:

- **Loss of certain types of consumer products from the market**: as noted earlier, formulations currently sold to the consumer would no longer be placed on the market, including artists' paints, writing inks, crayons, craft materials, correction fluids, toys, etc. Laser printers and copiers would become unusable.

  Certain packaging articles such as paper bakery bags would be hard to manufacture without $TiO_2$. All flexible food packaging made of plastics in which product information (e.g. batch number and consumption date) is printed with inks over a white area would have to be redesigned or would need to be combined with an adhesive paper label, which would impair the recycling of packaging waste;

- **Increased cost and loss of performance**: as $TiO_2$ displays unsurpassed performance in the applications of concern (alternative white pigments do not match $TiO_2$ with regard to opacity, whiteness and fastness properties), any reformulation of products would lead to the loss of performance. If consumers did not have access to high quality art and school products, they would need to use low quality products or use expensive electronic equipment such computers and tablets.

  Food packaging articles in which white colour has a protective function against sunlight could be replaced by more expensive and less recyclable alternatives involving multilayer materials (e.g. increase use of aluminium foil on flexible packaging).

Printers and copiers using toner would not work without toner, and people would have to purchase new printers and copiers of the inkjet type[47]. The cost of ink is higher than toner per printed page;

- **Loss of consumer satisfaction**: removal of artistic/recreational/school products from the market would deal a significant blow to creativity of children and adults alike. A switch to electronic products could be envisaged. In addition, as noted above, alternative pigments would generate poorer white colours.

  Inkjet printers are not suitable for large volume printing, and takes more time for a print than toner type printers; and

- **Adverse effects on public health**: elimination of $TiO_2$ from the packaging construction would lead to reduced opacity and thus reduced protection from light. This might lead to reduced shelf-life of the packed goods.

***Competitiveness impacts***

As noted above, increased manufacturing costs (due to the cost of more stringent worker health protection measures or due to the cost of reformulation) would make EEA-made formulations and articles less competitive when exported from the EEA.

In addition, users of $TiO_2$-based formulations, e.g. packaging manufacturers, would be disadvantaged as they would have to either adapt processes to allow their workers to use carcinogenic formulations (at a cost) or switch to poor quality $TiO_2$-free formulations. The use of $TiO_2$-based formulations outside the EEA would become cheaper and easier thus it would be more convenient to move the use outside the EEA, generate articles and then import these into the EEA.

The proposed classification may force the decline of EEA-based production of certain products and lead EEA businesses either to outsource this production to non-EEA third parties, or to invest in new production facilities outside the EEA.

On the other hand, in the longer term, other global jurisdictions may also adopt the new hazard classification resulting in a global impact which would create a level playing field but would still have a profound effect on the users of $TiO_2$-based inks, colours and toners.

## 4.5.5 Construction products and coatings

***Key market descriptors***

These products are generally considered to be part of the paints and coatings market but it should be noted that applications are very diverse and may rely on different properties of $TiO_2$. Within this group, one may identify mass and specialty applications such as:

- Adhesives and sealants requiring whiteness, opacity, good dispersion properties and weatherability for construction applications. In addition to white colour, $TiO_2$ can be found in virtually all sealant colours apart from black;

[47] $TiO_2$ may also be used in inkjet inks as a white colourant. However, white ink is limited to a special purpose and isn't used in all products. As a result, the impact of the proposed classification would be limited.

- Adhesives for non-construction applications, for instance, water- based gelatine adhesives for the paper and cardboard industry which are used in the back lining of books[48] or dispersion glues such as those used to glue textile fibres on paper to generate wallcoverings[49];

- Ablatives and fire protection coatings in which $TiO_2$ offers fire resistance performance alongside fire resistant/ intumescent components;

- Fillers, grouts, mortars with "fresh colours" and good durability; and

- Photocatalytic active materials (cement) used in construction to reduce the concentration of pollutants in the air. Photocatalytic cement can be used in concrete block paving, concrete road surfaces, noise barriers, roof tiles and facades, to create durable photocatalytic active surfaces

The number of responses collected was not sufficiently high to allow for a detailed analysis to be provided here, however the following can be noted:

- According to CEPE, construction materials such as plasters, caulks, fillers and mortars that contain $TiO_2$ are produced at a volume of 0.3 million tonnes per year and have a market value of €0.55 billion;

- Across the 10-25 relevant organisations that returned a completed questionnaire, the volume of relevant $TiO_2$-related products produced in the EEA is ca. 50,000 tonnes with a market value of ca. €115 million/y. Adhesives and sealants are the most prominent product groups in both volume and value terms. The responding companies have operations in Belgium, the Czech Republic, France, Germany, Greece, Hungary, Italy, Lithuania, the Netherlands, Poland, Portugal, Slovenia and the UK.

  According to the Association for the European Adhesive and Sealant Industry (FEICA), the European market for adhesives and sealants exceeded €13 billion in 2014. It is estimated that close to 15,000 standard adhesive and sealant formulations are in use in Europe, based on five formulation technology platforms: (a) reactive systems; (b) water-borne; (c) solvent-born; (d) hot melts; and (e) based on natural raw materials. There are about 450 adhesive and sealant companies in Europe manufacturing at some 700 sites. Several hundred of them are SMEs (SMEs hold only 18% of the market and the top 60 companies account for about 80% of adhesive and sealant sales in Europe). The European adhesive and sealant industry employs more than 41,000 workers, of which 6,000 are employed by SMEs (FEICA, 2015);

- The construction sector accounts for more than 5% of the total EU-28 (gross) value added[50]. According to consultation, the sealant sector accounts for approximately 0.1% of the total construction sector, therefore 0.005% of the total EU-28 value added; and



[48] These glues are generally yellow, brown or beige. $TiO_2$ is used to whiten the adhesive without changing other technical properties like other fillers would do.

[49] $TiO_2$ is used to whiten the dispersion so it can be used as a masterbatch and the desired colour can be added by the customer (i.e. the wallcovering manufacturer).

[50] Information available at http://ec.europa.eu/eurostat/statistics-explained/index.php/Construction_production_(volume)_index_overview (accessed on 23 October 2016).

- As regards photocatalytic cement, fewer than five companies are believed to manufacture such a product. Most of them are not SMEs.

***Relevant legislation***

**Table 4–12** summarises the relevance of different legislative instruments to the use of $TiO_2$ in construction products after the adoption of the proposed hazard classification. Additional detail is available in Annex 1.

**Table 4–12: Relevance of different regulatory instruments to construction products applications of $TiO_2$ following a harmonised classification of Carc Cat 1B**

| Relevant legislation | Relevant to construction products |
|---|---|
| CLP | Yes |
| Carcinogens and Mutagens at Work | Yes |
| Waste Framework | Potentially |
| Industrial Emissions | Potentially |
| REACH | **Annex XVII**: Yes – Consumer products |
| | **Annex XIV**: Potentially |
| Cosmetics | No |
| Toy Safety | Potentially |
| Food Contact Materials | Yes |
| Food Additives | No |
| Medicinal Products | No |
| Construction Products | Yes |
| Biocides | No (NB. $TiO_2$-based in-can preservatives (biocides) may be used for inks) |
| Medical devices | No |
| RoHS | Potentially.<br>It is relevant but impact not automatic. The list of restricted substances would have to be updated following a risk assessment |
| Tobacco additives | No |
| Other | Global Automotive Declarable Substance List (GADSL) |



***Impacts on the marketing and use of titanium dioxide-containing products***

*Possibilities and cost of reformulation*

When asked whether reformulation of their products is possible, the majority of companies indicated that it is not and as such estimates of the cost of reformulation were not offered. In a few cases, some users of $TiO_2$ noted that reformulation to inferior products might be possible. The cost of reformulation has been estimated from €0.2 million to over €5 million. The time that would be required for reformulation would be 1-5 years. Following reformulation, the new products would need to be qualified by downstream users and some examples have been provided: re-qualification by automotive OEMs may take up to 5 years and by the aerospace industry may take up to 10 years.

*Market and economic losses*

There is no complete overview of the affected markets. The information submitted to the online questionnaire would suggest that the split between consumer and industrial applications (generally in the form of mixtures) is 15 : 85 respectively. The proposed classification for $TiO_2$ would cause loss of sales and markets for a variety of reasons:

- **Restriction on the use of Carc Cat 1B substances**: supply of adhesives, sealants, caulks, fillers, etc. containing $TiO_2$ at a concentration above 0.1% by weight to consumers would be prohibited under Entry 28 of Annex XVII of the REACH Regulation;

- **Higher manufacturing costs**: more stringent measures for the control of worker exposure to $TiO_2$ dust would cause an increase to the cost and complexity of manufacture of these products. Even if $TiO_2$ is sourced in a formulation (e.g. a polymer matrix), the suppliers upstream are handling $TiO_2$ powder and would need to improve their workplace exposure controls thus making their products costlier for those downstream; and

- **Customer requirements and perceptions**: many customers would not accept formulations that contain a Carc Cat 1B substance. Automotive OEMs via their Global Automotive Declarable Substance List (GADSL) would require that the substance is not contained in products supplied to them. Replacement of $TiO_2$ would result in poorer quality products which would affect the faith of customers in the industry as products would no longer be their usual brilliant white.

*Impacts on downstream users*

As discussed earlier for paints and coatings, removal of DIY products from the market would affect the retailers of such products.

***Social impacts***

*Employment impacts*

Through loss of market share (as a result of a restriction on consumer uses), loss of product quality (following a reformulation) and loss of competitiveness against non-EEA manufacturers, it is possible that job losses within the EEA would arise. There is insufficient information to allow the quantification of such impacts.

*Impacts on the welfare of consumers*

The proposed classification for $TiO_2$ could have notable impacts on consumer choice and welfare. The following impacts should be noted:

- **Loss of consumer products from the market**: as noted above, consumer products that contain more than 0.1% by weight $TiO_2$ would be removed from the market, irrespective of the actual risk of exposure by inhalation. This would mean that a wide range of DIY products (adhesives, sealants, building materials, etc.) would no longer be available;

- **Increased cost and/or loss of technical performance**: formulations without $TiO_2$ would have worse weatherability and would become discoloured more quickly, leading to more frequent (and thus costlier) replacement;

- **Loss of consumer satisfaction**: alternative formulations, particularly for consumer use would generally be less white and would have worse weatherability. For example, white silicone sealants are used in the majority of kitchens and bathrooms and their $TiO_2$-free replacements would not produce the same aesthetically pleasing effect; and

- **Potential adverse impacts on public health**: $TiO_2$ is an irreplaceable component in intumescent products and coatings. The function of $TiO_2$ is as a nucleating agent and a main component of the developed char. It is absolutely critical to product performance and there are no known successful alternatives. These intumescent products are key and critical to the preservation of buildings in the event of a fire ensuring there is time for people to escape safely. Therefore, the very nature of these products is to preserve human life.

***Competitiveness and competition impacts***

*Competitiveness impacts*

As discussed for other applications earlier (e.g. paints and coatings), production of these products outside EEA would be less costly. This would affect the competitive position of EEA-based manufacturers and would make the import of $TiO_2$-based formulations for industrial use more attractive. On the contrary, EEA-made $TiO_2$-based formulations intended for export would become more expensive and thus less competitive. It is likely that the larger manufacturers would relocate their production facilities outside Europe and import the finished formulation back into Europe instead. SMEs may not be able to do this and would either be forced to close or would have to rely on third party toll producers outside of Europe to produce the finished formulation for them. This would be a substantial loss of a significant business, particularly for construction applications, where a large number of SME sealant formulators are producing sealant cartridges containing $TiO_2$.

On the other hand, consumer products reformulated to eliminate the use of $TiO_2$ would be of worse quality than before and their exports to non-EEA markets would suffer.

*Intra-EEA competition effects*

Manufacturers who supply both consumers and industry/professionals would have a disadvantage compared to manufacturers who supply only industry/professionals as they would potentially need to supply two separate types of formulations with and without $TiO_2$. This would increase the logistical complexities and ultimately the cost of manufacture. In addition, customers may also be given the incentive to turn to alternative products (e.g. boards rather than intumescent coatings).

## 4.6 Specific impacts on downstream users of specialty applications of titanium dioxide

### 4.6.1 Fibre applications

***Key market descriptors***

The key economic parameters of the use of $TiO_2$ are summarised below.

| | |
|---|---|
| Importance of the application | Man-made fibres that rely on $TiO_2$ for delustering and whiteness/opacity are widely used as articles for the production of carpets, wallcovering in houses, hotels, offices, cars, airbags, swimwear, garments (for example, viscose filament yarn which is used in high-class, high-fashion textile products of the most well-known and prestigious fashion brands), hosiery, laces, outwear, sportswear, shoes, bags, tent, flags, backpack, luggage, hygiene non-wovens (diapers for babies and incontinence articles for adults, viscose dull fibre uses in wipes, tampons and sanitary textiles), etc. |

which are daily in contact with the consumers. The order of importance would appear to be:

- Clothing textiles;
- Non-wovens and hygiene;
- Carpets and other household products;
- Automotive; and
- Others (geotextiles, fishing nets, etc.).

Delustered fibres are also used in cigarette tow (filters). Europe has the highest prevalence of tobacco smoking among adults (28%)[51].

Estimated $TiO_2$ tonnage used

Uncertain – some literature sources suggest that fibres may account for 1-2% of $TiO_2$ consumption but the 2013 Cefic data group fibres into the "Other" category which collectively accounts for 4% of total consumption.

Estimated tonnage of products that contain $TiO_2$

| Application | EEA production |
|---|---|
| Man-made fibres for textiles, carpets, non-wovens, etc. | 2-3 million tonnes/y* |
| Cigarette tow | Unknown |
| ** RPA estimate* | |

The combined value of the products sold by companies responding to the questionnaire is over €250 million/y.

Estimated value of markets

| Supply chain | EEA market value |
|---|---|
| Man-made fibres for textiles, carpets, non-wovens, etc. | €7.5-10 billion/y* |
| Cigarette tow | Unknown |
| ** RPA estimate* | |

The combined value of the products sold by companies responding to the questionnaire is over €250 million/y.

Estimates of Gross Value Added

Unknown.

Number of users of $TiO_2$

The European Man-Made Fibres Association (CIRFS) has 31 full members, 9 associate members. The Global Acetate Manufacturers Association (GAMA) has two member companies in the EEA.

Presence of SMEs

Most members of CIRFS are medium sized companies. There are no SMEs among the acetate tow manufacturers.



51 Information from http://www.euro.who.int/en/health-topics/disease-prevention/tobacco/data-and-statistics (accessed on 24 October 2016).

| | |
|---|---|
| Number of stakeholders that participated in consultation | Fewer than 10 organisations including the European Man-Made Fibres Association (CIRFS) and the Global Acetate Manufacturers Association (GAMA) |
| Locations of stakeholders that participated in consultation | CIRFS has member companies in Austria, Belarus, Czech Republic, France, Germany, Ireland, Italy, Lithuania, Netherlands, Portugal, Romania, Slovakia, Spain, Switzerland, Turkey and the United Kingdom. Its members account for ca. 85% of European production of the main fibres within the scope of CIRFS (polyester, polyamide, acrylic, viscose, acetate, elastane and aramid)[52]. Most important locations include Germany, Portugal, Italy, Slovenia, Croatia, and the UK. |
| Employment in the sector | The total number of jobs in the man-made fibre industry is estimated at around 20,000. |

***Relevant legislation***

**Table 4–13Errore. L'origine riferimento non è stata trovata.** summarises the legislation that would be of relevance to the use of $TiO_2$ in fibre applications in the EEA, after the adoption of the proposed hazard classification. Additional detail is available in Annex 1.

**Table 4–13: Relevance of different regulatory instruments to fibre applications of $TiO_2$ following a harmonised classification of Carc Cat 1B**

| Relevant legislation | Relevant to fibres |
|---|---|
| CLP | Yes |
| Carcinogens and Mutagens at Work | Yes |
| Waste Framework | Potentially |
| Industrial Emissions | Potentially |
| REACH | Potentially |
| Cosmetics | No |
| Toy Safety | Potentially.<br>Impact not automatic |
| Food Contact Materials | Yes |
| Food Additives | No |
| Medicinal Products | No |
| Construction Products | No |
| Biocides | No |
| Medical devices | Yes |
| RoHS | Potentially |
| Tobacco additives | Yes |
| Other:<br>- Oeko-Tex certification (see Section 8.2.3)<br>- Ecolabel (see Section 8.2.2) | Yes |

52 Information available at http://www.cirfs.org/Portals/0/Docs/2013%20CIRFS%20FACTSHEET.pdf (accessed on 24 October 2016).

***Impacts on the marketing and use of titanium dioxide-containing products***

*Possibilities and cost of reformulation*

Elimination or reduction of $TiO_2$ in fibres would mean that the level of fibre lustre and whiteness required by consumers could not be achieved and the number of affected products would be particularly large; this is already known through industrial-scale tests. Perhaps for specific uses of $TiO_2$ reformulation could be a technically feasible option, however the requalification of these particular products in the value chain would be a very complex, time consuming and costly process. It is not possible to be 100% sure of the outcome as to whether or not these reformulated products would be accepted in the marketplace or by appropriate regulatory or certifying bodies.

Some estimates on the time that would be required indicate that at least 2 years would be needed and the associated cost could range between €0.5 and €2 million. On top of that, additional costs would arise for the more costly raw materials used, including an increase in the amount of fibre used,) for masterbatch formulation; this was estimated by a fibre manufacturer at €0.3 million/y. It is of note that for an alternative to give the same results on fibres it would need to demonstrate properties similar to $TiO_2$ (i.e. be an insoluble chemically inert metallic oxide with a particles size below 1 µm).

On the other hand, for the use of $TiO_2$ in cigarette tow, a $TiO_2$-free product might be possible to manufacture and this is currently being studied.

*Market and economic losses*

There are two key elements that would lead to economic losses:

- **Increase in the manufacturing cost**: the need to introduce stricter measures for the protection of workers' health could increase manufacturing costs and would harm competitiveness. Also, as discussed in Section 4.4.4, any change to the classification of $TiO_2$-containing fibre waste would cause loss of profits as this material could not be sold for recycling. In addition, the annual cost burden and the investment costs for the substitution of $TiO_2$ would be significant, relative to company profits;

- **Restrictions under specific regulation**: under regulatory regimes such as the Toy Safety Directive and the regulations on food contact materials, the continued use of $TiO_2$-containing fibres would be dependent on securing an exemption or authorisation. For this, testing would need to be undertaken to demonstrate that, for instance, the $TiO_2$ in the polyamide and polyester yarn is completely bound and strongly encapsulated in the polymer, making its inhalation impossible. It can be estimated that commissioning such testing to specialist laboratories would come at a cost of €1-1.5 million;

- **Quality of $TiO_2$-free products**: it is not known if the manufacturing processes would deliver an acceptable quality without $TiO_2$, so replacement of $TiO_2$ would lead to loss of sales and market share;

- **Consumer perceptions**: due to the requirements of the production processes and the quality requirements of the end products, $TiO_2$ is present in the range of 0.1-1.5%. Industrial users of the fibres would be reluctant to use them in case their processes give rise to exposure to dusts, even if $TiO_2$ is to be found within a matrix. Most man-made fibres come into contact with consumers in everyday life (this includes clothing, underwear, sports clothing, etc.). $TiO_2$

contents above 0.1% by weight would affect consumers' perceptions, even if the risk for consumer exposure by inhalation is non-existent.

***Social impacts***

*Employment impacts*

A very significant proportion of the 20,000 jobs in the man-made fibres industry in Europe would be at risk. The companies that have provided a response to the questionnaire have a combined workforce of several thousand workers and estimates on potential jobs lost indicate that thousands of jobs would be lost. Some companies expect that their entire workforce would be at risk.

*Impacts on the welfare of consumers*

The proposed classification for $TiO_2$ could have notable impacts on consumer choice and welfare. The following impacts should be noted:

- **Loss of certain types of consumer products from the market**: if $TiO_2$ were to be substituted, the quality of end products would be impaired and unavoidably it would not be possible to successfully place some of the products on the market. There is a very large number of different polyamide products manufactured in the carpet and textile sectors and these are very often "tailor made" for each customer. For textiles, there could be a shift to natural fibres (cotton, wool) but as there is not a sufficient quantity of natural fibres to cover even half of the needs of a growing global population, a limitation of synthetic fibre production would result in severe market disruption;

- **Higher cost and loss of technical performance**: substitution of $TiO_2$ would bring into question the technical performance/suitability of fibres for several key applications such as non-woven wallpaper, filtration, hygiene and medical single use products. The cost of substitution would, at least in part, be passed on to the consumer;

- **Loss of consumer satisfaction**: several examples can be provided:

    - In the field of wallpapers, if synthetic fibres of suitable quality were no longer available, consumers would have use non-dimensionally stable wallpaper products that are much more difficult and much more time consuming to use, while the aesthetic result would also be negatively affected;
    - In automotive filtration, if synthetic fibres currently used in state-of-the-art production technologies for the manufacture of durable filtration media were no longer technically suitable, there would be higher maintenance costs due to more frequent oil changes;
    - Fibre used as filling material in high quality quilts/pillows would lose consumer acceptance when made from recycled feedstock, as the fibre appears more yellowish without $TiO_2$ pigment;
    - In the carpet sector, a switch to hard flooring (wood, ceramic, marble, etc.) would reduce the level of comfort (e.g. in hotels, airports, etc.); and

- **Adverse impacts on public health**: a sudden obligation upon the synthetic fibre industry to find a substitute for a reliable ingredient like $TiO_2$ might create situations where a substitute's effects are unknown, and the effects on human health might in time turn out to be adverse, while $TiO_2$ poses no real risk. $TiO_2$ also has a UV-protection function, thus with its potential replacement, protection against skin cancer might be reduced.

***Competitiveness impacts***

EEA-based companies would have to deal with the complexities, administrative burden and cost associated with using $TiO_2$ as a powder, while non-EEA competitors would carry on in their operations without this burden. Key competitors are mainly located in Asia where advantages already exist in relation to production costs. With the additional regulatory burden, the cost per kg of manufactured product would increase by several euro cents. Thus export competitiveness (for example, polyamide carpet yarn specialties are of importance in this field) would be affected. The industry is already under economic pressure.

It is very important to consider that over 80% of textiles purchased by EEA consumers are imported from China or other Asian countries. In addition, over 80% of these textiles are made with fibres and yarn manufactured in China, or other Asian countries. Whilst fibre material contains $TiO_2$ at a concentration above 0.1% by weight, many products that are one stage lower in the value chain (textile/nonwovens) contain less than 0.1% $TiO_2$ due to dilution effects from blending with other generic fibre components. Thus, non EEA-manufacturers of textiles/nonwovens would remain free to use unrestricted fibres from non-EEA sources without the burden of restrictions (concerns over fibre abrasion, etc.) and would still be able to export their articles to the EEA. In other words, article manufacture would become less costly outside the EEA.

In theory, a future harmonised classification of $TiO_2$ should oblige all countries to handle the substance in a similar way, to protect workers' health. Nevertheless the EEA wastes regulations are not the same as those in Asian or American countries.

As far as the tobacco industry is concerned, the industry today uses one common formulation of cellulose acetate with $TiO_2$. Following the implementation of the proposed classification, manufacturers would be forced to have a second line of products for export out of the EEA. This would result in considerable additional costs that might not be fully recovered by price increases.

### 4.6.2 Catalysts

Limited information is available on the use of $TiO_2$ in catalysts, although the importance of the relevant catalysts is significant. Catalysts uses may account for 1% of total $TiO_2$ consumption in the EEA or ca. 10 kt/y.

The proposed classification would generate new obligations for the catalysts manufacturers who would need to introduce new measures such as the use of closed production systems, improvement of air exhaust systems, improvement of PPE, etc. As already discussed such measures could attract considerable costs. Whether customers (users of the catalysts) would accept to use a catalyst that contains a carcinogen would be seen on a case by case basis.

Inability of catalysts manufacturers to use $TiO_2$ could have significant repercussions on the production of chemical substances that rely on the relevant catalysts and also on the users of those chemicals. One catalyst manufacturer has suggested that sales of a specific type of $TiO_2$ catalyst are associated with revenues of several millions of Euros. Loss of these catalysts would also wipe out a market for the produced chemical worth several hundreds of millions of Euros. Consequently, users of said chemical would need to source alternative products which are known to have a higher market price, reduced performance and lifetime/durability. Competitors of EEA companies along this supply chain would gain a market advantage if the use of $TiO_2$ would no longer be possible in the EEA and production of the chemical in question would move outside the EEA with associated loss of added value creation from the industry and loss of jobs.

### 4.6.3 Food and feed additives and packaging

***Key market descriptors***

Limited information has been collected from consultation which does not allow the presentation of sufficiently representative industry-wide figures. Given the numerous food categories in which $TiO_2$ can be used, it is appropriate to assume that it is quite widely used as a food colour in the EEA. The flexible packaging market in the EEA has a value of several billion euros and the value of the market for food packaging inks is the range of hundreds of millions or euros (actual figures are confidential and are not reproduced here).

***Relevant legislation***

**Table 4–14Errore. L'origine riferimento non è stata trovata.** summarises the legislation that would be of relevance to the use of $TiO_2$ in food and feed additives applications in the EEA, after the adoption of the proposed hazard classification. Additional detail is available in Annex 1.

**Table 4–14: Relevance of different regulatory instruments to food, feed additives and food packaging applications of $TiO_2$ following a harmonised classification of Carc Cat 1B**

| Relevant legislation | Relevant to food |
|---|---|
| CLP | Only in receiving and handling raw materials |
| Carcinogens and Mutagens at Work | Yes |
| Waste Framework | Potentially |
| Industrial Emissions | Potentially |
| REACH | Potentially |
| Cosmetics | No |
| Toy Safety | No |
| Food Contact Materials | Yes |
| Food Additives | Yes |
| Medicinal Products | No |
| Construction Products | No |
| Biocides | No |
| Medical devices | No |
| RoHS | No |
| Tobacco additives | No |
| Other | CoE Resolutions and the EuPIA Exclusion Policy impact upon the use of CMRs in food contact materials and packaging |

***Impacts on the marketing and use of titanium dioxide-containing products***

*Possibilities and cost of reformulation*

There is no other white colourant approved under Regulation 1333/2008 that meets the performance of $TiO_2$ and thus reformulation is not possible. The only other white additive is E170, calcium carbonate, which does not have the opacity of $TiO_2$ and has severe technical limitations as described in Section 9.4 of Annex 2:

- It is a much less effective white colour than $TiO_2$;
- It will readily react with any acids present in foods to generate carbon dioxide and a (possibly soluble) calcium salt with no white colouring properties;
- It could not be used as a colour in any foods with low pH as it would neutralise the acid present, adversely affecting the product flavour, quality and possibly shelf life;

- It also could not be used as a white colour in cake batters, scone doughs, etc. since it would interfere with the raising agent system;
- It could not be used as a replacement to produce white glitter powders since E555 (Potassium aluminium silicate - mica) is only authorised for use as a carrier for titanium dioxide (and E172 iron oxides which produce red/brown colour glitter powders); and
- It is normally used in foods to function as an acidity regulator, anticaking agent, stabiliser or nutrient source (of dietary calcium) rather than as a colour. It is also used as a firming agent in many canned or bottled vegetable products.

Overall, calcium carbonate could not in practice be used as a viable replacement for $TiO_2$ in most of its current applications as a food colour.

As regards food packaging, no other pigment can deliver the required performance in terms of opacity and ink film thickness. $TiO_2$ is used at large concentrations (e.g. 15-60%); alternatives such as ZnS would require even higher concentrations and would still not be able to provide the opacity and performance currently required by the packaging market.

The protective and decorative effect currently obtained with white inks (and in some other cases with $TiO_2$-coloured substrates like plastic film or paper) would no longer be achievable, forcing food packaging manufacturers customers to develop new packaging designs and possibly the use of different materials to compensate for the lack of hiding effect provided by white inks. This would require significant effort in terms of new packaging development, validation, marketing, possibly leading to an increased use of different material combinations (e.g. paper labels on plastic films) in place of packaging that is to date consolidated, validated by tests, accepted by the authorities, and trusted by the consumer.

*Market and economic losses*

According to Article 6 of Regulation 1333/2008, a food additive may be included in the Community lists in Annexes II and III only if it meets the following conditions and, where relevant, other legitimate factors, including environmental factors:

1. It does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer at the level of use proposed.

2. There is a reasonable technological need that cannot be achieved by other economically and technologically practicable means.

3. Its use does not mislead the consumer.

Given the extremely low probability of exposure to $TiO_2$ by inhalation through food and the lack of feasible substitutes of equivalent performance, it may be presumed that an approval for the continued use of $TiO_2$ could be secured. The mechanism for securing an approval would have to be led by the Member States' Food Safety Authorities.

However, classification of a food ingredient as Carc Cat 1B is likely to cause significant concern among consumers and consequently a drop in sales of those products identified as containing the white colourant.

In respect of food contact materials, the implications of the proposed classification on the manufacture of food contact materials could potentially be severe, but the lack of exposure by inhalation might prevent extensive market losses. The following impacts may be envisaged:

- **Plastic contact materials**: Recital 27 of the Plastics Regulation (EU/10/2011) indicates that CMR substances should not be used in plastic food contact materials or articles without previous authorisation. Authorised substances are included in the Union list and $TiO_2$ is currently an authorised substance, under entries 610, 805 and 873 in Table 1 of Annex I, for use as an additive or polymer production aid. In theory, the substance might be reassessed by EFSA but the probability of exposure by inhalation in this context is small. As such, the likelihood of $TiO_2$ being removed from the Union List would probably be low. Furthermore, Regulation 282/2008/EC on recycled plastic materials and articles intended to come into contact with foods prescribes that only authorised monomers and additives should be added to the recycled plastics and their migration limits should also be respected by recycled plastic food contact materials. Use of $TiO_2$ in recycled plastic would be unlikely to be authorised, if no longer on the Union List;

- **Active and intelligent packaging materials**: Regulation (EC) No 450/2009 requires that CMR substances cannot be used in such materials and packaging even if not in direct contact with food or the environment surrounding the food and even if they are separated from the food by a functional barrier;

- **Inks in contact materials**: the EuPIA Exclusion Policy does not allow carcinogenic components inside food packaging, not even behind a functional barrier. Therefore, the proposed classification would *de facto* prohibit the use of $TiO_2$-based printing inks unless an exception was considered appropriate (see Section 8.2.2 of Annex 1 for more details); and

- **Food contact materials without harmonised legislation**: Framework Regulation 1935/2004 on food contact materials includes 17 categories of food contact materials in its Annex i. Of them, some may be of relevance to $TiO_2$. Also, only a few types of contact materials have been subject to harmonised legislation, for example, plastics as shown above. For the remaining contact materials, and until harmonised rules are introduced, Article 3 of the Framework Regulation applies under which food contact materials should not transfer their constituents to food in quantities which could: (a) endanger human health; or (b) bring about an unacceptable change in the composition of the food; or (c) bring about a deterioration in the organoleptic characteristics thereof. Additional information on the existing regulatory framework on food contact materials is provided in Sections 7.1.8 and 7.2.1 of Annex 1.

In any case, the presence of a carcinogenic substance in food packaging (in plastics, labels, inks and other materials) could bring about a major market change, a shift in public opinion and unpredictable reactions from consumers. It is worth remembering that safety criteria used for food contact materials are typically far stricter than for the evaluations of the safe use of chemicals in general with limits of 10, 0.1 or even 0.01 ppb in food contact and drinking water materials as opposed to 0.1-0.01% by weight for CMR chemicals in general, industrial and professional use.

***Social impacts***

*Employment impacts*

Insufficient information is available to estimate the total employment associated with the use of $TiO_2$. An industry association representing companies in the food industry has indicated that the use of $TiO_2$ is small in relation to other food ingredients handled (automatically or manually) and that it is therefore unlikely that social impacts can be attributed to any ban imposed. The association has stated that it would not anticipate any direct job losses in respect of the current usage of $TiO_2$.

*Impacts on the welfare of consumers*

The proposed classification for $TiO_2$ could have impacts on consumer choice and welfare. The following impacts should be noted:

- **Loss of certain types of consumer products from the market**: given the absence of other approved white colourants of similar opacity and the low probability of consumer exposure to $TiO_2$ by inhalation, it can be assumed that market availability of foodstuff that contains the substance would not be impacted. It is also worth noting that some $TiO_2$-containing products (e.g. confectionery) are deemed 'discretionary products', rather than staple goods, and so consumers might be able to switch to other products in the range. Food products could be produced with different decorations. On the other hand, a greater impact on the market presence of food packaging products could be expected. For example, white shopping and paper bakery bags would be hard to manufacture without $TiO_2$. All flexible food packaging made of plastics which has product information (e.g. batch number, consumption date) printed with ink over a white area could disappear, or be combined with an adhesive paper label, which would hinder the recycling of the packaging waste;

- **Increased cost and loss of performance**: assuming a continued use of $TiO_2$, impacts on food products would be limited. If $TiO_2$ were to be replaced by calcium carbonate (E170), additional loadings would be required and the opacity of the feedstuff would be worse thus impairing the aesthetic properties of the product. On the other hand, in relation to food packaging, white articles with a protective function against sunlight could be replaced by more expensive and less recyclable alternatives involving multi-materials (e.g. increased use of aluminium foil or paper on plastic flexible packaging). Alternative white pigments do not match $TiO_2$ in terms of opacity, whiteness and fastness properties and/or contain substances such as barium;

- **Loss of consumer satisfaction**: it is almost impossible to match the effects of $TiO_2$ or $TiO_2$-containing pearlescent pigments with other ingredients. The absence of white from the portfolio of colours available for the graphic communication of brand and product information in packaging and food packaging would result in the disengagement of customers from their preferred brands and a general perception of decreased quality in consumer goods or foods applying this kind of "whiteless" packaging; and

- **Adverse impacts on public health**: loss of $TiO_2$ would make it very difficult to display information that is important to the consumer (e.g. food ingredients, safety). Since packaged food would no longer be protected from light degradation due to the lack of opaque films, there would be a significant increase in the likelihood of food poisoning resulting from food going off in the packet before its sell-by date. This would probably result in reduced sell-by dates, and increased volumes of food being discarded beyond this date. This would affect the whole food supply chain (supermarkets etc.).



***Competitiveness impacts***

The need for more stringent measures for workers' health protection would affect the manufacturing cost basis of feedstuff producers and food packaging manufacturers in the EEA. When food or food packaging are exported to extra-EEA markets (such as Turkey, North and South America and Africa), the increased cost would hinder companies' ability to compete with local producers or extra-EEA producers who would not be affected by the proposed classification. Printed articles made outside the EEA would not be covered by the requirements of the CLP Regulation and could therefore be imported into the EEA, while they could not be manufactured in the EEA due to non-availability of $TiO_2$-based inks.

### 4.6.4 Pharmaceuticals

***Key market descriptors***

Consultation has generated little information that would help us provide an overview of the markets for $TiO_2$-containing pharmaceuticals. By way of background, the European pharmaceuticals industry involves 1,900 companies (members of the European Federation of Pharmaceuticals Industries and Associations – EFPIA) has a market value (ex-factory) of ca. €192 billion, a positive trade balance of ca. €86.5 billion and employs ca. 725,000 workers (EFPIA, 2016).

The German Medicines Manufacturers' Association (BAH) has noted that its more than 320 members may use between 100 kg and several tonnes of $TiO_2$ per year.

***Relevant legislation***

**Table 4–15** summarises the legislation that would be of relevance to the use of $TiO_2$ in pharmaceuticals applications in the EEA, after the adoption of the proposed hazard classification. Additional detail is available in Annex 1.

**Table 4–15: Relevance of different regulatory instruments to pharmaceuticals applications of $TiO_2$ following a harmonised classification of Carc Cat 1B**

| Relevant legislation | Relevant to pharmaceuticals |
|---|---|
| CLP | Applies to raw materials, but not to medicines (for human or animal use) |
| Carcinogens and Mutagens at Work | Yes |
| Waste Framework | Potentially |
| Industrial Emissions | Potentially |
| REACH | Potentially |
| Cosmetics | No |
| Toy Safety | No |
| Food Contact Materials | No |
| Food Additives | Yes<br>$TiO_2$ used in pharmaceuticals as colourant has to meet the criteria purity of E171 also used in food |
| Medicinal Products (colouring matters) | Yes |
| Construction Products | No |
| Biocides | No |
| Medical devices | No |
| RoHS | No |
| Tobacco additives | No |

***Impacts on the marketing and use of titanium dioxide-containing products***

*Possibilities and cost of reformulation*

$TiO_2$ is added in film coatings because this adheres to and covers the tablet core best. Without the use of $TiO_2$, the colour is not as smooth and homogeneous, and the colour, spots, and different coloured powder particles show through. Better coverage means better stability of the ingredients and better appearance.

As noted by BAH, there are no alternatives available offering the same/required characteristics of $TiO_2$ (excellent white pigment, chemical inertness, high stability against UV light) and some may be accompanied by their own hazards (e.g. ZnO). Much higher volumes of alternative pigments and longer application times would be required to obtain a similar whiteness.

Since $TiO_2$ is used in the great majority of coloured pharmaceutical and dietary supplement tablets and capsules, either as a sole colourant or in combination with other pigments to produce a range of colours, it is estimated that $TiO_2$ is used in thousands of medicinal and dietary supplement products globally. This is especially significant since medicinal product manufacturers and global regulatory authorities have carefully reviewed drug and dietary supplement products for potential hazards within the context of clinical trials and other safety studies involving animals and humans (Colorcon, 2016).

Therefore, there would be a need for complete reformulation of very many products with a high effort not only in terms of R&D. A change in the formulation of a medicinal product requires comprehensive studies of efficacy, safety and stability of the new formulations. New stability studies would last for several years (the shelf-life of most medicines is three or more years). A technical dossier showing compatibility, stability and drug efficacy would need to be developed, which is expected to cost several million Euros per medicinal product. Since $TiO_2$ is used in hundreds of pharmaceutical products in Europe, the total industry costs for a change could easily be in the range of billions of Euros. Only after all of these activities have been carried out, which may take years, could reformulated products be brought on the market to replace the existing portfolio in the EEA.

Finally, it is worth noting that testing the stability of the newly changed formulations would necessitate an unprecedented volume of tests. Their organisational and financial challenges would exceed anything previously seen in this field (VCI, 2016).

*Market and economic losses*

There are several elements that would lead to economic losses:

- **Possibilities for an exemption from a restriction on the use of $TiO_2$**: according to a 2007 opinion by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency, "*in the event that CMR toxicity has been identified for an excipient, the rule is to avoid and replace this excipient. In the rare cases where this would not be possible, the use of such CMR excipients in a medicinal product would only be considered after careful evaluation of the benefits of the medicinal product in the target patient population versus the potential risks (…) any risk identified for an excipient and in particular a CMR substance, would be acceptable only on condition that this excipient cannot be substituted with a safer available alternative, or that the toxicological effects in animal models are considered not relevant for humans (e.g. species specific, very large safety ratio), or where the overall benefit/risk balance for the product outweighs the safety concern with the product. Overall, the use of any excipient with a known potential toxicity, and which could not be avoided or replaced, would only be authorised if the safety profile was considered to be clinically acceptable in the conditions of use, taking into account the duration of treatment, the sensitivity of the target population and the benefit-risk ratio for the particular therapeutic indication*" (European Medicines Agency, 2007). As a result, and given the discussion presented earlier on food additives and how the use of $TiO_2$ in food might continue after the introduction of the proposed classification, it is possible that $TiO_2$ use in pharmaceuticals might continue given that inhalation exposure is generally of no relevance to medicine consumption. The cost of this review and approval process cannot be estimated; however the large number of impacted products could make this a costly exercise.

It can be envisaged, however, that pharmaceutical companies would in many cases elect not to use $TiO_2$ due to perceptions about its safety whether substantiated or not.

If the use of $TiO_2$ in the EEA were to be prohibited, it could be expected that countries outside the EEA would follow suit. Then the manufacturers would have to carry out the same activities as mentioned above, for example re-registration. This could take additional years and lead to additional high costs. These thousands of regulatory induced variations would not confer any additional benefit to the patients;

- **Increase in the manufacturing cost**: if an exemption were granted to allow a particular use of a Carc Cat 1B substance in pharmaceuticals, the need to comply with worker safety legislation would mean additional costs for the protection of workers from inhalation of $TiO_2$ powders. This would increase the cost of manufacturing medicines and thus could lead to loss of competitiveness and market share. According to BAH, for some small companies the costs associated with the continued use of $TiO_2$ might be so high that the companies would be forced to stop manufacturing some of their products;

- **Patient perceptions**: it would clearly be confusing for patients to be informed that an ingredient used in so many different medicinal products is actually a carcinogen. While there is essentially no safety risk associated with consuming pharmaceuticals, dietary supplements and foods containing $TiO_2$, it is unlikely that patients and the public at large would be sufficiently informed to know that the critical route of exposure is inhalation and may become reluctant to orally consume medication they perceive as potentially detrimental to their health[53]. Such perceptions could have an adverse impact on the sales of pharmaceuticals and nutraceuticals and would inevitably cause some companies to try to unnecessarily reformulate their products due to concern over consumer perceptions.

***Social impacts***

*Employment impacts*

Employment impacts cannot be estimated as they would largely depend on whether $TiO_2$ would remain an approved excipient. If reformulation became necessary, the large cost of reformulation and variations to marketing authorisations could have an impact on the levels of employment, particularly among smaller companies in the pharmaceuticals sector.

*Impacts on the welfare of consumers*

The proposed classification for $TiO_2$ could have notable impacts on consumer choice and welfare. The following impacts should be noted:

- **Loss of consumer products from the market**: if a reformulation is required, it can be considered certain that reformulation of some products would prove too costly with a consequent removal of products from the market;



[53] The US Food and Drug Administration (FDA) has reported in their Inactive Ingredient Database that up to 49.27 mg of $TiO_2$ per dosage form may be safely used. The Japanese Pharmaceutical Excipients Directory indicates that up 384 mg of $TiO_2$ per day may be safely consumed (Colorcon, 2016).

- **Increased cost and loss of technical performance**: the cost of reformulation would most likely be passed on to consumers (patients);

- **Loss of consumer satisfaction**: clearly, if $TiO_2$ is classified as a carcinogen, its continued use in medicinal products would cause significant confusion and alarm among patients. If $TiO_2$ is substituted, the unsightly appearance of medicinal products without any real health benefit would cause dissatisfaction and reduce patients' confidence in the quality of the products. Moreover, $TiO_2$ has a very high level of stability under UV light enabling further protection of the APIs of medicinal products, as is the case with the capsule shells of opaque capsules, for example. Its substitution (as well as its removal from the packaging) could lead to shorter shelf lives and expiry dates for medicinal products;

- **Adverse impacts on public health**: whether $TiO_2$ would be reformulated out of products or would continue to be used with higher manufacturing costs, ultimately the increased cost of medication would be passed on to the national health services of EEA Member States. If reformulation took place, pharmaceuticals manufacturers might choose to use a potential $TiO_2$ replacement with a less well understood safety profile and/or shorter history of use, thereby increasing the risk of harm to consumers. In addition, the use of $TiO_2$ alongside other colourants enables pharmaceuticals manufacturers to produce medicinal products with a great variety of colours. Coloured pharmaceutical products are highly desirable, since they support brand identification and reduce the potential for medication errors. Without $TiO_2$, the available colour palette would be much more limited and as the number of possible colour options for pharmaceutical products decreases, the probability of medication errors increases.

***Competitiveness and competition impacts***

*Impacts on the competitiveness of EEA-based companies*

EEA pharmaceuticals companies also sell their medicinal products outside the EEA. An increase in their cost of manufacture and their market prices would lead to declining sales figures outside the EEA.

*Impacts on intra-EEA competition*

Particularly for SMEs it would be difficult to invest in the higher safety requirements for manufacturing, or in reformulating products. It could be that some smaller companies would prove unable to hold on to their full portfolio or face the risk of business closure. A concentration of the business activity to some larger companies would be a possibility.

## 4.6.5 Cosmetics

***Key market descriptors***

The key economic parameters of the use of $TiO_2$ are summarised below.

| | |
|---|---|
| Importance of the application | In cosmetics, $TiO_2$ is widely used as a colourant, as an opacifier or as UV filter and is chosen due to its safety, efficacy and performance. $TiO_2$ is one of the few globally approved UV filters/sunscreen actives which are of relevance for global formulations. $TiO_2$ is regulated under the European Cosmetic Products Regulation (1223/2009) as a cosmetic colourant (CI 77891, Annex IV) approved for all cosmetic products without any restrictions and as a UV filter (Annex VI) with a |

| | |
|---|---|
| | maximum concentration of up to 25%. |
| Estimated $TiO_2$ tonnage used | Relatively low – less than 1% of total EEA consumption of $TiO_2$. |
| Estimated tonnage of products that contain $TiO_2$ | Unknown. According to Cosmetics Europe, a search in the Mintel Global New Products Database (GNPD) indicated that over 20,000 cosmetics products launched the last 5 years contained $TiO_2$. This is over 10% of all European cosmetic product launches included in this database. |
| Estimated value of markets | Information specific to $TiO_2$-based cosmetic products is not available. More widely, the European cosmetics and personal care market was valued at €77 billion at retail sales price in 2015 and is the largest in the world. Skin care products are the largest segment with a total value of €19.9 billion while the value of decorative cosmetics stands at €10.7 billion per year (Cosmetics Europe, 2016b). |
| Estimates of Gross Value Added | According to Cosmetics Europe, the cosmetics industry brings at least €29 billion in added value to the European economy every year, of which approximately €8 billion is contributed directly by the manufacture of cosmetic products (the remaining €21 billion is generated indirectly through the supply chain). |
| Number of users of $TiO_2$ | There are more than 5,000 enterprises manufacturing cosmetics in Europe (source: Cosmetics Europe). |
| Presence of SMEs | The vast majority of cosmetics companies are SMEs. In 2015, there were 4,605 SMEs manufacturing cosmetics in Europe (source: Cosmetics Europe). |
| Number of stakeholders that participated in consultation | Three key trade associations have participated, Cosmetics Europe, European Federation for Cosmetic Ingredients (EFfCI) and ASPA-INGRECOS (the French member of EFfCI) plus a small number (<5) of individual companies. |
| Locations of stakeholders that participated in consultation | Cosmetics Europe represents companies across the EU. Its membership consists of 27 national associations of the EU Member States and beyond, 17 major international companies, four supporting association members, four supporting corporate members and three correspondent members. Cosmetics Europe represents more than 4,000 companies throughout the EU via the active representation of its member national associations. EFfCI represents more than 100 cosmetic ingredients companies in Europe.<br><br>Further downstream, there are 20,100 enterprises involved in the wholesale of cosmetics (with significant numbers of companies located in Italy, Spain and France) and 45,700 specialist stores and 55,000 retail outlets retailing cosmetics. About half a million hairdressing and beauty salons (the majority of which are also SMEs or micro-enterprises) also rely on the use of cosmetics; the number of European spas is also growing and may be a source of inward |

| | |
|---|---|
| | investment to Europe in the form of "wellness tourism" (source: Cosmetics Europe). |
| Employment in the sector | The cosmetics industry supports at least 2 million jobs, including direct, indirect and induced economic activity. Of these, 152,000 workers are employed directly in the manufacture of cosmetic products, and around 1.6 million workers are employed indirectly in the cosmetics value chain (source: Cosmetics Europe). |

***Relevant legislation***

**Table 4–16Errore. L'origine riferimento non è stata trovata.** summarises the legislation that would be of relevance to the use of $TiO_2$ in cosmetics applications in the EEA, after the adoption of the proposed hazard classification. Additional detail is available in Annex 1.

**Table 4–16: Relevance of different regulatory instruments to cosmetics applications of $TiO_2$ following a harmonised classification of Carc Cat 1B**

| Relevant legislation | Relevant to cosmetics |
|---|---|
| CLP | Yes |
| Carcinogens and Mutagens at Work | Yes |
| Waste Framework | Potentially |
| Industrial Emissions | Potentially |
| REACH | Potentially (for worker exposure or future SVHC activity) |
| Cosmetics | Yes |
| Toy Safety | Potentially.<br>Impact not automatic |
| Food Contact Materials | No |
| Food Additives | Yes<br>$TiO_2$ used in cosmetics as colorant has to meet the criteria purity of E171 also used in food |
| Medicinal Products | No |
| Construction Products | No |
| Biocides | No (but Ag/Ti preservatives listed in Cosmetic Products Regulation) |
| Medical devices | No |
| RoHS | No |
| Tobacco additives | No |

***Impacts on the marketing and use of titanium dioxide-containing products***

*Possibilities and cost of reformulation*

There is currently no guarantee that suitable alternatives for $TiO_2$ which are technically and economically feasible with the same efficiency can be found.

$TiO_2$ has an excellent safety profile, as recently confirmed by the Scientific Committee on Consumer Safety (SCCS) for its current cosmetic uses. Other colourants, opacifiers and UV filters may be subject to scrutiny themselves or less preferred by consumer (groups), and thus may not be suitable substitutes for $TiO_2$, even if performance and efficacy issues could be theoretically overcome.

Reformulation of cosmetic products to substitute critical ingredients such as $TiO_2$ cannot simply be a one-to-one replacement and would require full R&D involvement including formulation, packaging and stability assessment and conducting a regulatory and safety assessment. This could be expected to lead to costs in the range of tens of millions of Euros spread over the typical lead time for such reformulation programmes (3-8 years).

*Market and economic losses*

There are several elements that would lead to economic losses:

- **Restriction under the Cosmetic Products Regulation and cost of securing an exemption**: first and foremost, the use of $TiO_2$ is subject to the provisions of the Cosmetic Products Regulation. Article 15(2) of the Regulation prescribes that "*the use in cosmetic products of substances classified as CMR category 1A or 1B under Part 3 of Annex VI to Regulation (EC) No 1272/2008 (CLP) shall be prohibited*". Therefore, the immediate effect of the proposed classification would be an initiation of a risk management procedure that can result in a ban on the use of the substance.

  An exemption from this ban is possible and indeed the SCCS has already looked into the safety of $TiO_2$ in cosmetics products and has concluded their marketing to consumers in the EEA[54] in line with the regulatory requirements does not pose a risk to human health. Nevertheless, an exemption can only be granted in very exceptional cases, when a series of stringent conditions are fulfilled (the substance complies with the food safety requirements as defined in Regulation (EC) No 178/2002; there are no suitable alternative substances available; an application is made for a particular use of the product category with a known exposure; and it has been evaluated and found safe by the SCCS for use in cosmetic products – this must take into account exposure to these products, overall exposure from other sources and vulnerable population groups).

  The nano-form of $TiO_2$ has been reviewed by the SCCS in 2013[55] and has been authorised for use as a UV filter in cosmetic products in August 2016. It is expected that the existing dossier would be the basis for a request for review by the SCCS, having been adapted to cover also the non-nano-form.

  It is to be noted that such exemptions are meant to be the exception i.e. that each application would be very carefully reviewed on whether an exemption is actually warranted. There is precedence where applications for exceptions were not granted although (in industry´s view) all conditions had been fulfilled.

  An estimate of the cost of submitting a request for an exemption provided in consultation exceeds €1 million.

  In case an exemption would not be granted for use of $TiO_2$ in cosmetic products, a very large number of cosmetic products would be impacted and a very useful, safe ingredient would be lost. Users of $TiO_2$ would lose flexibility in their applications and the trend towards natural products (i.e. products that avoid synthetic ingredients) would be obstructed;



[54] The use of $TiO_2$ in cosmetic products is longstanding and an extensive toxicological data set is available. The safety of $TiO_2$ has been acknowledged by a wide range of scientific and regulatory bodies throughout the world (e.g. EU EFSA, US FDA), resulting in its safe use in various products including food products. For cosmetic products, the SCCS has reviewed and concluded on the safety of $TiO_2$ on various occasions.

[55] Available at http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_136.pdf (accessed on 21 October 2016).

- **Increase in the manufacturing cost**: even in case an exemption would be granted to allow a particular use of a Carc Cat 1B substance in cosmetics products, the need to comply with worker safety legislation would mean additional costs for the protection of workers from inhalation of $TiO_2$ powders. This would increase the cost of manufacturing cosmetic formulations and products and thus could lead to loss of competitiveness and market share. Some consultees expressed concern that these costs would be so high that production economics could become very unfavourable; and

- **Consumer perceptions**: if $TiO_2$ was to be removed from cosmetic formulations, products of inferior performance may not meet consumers' needs and expectations and may thus lead to loss of business for the affected product categories. If an exemption was granted for the continued use of $TiO_2$, the communication of such classification to the public would pose the risk of causing unnecessary alarm among consumers who may wish to avoid the use of cosmetic products that contain a carcinogenic substance.

***Social impacts***

*Employment impacts*

A discussion on the overall effects on employment across the EEA cannot be provided due to the lack of specific information. However, it is clear that $TiO_2$ is an important ingredient so unless an exemption under the Cosmetic Products Regulation was secured, a downsize of operations would ensue and job losses would be unavoidable including downstream links in the supply chain (e.g., hairdressers, nail studios, etc.).

*Impacts on the welfare of consumers*

The proposed classification for $TiO_2$ could have notable impacts on consumer choice and welfare. The following impacts should be noted:

- **Loss of certain types of consumer products from the market**: a restriction on the use of $TiO_2$ would have a clear impact on the market availability of many products used by consumers on a daily basis, e.g. skin care products, toothpaste, make-up products (foundation, eye shadow, depilatory products, etc.);

- **Increased cost and loss of technical performance**: in sunscreens, $TiO_2$ can be replaced by ZnO but the two substances are different in terms of efficiency. Sunscreens would require increased UV filter dosages thus their formulations would cost more, and would be undesirably whiter on the skin (the $TiO_2$ nano-form makes finished products appear not very white when applied to the skin). In cosmetic applications where opacity is the desired effect, no alternative can match the performance of $TiO_2$. Furthermore, alternative pearlescent pigments are not available;

- **Loss of consumer satisfaction**: without $TiO_2$ as a whitening pigment, make-up products and overall skin care products would be less efficient. Also, depending on application, alternative formulations may display discolourations in the formulation, staining of clothing and narrower range of colour choices; and

- **Adverse impacts on public health**: under the Cosmetic Products Regulation there are only two mineral UV filters authorised: $TiO_2$ and ZnO. ZnO contributes mainly to UVA protection and has a relatively low performance against UVB radiation whilst $TiO_2$ provides UVB protection which is a major contributor to high Sun Protection Factor (SPF) products[56]. Clearly, UV filters are important in protecting the public from skin cancer following from exposure to the sun. Replacement of $TiO_2$ would mostly affect children's products and formulations for people with sensitive skin as the formulators would need to use chemical UV filters which are less preferred for these consumer groups. A lower level of skin protection from the sun, especially from a young age, could have a very detrimental health effect with the development of a higher number of skin cancer cases later in life.

***Competitiveness and competition impacts***

*Impacts on the competitiveness of EEA-based companies*

Whilst any restriction on the use of $TiO_2$ in cosmetic products would apply equally to EEA-made and non-EEA-made cosmetics placed on the EEA market, the EEA cosmetics industry is a major exporting force and the proposed classification would cause increased manufacturing costs and thus loss of competitiveness on the global level. Relocation of businesses out of the EEA could be a possibility for some EEA-based companies; often, EEA-based companies have sister companies outside the EEA, for example USA, Japan or China, so, one possible business strategy could be to relocate manufacturing operations outside the EEA.

In case of classification of $TiO_2$, there would be detrimental competitive effects in all cases. Even if an exemption was granted and the use of $TiO_2$ was allowed to continue EEA-based cosmetics manufacturers would be disadvantaged within their own "home" EEA market because importers who manufacture outside of the EEA area could manufacture their products at a lower cost and would thus be exporting cheaper $TiO_2$-containing products to the EEA.

*Impacts on intra-EEA competition*

SMEs will be put at a greater disadvantage by a titanium dioxide classification. Larger EEA-based manufacturers of cosmetic products with a capability of moving certain production processes outside of the EEA would be able to do so and maintain a better competitive position in comparison to SMEs or, more generally, companies without an international footprint.

### 4.6.6 Elastomers

Limited information is available on the use of $TiO_2$ in rubber products. Some examples of impacts arising from the proposed classification might include:

- **General rubber goods (GRG)**: the production of non-black/coloured rubber components depends on $TiO_2$. Without the possibility to use $TiO_2$, production could be discontinued and/or moved outside the EEA. Rubber manufacturers' customers would buy these components from non-EEA manufacturers;

- **Tyres**: tyres with white sidewalls containing $TiO_2$ pigment may be replaced by tyres with black sidewalls without any loss of performance. This application would not be expected to have a

[56] Commission Recommendation 2006/647/EC notes that UVB radiation is the main contributor to increased cancer risk, although, the risk generated through UVA radiation cannot be neglected. Furthermore, UVA radiation is cause of premature ageing of the skin. Sunscreen products should contain both UVB and UVA protection. An increased sun protection factor (i.e. mainly UVB protection) should include an increase in the UVA protection as well. Therefore, the protection against UVA and UVB radiation should be related.

severe socio-economic impact. There may be a certain business impact if the application would need to be abandoned; white sidewall tyres would be imported from outside the EEA; and

- **Other rubber products**: rubber-to-substrate parts serve a variety of purposes such as vibration reduction, improved flexibility, etc. $TiO_2$ is also used as a filler in food-contact rubber articles for repeated use. Impacts from replacement of $TiO_2$ cannot be estimated.

The socio-economic parameters of these applications are not known, although it is understood that the majority of GRG manufacturers are SMEs (>95%).

### 4.6.7 Pigment manufacture

***Key market descriptors***

The key economic parameters of the use of $TiO_2$ are summarised below.

| | |
|---|---|
| Importance of the application | Pigments and pigment formulations are the basis of colouring a wide range of products: paints, coatings, plastics, ceramics, glass, rubber, etc. It should be noted that some pigment-related discussion may appear elsewhere in this section (e.g. Complex Inorganic Pigments are discussed under ceramics, artists' colours are discussed under inks, etc.) |
| Estimated $TiO_2$ tonnage used | Data encompassing all pigments are not available. Pigments are ultimately used in the other applications discussed here and thus are considered under the respective applications. |
| Estimated tonnage of products that contain $TiO_2$ | As above, all-encompassing data are not available. The volume of pigments/formulations produced by manufacturers who have provided information to the questionnaire is in the range of tens of thousands of tonnes. |
| Estimated value of markets | The market value of pigments/formulations produced by manufacturers who have provided information to the questionnaire is in the range of €50-75 million/y. The total annual turnover of this sector is about €8.1 billion (Eurocolour, 2016). |
| Estimates of Gross Value Added | No data available. |
| Number of users of $TiO_2$ | Eurocolour is the umbrella association for manufacturers of pigments, dyes and fillers in Europe. Eurocolour has both association members and direct company members. All together Eurocolour represents about 100 companies within Europe (Eurocolour, 2016). |
| Presence of SMEs | 75 % of Eurocolour's members are SMEs (Eurocolour, 2016). |
| Number of stakeholders that participated in consultation | <10, but several pigment manufacturers may be included under other applications below. |

| | |
|---|---|
| Locations of stakeholders that participated in consultation | Not provided here due to small number of participants. |
| Employment in the sector | Eurocolour members have a total of 23,000 employees in Europe. |

***Relevant legislation***

**Table 4–17** summarises the legislation that would be of relevance to the use of $TiO_2$ in pigments applications in the EEA, after the adoption of the proposed hazard classification. Additional detail is available in Annex 1. The table only focuses on the manufacture of pigments, not their downstream consumption.

**Table 4–17: Relevance of different regulatory instruments to pigments applications of $TiO_2$ following a harmonised classification of Carc Cat 1B**

| Relevant legislation | Relevant to pigments |
|---|---|
| CLP | Yes |
| Carcinogens and Mutagens at Work | Yes |
| Waste Framework | Potentially |
| Industrial Emissions | Potentially |
| REACH | Potentially |
| Cosmetics | No |
| Toy Safety | No |
| Food Contact Materials | No |
| Food Additives | No |
| Medicinal Products | No |
| Construction Products | No |
| Biocides | No |
| Medical devices | No |
| RoHS | No |
| Tobacco additives | No |

***Impacts on the marketing and use of titanium dioxide-containing products***

*Possibilities and cost of reformulation*

Pigment manufacturers may be able to reformulate their products; however, this would be at the expense of performance and at a considerable cost. Some past attempts to implement alternatives have been unsuccessful; for example, for example, showing poor brilliance of fluorescent colours. Some manufacturers, however, may be forced to reformulate as their internal policies may prevent them from using a Carc Cat 1B substance, even if its performance cannot be matched by the available alternatives.

Some estimates on the costs of reformulation have been provided and these would clearly depend on the number and variability of the affected products. For instance, for one pigment manufacturer, the cost would be ca. €200 per formulation and considering the number of formulations affected (more than 20,000 formulations for synthetic resins and plastics), the total cost could exceed €4 million. Another manufacturer expects a reformulation cost in the range of €50,000-100,000. These costs would consume funds intended for other planned R&D and for supporting regulatory-driven initiatives aimed at reducing or eliminating other molecules with well-characterised and more widespread risks.

*Market and economic losses*

There are several elements that would lead to economic losses:

- **Increase in the manufacturing cost**: the additional measures that may be required for the protection of workers and the handling of waste could increase manufacturing costs making products less competitive. However, it is correct that some pigment manufacturers may already have experience with handling and processing carcinogens (for instance, from the times of producing lead-containing or chromium-containing pigment blends). On the other hand, using alternative substances would also increase manufacturing costs. As detailed in Annex 2, known alternatives are much less efficient and thus would require higher loadings to achieve the necessary opacity with negative impacts on cost, technical quality and effectiveness, and ultimately the competitiveness, of the product;

- **Company policies and process and product requirements**: for some companies the classification of a raw material as Carc Cat 1B would mean the discontinuation of use. Also, there are products that have been marketed as alternatives to pigments bearing hazardous properties (e.g. chrome-based pigments) and as such the use of a raw material classified as Carc Cat 1B would make such products unmarketable; and

- **Customer perceptions**: the proposed classification would result in pigment formulations being similarly classified and being stigmatised irrespective of the risk of exposure. This would disincentivise downstream users from using them as they would also need to take measures for the control of the exposure of their workers to $TiO_2$. Beyond emotional responses to the presence of a Carc Cat 1B, customers may also need to adhere to Restricted Substance Lists, particularly in the case of manufacturing consumer products, and thus would avoid using $TiO_2$-based pigments to prevent any negative impact on their reputation.

***Social impacts***

*Employment impacts*

Quantified estimates across the pigment manufacturing industry cannot be provided due to the relatively small number of companies that have contributed information by means of a completed questionnaire. However, among those companies that have responded, estimates of potential job losses range between zero and 25% of their workforce.

*Impacts on the welfare of consumers*

Pigments are generally not sold to consumers (artists' colours and the like are considered elsewhere in this report). Impacts may arise in relation to the use of consumer products that contain $TiO_2$-based pigments but these are discussed under the other sector-specific applications presented elsewhere in this report.

***Competitiveness and competition impacts***

*Impacts on the competitiveness of EEA-based companies*

EEA-based pigment manufacturers (and their customers) would need to bear the cost of additional exposure control measures and would see their products (a) perform worse, and (b) cost more to manufacture, if reformulated to eliminate $TiO_2$. The majority of products are tailor-made, are developed for specific applications and are approved by customers. New formulations would not hold approvals and would need to be tested and qualified by customers. This would require time and be costly. Exports of EEA-made pigments would become less competitive as non-EEA manufacturers supplying non-EEA markets would not need to declare or be restricted by their continued use of $TiO_2$.

If processed $TiO_2$ (e.g. masterbatches in which $TiO_2$ is inaccessible inside the plastic matrix) were freely imported, the European downstream users (e.g. producer of masterbatches, pigment preparations) would be confronted with a competitive disadvantage in the home market as well.

Under these circumstances the production of intermediates with $TiO_2$ contents above 0.1% by weight as well as the manufacture of finished products could be driven out of the EEA.

*Impacts on intra-EEA competition*

Within the EEA, SMEs would likely be disadvantaged vis-à-vis their larger counterparts because of limited capabilities (R&D, marketing, equipment) in order to protect their workers and formulate feasible alternatives. Large companies with wide ranges of products would be better placed to cope with a loss of $TiO_2$-containing products compared to smaller businesses which concentrate on a smaller product portfolio.

### 4.6.8 Ceramics

***Key market descriptors***

The key economic parameters of the use of $TiO_2$ are summarised below.

Importance of the application

$TiO_2$ finds wide application in the ceramics sector at different levels of the supply chain:

1. As a raw material used upstream from the manufacturer of the ceramic product, such as:
   - Raw material in the manufacture of Complex Inorganic Pigments which find ceramic applications (e.g. tiles);
   - Pigment in formulations for ceramic products (tiles, bricks), including specialist pigment ($TiO_2$ used as an additive for the development of yellow colour in digital tile printing); and
   - Opacifier in frits[57], glazes and enamels – enamels can find industrial uses but also consumer uses (e.g. tableware);

2. As a raw material used by the manufacturer of the ceramic product, namely a photocatalytic coating on construction products (e.g. certain ceramic wall tiles or roof tiles); and

3. As an impurity in essential raw materials used by ceramics manufacturers. Examples include:
   - Refractory products; and



[57] Frits are ceramic compositions that have been fused in a special fusing oven, quenched to form a glass, and granulated. Frits form an important part of the batches used in compounding enamels and ceramic glazes.

– Abrasive products (inorganic bonded abrasives, organic bonded abrasives and coated abrasives).

A discussion on the applications relevant to point 3 above is provided in Section 4.7.1 rather than immediately below.

Estimated $TiO_2$ tonnage used

Low – less than 1% of total consumption. In the enamel industry, ca. 1,000 t/y are used (Cerame-Unie, 2016).

Estimated tonnage of products that contain $TiO_2$

| Application | EEA production |
|---|---|
| Complex Inorganic Pigments | 11 ktonnes/y |
| Frits and related $TiO_2$ mixtures | 230 ktonnes/y |

Estimated value of markets

| Application | EEA market value |
|---|---|
| Complex Inorganic Pigments | €35 million/y |
| Frits and related $TiO_2$ mixtures | €130 million/y |
| European ceramic tiles and porcelain enamel manufacturing sector (based on Cerame-Unie data) | €9 billion/y |

Estimates of Gross Value Added

GVA data are unavailable.

The European ceramic tiles and porcelain enamel manufacturing sector in Europe has a turnover of around €9 billion and ca. $^{1}/_{3}$ of it is associated with the Spanish ceramic tiles manufacturing sector.

Number of users of $TiO_2$

| Application | Number of $TiO_2$ users |
|---|---|
| Complex Inorganic Pigments | 40 |
| Ceramic decorating/glass colours | 30 |
| Frits | 34 companies plus affiliates |
| Enamel products (companies using enamel coatings on cookware, hot water tanks, silos, ovens, cooktops, architecture, etc.) | 100-150 companies |

The ceramics industry as a whole encompasses about 2,000 companies.

Presence of SMEs

| Application | SME presence |
|---|---|
| Ceramics industry in general | 80% |
| Complex Inorganic Pigments | 50-60% |
| Ceramic decorating/glass colours | >80% |
| Frits | Large majority |
| Enamel products | 80% |
| White flatware, hollowware and cookware | Large majority |
| *NB. Spain's ceramic tile manufacturers: 75%* | |

| | |
|---|---|
| Number of stakeholders that participated in consultation | 10-25, including two industry associations and two REACH Consortia. |

Locations of stakeholders that participated in consultation

| Application | Locations |
|---|---|
| Complex Inorganic Pigment | DE, IT, NL, ES, UK. Most important manufacturers are located in Spain and Italy |
| Ceramic colour pigments | Several; examples confirmed by consultation: BE, DE, IT, NL, PL, PT, ES |
| Frits | BE, CZ, FR, DE, IT, NL, ES, UK. Most important manufacturers are located in Spain, Italy and Germany. More than 80% of frits and related mixtures are produced in Spain |
| Tableware | Very many small manufacturers can be found in Mediterranean islands (Malta, Majorca) |

Employment in the sector

| Application | Number of workers |
|---|---|
| Complex Inorganic Pigments | 2,000 |
| Frits | 3,200 |
| European sector of ceramic tiles and porcelain enamel | 45,000 |
| *Note: the Spanish sector of frits, inorganic pigments and preparations employs more than 3,500 workers, with the majority involved in frits manufacture. The number of workers in tile manufacture in Spain is 15,000* | |

***Relevant legislation***

**Table 4–18** summarises the legislation that would be of relevance to the use of $TiO_2$ in ceramics applications in the EEA, after the adoption of the proposed hazard classification. Additional detail is available in Annex 1.

**Table 4–18: Relevance of different regulatory instruments to ceramics (frits, enamels, tiles, consumer ceramics) applications of $TiO_2$ following a harmonised classification of Carc Cat 1B**

| Relevant legislation | Relevant to ceramics |
|---|---|
| CLP | Yes |
| Carcinogens and Mutagens at Work | Yes |
| Waste Framework | Potentially |
| Industrial Emissions | Potentially |
| REACH | Potentially |
| Cosmetics | No |
| Toy Safety | No |
| Food Contact Materials | Yes |
| Food Additives | No |
| Medicinal Products | No |
| Construction Products | No |
| Biocides | No |
| Medical devices | No |
| RoHS | Potentially |
| Tobacco additives | No |

***Impacts on the marketing and use of titanium dioxide-containing products***

*Possibilities and cost of reformulation*

The unanimous view of the relevant consultees is that reformulation is not possible as $TiO_2$ is an indispensable component of frits and thereafter the glazes and enamels manufacture. It is important to note the close links of these applications to the manufacture of inorganic pigments which are used in the pigmentation of ceramic structures.

*Market and economic losses*

The use of a Carc Cat 1B substance is not regulated in these products by legislation other than horizontal legislation (i.e. CLP, CMD, IED and the Waste Framework Directive). As a result, market losses would arise as a result of making manufacturing more costly (due to the more extensive worker protection measures required). It should be noted that several stakeholders falling under the 'ceramics' umbrella would be affected, e.g. pigment manufacturers but also pigment users (for instance, manufacturers of ceramic glazes) and the manufacturers of ceramic-ware who handle $TiO_2$-containing products in 'unfired' form; all these actors would also have to adopt appropriate worker protection measures.

Market losses would be expected on account of the customers' and end consumers' reaction to the presence of a carcinogen in ceramic products; this could make them reluctant to use mixtures and articles that contain $TiO_2$, even if firmly contained within a glass matrix (it must also be taken into account that other raw materials may contain $TiO_2$ as an impurity). In applications where it frequently comes into contact with the consumer, e.g. ceramic/enamelled cookware, the presence of a carcinogen would be near impossible to justify.

We also need to consider here the use of $TiO_2$ in the manufacture of cutlery, flatware and holloware. These articles are not necessarily ceramics but are food contact articles such as several ceramic products and also have links to enamel manufacture. Consultation with the relevant trade association, FEC, suggests that manufacturers of white and pastel food contact articles would be concerned that the proposed classification for $TiO_2$ would lead to the substance being re-assessed by EFSA and this could result in a more severe classification for food contact article applications. This could make the manufacture of such articles in the EU more complicated, if not impossible.

***Social impacts***

*Employment impacts*

A significant number of jobs could be at risk as a result of lost competitiveness but it is not possible to provide a specific estimate on job losses.

*Impacts on the welfare of consumers*

Although in principle use of $TiO_2$ would be allowed to continue in the EEA, the proposed classification would make the use of the substance more complex and costly in the EEA. This could mean that non-EEA made products could progressively replace EEA-made ones on the market.

From a more theoretical perspective, complete loss of $TiO_2$-containing ceramic products from the consumer market could have adverse consequences:

- The available range of colours would diminish. $TiO_2$ allows tile manufacturers to transform the clay body into a white colour. This either allows the product to be white or means that it can be other light colours (white, yellow, metallic, grey, etc.). Alternative pigments cannot achieve the same colouring; ceramic tiles coloured with orange pigments and with a characteristic brown tonality would disappear; and

- The range of available tile products would be affected. Certain roof tiles/bricks could no longer be produced. It would no longer be possible to manufacture enamelled hot water tanks/boilers (N.B. ca. 90% of all hot water tanks used in Europe are enamelled hot water tanks). Without $TiO_2$-containing enamels, it would no longer be possible to manufacture enamelled cookware or enamelled steel/cast iron sanitary ware. Replacement of enamelled hot water tanks with stainless steel ones would not be affordable.

***Competitiveness impacts***

The need to handle a range of carcinogenic raw materials ($TiO_2$ and materials that contain it intentionally or as an impurity) could increase manufacturing costs and lead to loss of competitiveness for manufacturers of frits and, downstream, of ceramic articles, as companies outside the EEA would not have to face such additional costs.

Relocation would be given consideration. For instance, companies manufacturing Complex Inorganic Pigments, ceramic inks and frits are strong exporters (70% of pigments/frits production is exported) so if barriers arose in the European market, which only represents a relatively small proportion of sales, companies would be encouraged to relocate manufacture outside Europe. Rutile pigments are largely used for yellow and brown colours in the tile industry. This industry is still of great importance in some Italian and Spanish regions. Regulatory pressure may force this industry to Asia-Pacific, a trend that has been on its way for cost reasons for some time now.

Relocation of pigment/frit manufacture could also encourage actors downstream in the supply chain (e.g. manufacturers of ceramic tiles or enamelled products) to relocate. Such relocations would result in a loss of EEA jobs and also a reduction in funding going into R&D in the EEA. The European abrasives industry is also exporting worldwide and is a leader in the world economy: over 30% of the production is exported worldwide. Furthermore, in some cases companies may not use carcinogenic products as company policy; they may decide to cease production in the EEA in order to adhere to company policy.

On the other hand, if a restriction was imposed on the presence of $TiO_2$ in ceramic-based food contact materials, this would apply equally to both EEA-based and non-EEA manufacturers of such articles who would need to comply with EU food contact material legislation.

## 4.6.9 Glass

***Key market descriptors***

The key economic parameters for the use of $TiO_2$ are summarised below.

| | |
|---|---|
| Estimated $TiO_2$ tonnage used | Low - less than 1% of total. |
| Estimated tonnage of products that contain $TiO_2$ | No data specific to $TiO_2$. More generally, in 2015, the EU-28 glass production reached a volume of 34 million tonnes of which 670,000 tonnes were special glass[58]. |
| Estimated value of markets | No data. |
| Estimates of Gross Value Added | No data. |
| Number of users of $TiO_2$ | 70 (special glass); 1,200 glass manufacturers across the EU[59] |
| Presence of SMEs | 10% (special glass) |
| Number of stakeholders that participated in consultation | <5 |
| Locations of stakeholders that participated in consultation | Brussels (but with members from Austria, Bulgaria, France, Germany and the United Kingdom using $TiO_2$ or $TiO_2$-based products) |
| Employment in the sector | No data specific to $TiO_2$ use. More generally, the EU-28 glass industry employs about 185,000 people (incl. processors)[60]. |

***Relevant legislation***

**Table 4–19** summarises the legislation that would be of relevance to the use of $TiO_2$ in glass applications in the EEA, after the adoption of the proposed hazard classification. Additional detail is available in Annex 1.

**Table 4–19: Relevance of different regulatory instruments to glass applications of $TiO_2$ following a harmonised classification of Carc Cat 1B**

| Relevant legislation | Relevant to glass |
|---|---|
| CLP | Yes |
| Carcinogens and Mutagens at Work | Yes |
| Waste Framework | Potentially |
| Industrial Emissions | Potentially |
| REACH | Potentially |

58 Information available at: http://www.glassallianceeurope.eu/images/cont/panorama-2015_file.pdf (accessed on 20 October 2016).

59 Information available at: http://www.glassallianceeurope.eu/images/cont/gae-leaflet-may-2012_1_file.pdf (accessed on 20 October 2016).

60 Information available at: http://www.glassallianceeurope.eu/en/industries (accessed on 20 October 2016).

| Table 4–19: Relevance of different regulatory instruments to glass applications of $TiO_2$ following a harmonised classification of Carc Cat 1B | |
|---|---|
| **Relevant legislation** | **Relevant to glass** |
| Cosmetics | No |
| Toy Safety | No |
| Food Contact Materials | Yes |
| Food Additives | No |
| Medicinal Products | No |
| Construction Products | No |
| Biocides | No |
| Medical devices | Potentially |
| RoHS | Potentially |
| Tobacco additives | No |

***Impacts on the marketing and use of titanium dioxide-containing products***

*Possibilities and cost of reformulation*

Reformulation to eliminate or reduce $TiO_2$ presence to a concentration of below 0.1% would not be possible in glass products if the same properties are required. $TiO_2$ is not substitutable as a raw material, be it for glass manufacture or decoration, because its use is essential to achieve a certain optical quality/property of the glass which cannot be achieved otherwise. Even if a suitable substitute could be found (this is very unlikely), the reformulation would be associated with costs far higher than the compliance costs. Furthermore even if an alternative to $TiO_2$ use could be found, the formulation change may for instance result in damage to the mould or require larger tubes. In other words, substitution would not only be a matter of a new composition.

*Market and economic losses*

Higher costs associated with increased requirements regarding protective measures for professional/industrial users of articles would impact on profitability and/or markets. It is furthermore expected that there would be a loss of business for companies using $TiO_2$ in glass applications resulting from a reduction in market acceptance, especially in end consumer applications. $TiO_2$ will be stigmatised and, thus, even if legally it could be used, it would effectively be banned in consumer applications/products as downstream users not wanting CMR substances in their products/articles keep "blacklists" of suppliers and consumers are likely to turn away from such articles.

***Social impacts***

*Employment impacts*

No estimates can be provided. If subsequent regulatory action was taken (for example, listing of the substance on the REACH Candidate and Authorisation Lists), EEA producers would lose out on markets at the expense of imported articles, potentially leading to job reductions within the EEA.

*Impacts on the welfare of consumers*

$TiO_2$-based glass offers significant health benefits – medical/public health protection, drug safety (inertness of medical drug containers), eye protection and visual correction, high end medical applications that save lives. However, if these products could not be manufactured in the EEA as a result of the repercussions of the proposed classification, they would be imported as finished articles from outside the EEA and consequently consumers would still have access to them.

If consumers still wished to buy EEA-made products, they would be forced to buy:

- Less effective optical products (thicker, less clear);
- Products which are less resistant to abrasion and hardness on the surface;
- Products with spectral characteristics that would not meet the requirements of current regulations, in particular in the pharmaceutical sector, where protection of medicinal products from UV radiation would be worse.

***Competitiveness and competition impacts***

*Impacts on the competitiveness of EEA industry*

A Carc Cat 1B harmonised classification for $TiO_2$ would mean EEA based companies using the substance in coatings for glass would incur significant increases in costs, with articles being more expensive than those that have been imported and which would be priced more competitively due to lower costs resulting from lack of regulatory requirements associated with the protection of workers. As a result, it is likely that the manufacture of articles using $TiO_2$ as paints would move outside of the EEA where costs would be lower.

It can also be envisaged that the proposed Carc Cat 1B classification could lead to the listing of the substance under the REACH Authorisation List. If the premise that glasses are substances in which components are intermediates transformed during glass production is contested by ECHA and this use were not authorised, or if the costs associated with the Authorisation process were too high, EEA-made glass would become costlier and thus more vulnerable to cheaper imports of glass made with $TiO_2$ outside the EEA.

*Impacts on intra-EEA competition*

Regarding hollow and domestic glass, customers generally wish to purchase from a single supplier and do not wish to purchase, say, non-decorated articles from an EEA supplier and $TiO_2$-decorated ones from a non-EEA supplier. As a result, those EEA manufacturers who also have plants in countries on the borders with the EEA may gain market share at the expense of those which only have capacity within the EEA.

## 4.6.10Medical devices

***Key market descriptors***

Information available is limited to dental restoration products. The Federation of the European Dental Industry (FIDE) represents nearly 600 companies located in Austria, Belgium, Denmark, France, Italy, Luxembourg, the Netherlands, Spain and the UK. Among them, Germany, Italy, the UK, France and Spain are the most important locations for manufacturers of dental restoration products that contain $TiO_2$. Many companies (85 %) of the dental industry in Europe are SMEs.

The volumes of $TiO_2$-based products manufactured range from a few hundred kilograms to 100 tonnes per company per year.

In addition, most devices contain small amounts of $TiO_2$ as pigment in plastic parts, as discussed above.

***Relevant legislation***

**Table 4–20** summarises the legislation that would be of relevance to the use of $TiO_2$ in medical device applications in the EEA, after the adoption of the proposed hazard classification. Additional detail is available in Annex 1.

| **Table 4–20: Relevance of different regulatory instruments to medical devices (dental restoration materials) applications of $TiO_2$ following a harmonised classification of Carc Cat 1B** | |
|---|---|
| **Relevant legislation** | **Relevant to medical devices** |
| CLP | Yes |
| Carcinogens and Mutagens at Work | Yes |
| Waste Framework | Potentially |
| Industrial Emissions | Potentially |
| REACH | Potentially |
| Cosmetics | No |
| Toy Safety | No |
| Food Contact Materials | No |
| Food Additives | No |
| Medicinal Products | No |
| Construction Products | No |
| Biocides | No |
| Medical devices | Yes |
| RoHS | Potentially |
| Tobacco additives | No |



***Impacts on the marketing and use of titanium dioxide-containing products***

*Possibilities and cost of reformulation*

In the field of dental restoration products, there are currently no feasible alternatives available. A replacement of $TiO_2$ by another white pigment is not possible, because alternatives either do not achieve the same shading effect or must be used in much higher concentrations, which could affect the performance of the product or result in undesired toxicological effects compromising the biocompatibility of the products (German Medicines Manufacturers Association, 2016). Some alternative white pigments are hazardous (e.g. ZnO in respect of the aquatic environment) or show similar inhalation hazards as $TiO_2$, based on their particle size.

Due to their poor refractive indices, the loading of the alternatives would probably increase by a factor of 10-100 in comparison to $TiO_2$. This would consequently mean the use of a lower polymer loading. This change to the formulation would lead to significant changes to the physical properties of the materials to the extent that that they would no longer meet the existing requirements.

In practice, the aesthetic restorative treatment would no longer be feasible because $TiO_2$ is an essential basic element for the colour scheme and the adjustment of translucency and opacity of the materials. The result would be that essential materials could no longer be produced. This would result in the complete reformulation of many products involving significant effort:

- Performance and aesthetics of products would need to be maintained and verified. $TiO_2$ safeguards the stability and hygienic properties of the products and for dental impression materials helps make the impressions scannable (e.g. allows the easy scanning of impressions in the digital workflow for producing indirect restorations);
- Handling properties (usability of products) would have to be demonstrated;
- The shelf-life of products would need to be verified (this step alone can take several years);

- Possibly, biological re-evaluations would be needed including animal testing according to ISO 10993-series[61] and ISO 7405[62]; and
- Possibly clinical evaluations (including clinical studies) would be needed. These re-evaluations would be needed to verify the fulfilment of essential requirements of the Medical Devices Directive to prepare a new declaration of conformity (EC marking).

Only after all these activities could reformulated products be brought onto the market to replace the existing product portfolio in the EEA. As there are many products that would be affected, the aforementioned activities would take years and be accompanied by significant costs for each product.

The replacement of $TiO_2$ would require re-registrations in some non-EEA countries which could take additional years and lead to additional high costs.

*Market and economic losses*

**Possibilities for continued use of $TiO_2$ through an exemption under the new Medical Devices Regulation**: the new Medical Device Regulation (NB. expected to be published at the end of 2016 or the beginning of 2017) allows the use of CMR substances as per paragraph 7.4.2 of Annex I (General Safety and Performance Requirements) as long as justification is provided (this includes exposure data and an analysis of alternatives). Continued use of $TiO_2$ would be more complicated, but not impossible, as inhalation exposure and risks can be readily shown to be low; however, a certain effort would be needed to prepare the full documentation. Due to the high number of products this effort (either internal or by external experts in case of SMEs) would be significant.

Much more critical would be the future availability of the raw material. The proposed classification would cause significant market upset and would affect the availability of all $TiO_2$ products on the market. Change of the supplier would result in significant efforts for product re-qualification to comply with all Medical Device Regulation requirements. SMEs would need substantial external support (especially toxicologists) to achieve this.

**Market pressures**: medical devices are not excluded from the requirements of the REACH Regulation. Substances and mixtures which are used in medical devices are comprehensively under an obligation to be registered and approved as appropriate. Medical devices are only exempted from REACH Title IV (Information in the Supply Chain) if they are used invasively or used in direct physical contact with the human body. This means that medical devices, such as dental fillings, that are introduced directly into the tooth by the dentist are exempted from REACH Title IV but that the Regulation's Title IV would apply if the medical device is processed by a dental technician before application on the patient. This implies a lot of work without additional benefit for the patients (German Medicines Manufacturers Association, 2016).

In addition, Annex I (paragraph 7.4.5) to the new Medical Devices Regulation prescribes the following: "*If devices, parts thereof or materials used therein as referred to in Section 7.4.1 contain substances referred to in points (a) or (b) of Section 7.4.1 in a concentration above 0.1% weight by weight (w/w), these devices shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging, with the list of such substances*….". Due to these labelling obligations, users (dentists) and patients would be aware of the presence of a Carc Cat 1B

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61 Standard on the biological evaluation of medical devices.

62 Standard on the evaluation of biocompatibility of medical devices used in dentistry.

substance in the product. Even if no significant user and patient exposure by inhalation would be expected, there would be strongly negative perceptions against the continued use of such products on patients.

***Social impacts***

*Employment impacts*

FIDE has suggested that, in the dental products industry, many companies are SMEs. Smaller companies could be particularly overwhelmed by the high costs associated with implementing safety measures for $TiO_2$ handling during manufacture or the replacement of $TiO_2$and there would be a risk that some of these companies could not survive and employees would be made redundant. In addition, for multinational companies there would be a risk that manufacturing would be relocated from EEA-based sites to non-EEA based sites. This could lead to a significant loss in employment in the EEA. A specific estimate of likely job losses cannot be provided.

*Impacts on the welfare of consumers (patients)*

Consumers in this context are the patients receiving dental work using the impression materials that currently contain $TiO_2$. Impacts on patients would vary depending on whether reformulation with an inferior alternative could take place:

- If $TiO_2$ would continue to be used (in line with the provisions of the new Medical Devices Regulation), the proposed classification as carcinogenic would cause a substantial uncertainty among patients and would lead to a refusal of products containing $TiO_2$; and

- If $TiO_2$ were removed from the formulations, its replacement would not constitute an improvement in health, patient safety or environmental protection, but would cause technological regression as it would generate costlier products of poorer performance and aesthetics. Patients would experience a loss of satisfaction.

***Competitiveness and competition impacts***

*Competitiveness of EEA businesses*

For dental materials – and probably most medical devices – the justification for keeping $TiO_2$-containing products on the market in line with the new Medical Devices Regulation is that it would not be particularly burdensome due to the non-existent or very low risk of inhalation exposure to the substance. However, the administrative burden of securing an exemption under the Regulation would be significant due to the large number of affected products. In addition, the measures that would be required for the protection of workers' health at the workplace from exposure to a Carc Cat 1B could generate significant new costs. Such costs would not be faced by non-EEA manufacturers of dental materials. Due to this, EEA-based manufacturing companies of medical devices would have a clear disadvantage compared to their non-EEA competitors.

*Intra-EEA competition*

For SMEs in particular, it would be very hard to make the necessary investments for the further protection of their workers from inhalation exposure to $TiO_2$. Under the financial pressure of the additional worker protection measures, SMEs' profits would be adversely affected and some small companies might be priced out of the market. This could promote an increase in the market shares of the larger players and the consolidation of the industry (which would decrease the level of competition).

## 4.6.11 Detergents

***Impacts on manufacturing processes***

A low number of relevant companies have provided an input to this analysis. Impacts on the manufacturing of detergents and the management of production waste would appear to be aligned with the analysis already presented above.

***Impacts on product availability and performance***

The proposed classification would mean that consumer mixtures containing $TiO_2$ (e.g. hand dish washing liquids) could no longer be placed on the market and that particular product forms might be lost (e.g. aerosols). In turn, this would result in a loss of consumer utility and an increase in product prices. Furthermore, product performance would be reduced. Enzyme products used in detergent products for laundry and dish washing applications help to break down stains that are otherwise hard to remove with conventional surfactants alone. If the $TiO_2$ coating of enzymes could not be replaced by a substitute delivering the same stability and performance, then the enzyme suppliers could not guarantee a safe use of the granular enzyme and a brilliant performance in the end product. This would have a negative impact on the laundry and cleaning producers and, as a consequence, a negative impact for the end user, i.e. the consumer.

***Impacts on intra-EEA competition***

The proposed classification would result in a reduction in the portfolio of products available, and this would lead to a reduction in the level of competition within the EEA as there would be fewer companies supplying fewer products to the consumer.

## 4.6.12 Biocides

JMAC Composite is the reaction mass of $TiO_2$ and silver chloride and is a preservative active with antimicrobial properties that reduces the spread of bacteria over the long term. It is claimed to have low toxicity, non-sensitising performance and very low environmental impact. JMAC meets Ecolabel standards for use in paints and coatings (Clariant, 2016).

Manufacturers of paints and coatings benefit from easy and economical formulation. The JMAC biocides are effective at very small ppm addition levels and offer low viscosity liquid dispersion. Safe handling is assured through the non-flammable and non-corrosive nature of JMAC (Clariant, 2016).

For in-can preservation, the excellent thermal and pH stability of JMAC biocides means they can be used in a wide range of industrial applications, such as polymer emulsions, paints, sealants and adhesives (Clariant, 2016). The product supports sustainable consumption of consumer products.

Under the Biocidal Products Regulation, $TiO_2$ could no longer be used unless an exemption could be secured, however, this would be a very challenging task.

### 4.6.13Summary

**Table 4–21** summarises the key market metrics presented above for the different applications of $TiO_2$.

As shown in the table, whilst for the major applications of $TiO_2$ detailed information is available, for the majority of minor applications, information is incomplete or non-existent. As demonstrated throughout this Section 4 of the report is difficult to estimate what the exact outcome of the proposed classification might be. The proposed classification might have different impacts in different contexts. It could result in:

- An outright ban on use due to the existing regulatory framework (DIY paints, coating and construction products, detergents, etc.);
- A ban under the existing regulatory framework unless an exemption or derogation can be secured and the probability of achieving this uncertain (cosmetics, food, pharmaceuticals, biocides);
- A ban under industry-led initiatives which may allow scope for exemptions (see the Exclusion Policy of EuPIA for carcinogens in printing inks); or
- An increase in manufacturing costs which might or not result in the removal of some $TiO_2$-containing products from the market.

More widely, the extent to which the additional regulatory burden, supply chain and consumer perceptions and wider market dynamics would affect the use of $TiO_2$ and the marketing of products that rely on/contain $TiO_2$ cannot be defined with accuracy.

There are also several cost elements that would arise on which limited reliable information is currently available across the range of $TiO_2$'s applications, for instance:

- The true cost of implementing improved worker protection controls: a wide range of estimates have been provided but whether such costs would be incurred (as opposed to operation shutdowns or business relocation) cannot be estimated with certainty;

- Changes to the cost of disposal of $TiO_2$ containing waste are uncertain. Whilst there is scope for a wide range of wastes becoming labelled as hazardous, the existing legislative framework allows for exemptions under Article 7(3) of the Waste Framework Directive so that re-classification of such wastes be avoided;

- The cost of reformulation of products that contain $TiO_2$: in some cases, some estimates have been provided for different applications, but the cost in each sector and across sectors cannot be estimated. In addition, in some cases, for example pharmaceuticals, reformulation would also mean applications for variations to existing marketing authorisations. These could be accompanied by a substantial cost which cannot be estimated at present; and

- The cost of transportation of goods – if the $TiO_2$ manufacturing basis in the EEA collapsed, $TiO_2$ pigment would need to be imported in substantial volumes from outside the EEA. At the same time, significant volumes of articles treated with or containing $TiO_2$ would be imported into the EEA due to the reduction in the use of $TiO_2$ pigments and formulations in the EEA. Information that would allow us to estimate the additional cost of this trade is not available.

| Table 4–21: Summary of key metrics of markets for the different applications of $TiO_2$ | | | | | | |
|---|---|---|---|---|---|---|
| **Application area** | **Potentially affected turnover** | **GVA** | **Number of companies** | **Share of SMEs** | **Number of workers** | **Downstream markets** |
| Paints & coatings | Arch: €6.2 billion/y<br>Ind: €8.2 billion/y<br>Constr: €0.55 billion/y | €5 billion | 800 | 85% | 110,000 | Value: €750 billion<br>Workers: 1,000,000<br>(incl. 30,000 in DIY retail) |
| Plastics | €270 billion | €118.4 billion | 55,000 | >>50% | 1,500,000 | Value: €650 billion<br>Workers: 4,500,000 |
| Paper and wallcoverings | >€1.7 billion<br>Total sector: €75 billion | >€0.34 billion | Wallcoverings: 54 CEPI members: 515 | >>50%<br>(perhaps not for laminates) | Total sector: 208,000 | Value: €4.9 billion<br>Workers: 1,051,700 |
| Inks | >€3.3 billion | Included in paints & coatings | >150 | >85% | Included in paints above | Value: €200 billion<br>Workers: >50,000 |
| Construction products | Included in paints & coatings | No data | Adhesives & sealants: 450 | >>50% | Adhesives & sealants: 41,000 | No data |
| Fibres | €7.5-10 billion | No data | 42 | >50% | 20,000 | Could be included in plastics above |
| Catalysts | No data | | | | | |
| Food, feed and packaging | No data | No data | No data | No data | No data | No data |
| Pharmaceuticals | Total sector: €192 billion | No data | Total sector: 1,900 | No data | Total sector: 725,000 | No data |
| Cosmetics | Total sector: €77 billion | Total sector: €8 billion | Ingredients: 100<br>Cosmetic products: 5,000<br>Distribution: 120,800 | 92% | Total sector: 152,000 | GVA: €21 billion<br>Workers: 1,600,000 |
| Elastomers | No data | | | | | |
| Pigments | $TiO_2$-specific: Unknown<br>Total sector: €8.1 billion | No data | 100 | 75% | 23,000 | |
| Ceramics | €174 million<br>Total ceramics and enamel: €3 billion | No data | >200<br>Total sector: 2,000 | >80% | >50,000 | No data |
| Glass | No data | No data | 70<br>Total sector: 1,200 | 10% | Total sector: 185,000<br>(incl. processors) | No data |
| Medical devices | No data | | | | | |
| Detergents | | | | | | |
| Biocides | | | | | | |

Overall, there is significant uncertainty over the monetised scale of the impacts arising from the proposed classification for $TiO_2$. However, this cannot prevent us from reaching some clear, general conclusions:

- The value of markets that would be affected would be very large. The combined estimated value of paints, coatings, construction products, inks, plastics, fibres and wallcoverings that contain $TiO_2$ exceeds €300 billion. The value of downstream markets is a multiple of this. For paints and coatings for instance, it can be estimated that downstream markets could be 50 times larger in value;

- The number of companies affected would be very large and most of those would be SMEs. For instance, the report has reported the existence of 800 paint and ink manufacturers, 55,000 plastic converters, 55 wallcovering manufacturers, 5,000 cosmetics manufacturers. Further downstream, distributors, formulators and users amount to hundreds of thousands of companies;

- The number of workers whose employment would be affected is also large. Information available for paints, coatings, construction products, plastics, pigments, fibres and cosmetics suggest an overall employment of over 2 million workers involved in the manufacturing of formulations and articles that contain $TiO_2$. Further downstream, the number of workers handling and using these formulations and articles becomes very much larger: an estimated 1 million workers might use $TiO_2$-containing paints and coatings and 4.5 million workers are using plastics containing $TiO_2$;

- Consumer uses would be particularly affected. The DIY sector would be subject to unprecedented pressure with a very large number of formulations (paints, coatings, adhesives, sealants, fillers, etc.) being labelled 'for professional use only'. The cost of renovation and maintenance of properties would significantly increase and become exclusive to professional builders and decorators, unless consumers disregard the rules. The presence of a carcinogen in a multitude of products found in homes, offices, shops, vehicles, food and its packaging, pharmaceuticals, cosmetics, medical devices, toys, magazines would cause significant market upset, changes in aesthetics, increased costs and ultimately a great source of confusion and concern over exposure to $TiO_2$ (which in most cases is minimal or non-existent); and

- Industrial processes that involve $TiO_2$ would become substantially more costly in the EEA as a result of compliance with existing regulation. Unilaterally classifying a substance as ubiquitous as $TiO_2$ as a Carc Cat 1B would seriously undermine the competitiveness of the EEA industry. Mobility within supply chains would increase and relocation of production processes outside the EEA would become more attractive.



## 4.7 Impacts outside the titanium dioxide supply chains

### 4.7.1 Impacts on industrial minerals that contain titanium dioxide impurities

Many industrial minerals contain $TiO_2$ as a natural impurity up to 4% by weight ($TiO_2$ is also a common component in soils and sea sand). Examples include:

- Kaolin;
- Bentonite;
- Perlite;

- Mica;
- Diatomite;
- Ball clays;
- Refractory calcined clay (chamotte);
- Calcined bauxite;
- Brown fused alumina;
- Andalusite;
- Zircon (natural zirconium silicate);
- Synthetic mullite;
- Refractory clay; and
- Metal working slags.

This means that if $TiO_2$ were to be classified as Carc Cat 1B, all these industrial minerals would also have to be classified as Carc Cat 1B. This would significantly affect their handling, processing and use. A discussion on some of these minerals, including details of their applications and markets is provided below. Therefore, it is important that we consider the markets and applications for these minerals. The combined market value of these minerals is very substantial and the market value of products that rely on them is even greater.

***Kaolin***

Kaolinite is a clay mineral with the chemical composition $Al_2Si_2O_5(OH)_4$. It is also known as pigment PW19 (Colour Index generic name) / 7004CI (C.I. Constitution number). It is described as "*white clay rock, mostly natural hydrated aluminium silicate with impurities of magnesium, iron carbonates, ferric hydroxide, mica, quartz-sand, etc.*" and the CAS Number 1332-58-7.

Anatase is an impurity in kaolin and the target is to remove the material through industrial beneficiation processes. However, residues remain in kaolin end-products. The presence of $TiO_2$ in kaolin is **up to 2.5%**, i.e. exceeds the 0.1% by weight carcinogenicity classification limit.

Kaolin is used as an extender often to reduce the loading of $TiO_2$. Due to the presence of $TiO_2$ impurities in kaolin, however, kaolin would not be a suitable alternative for $TiO_2$ if the proposed classification for $TiO_2$ was adopted.

Kaolin currently finds a wide range of applications, including (IMA Europe, undated):

- **Paper**: in the bulk of the paper and to coat its surface. Examples include papers for magazines and brochures, art paper, cartons and boxes, etc.;
- **Ceramics**: whitewares (tableware, sanitaryware, and wall and floor tiles);
- **Fillers**: its whiteness or near whiteness, make it suitable as a filler or pigment;
- **Paint**: calcined kaolins are widely used in satin and matt paints. Kaolin is particularly useful as a partial replacement for $TiO_2$ pigment, as noted above;
- **Rubber**: used in high value thermoplastic elastomers for a variety of applications and in rubber insulation on high voltage power lines;
- **Plastics**: major application is in PVC cables where its main function is to improve electrical properties. Other important applications include specialty films where it imparts anti-blocking or infrared absorption characteristics. Chemically treated, calcined kaolin is one of the major additives used in the manufacture of automotive parts based on engineering thermoplastics;
- **Refractories**: used to build structures subjected to high temperatures, ranging from simple to sophisticated products, e.g. from fireplace brick linings to re-entry heat shields for the space shuttles. In industry, they are used to line boilers and furnaces of all types-reactors, ladles, stills, kilns and so forth;

- **Fibreglass**: improves the integration of fibres in products requiring strengthened plastics: cars, boats and marine products, sporting goods and recreation products, aviation and aerospace products, circuit board manufacturing, fibreglass insulation, fibreglass air filters, fibreglass tanks and pipes, corrosion resistant fibreglass products, fibreglass building and construction products, etc.; and
- **Cosmetics and pharmaceuticals**: 'British Pharmacopoeia Light Kaolin' (BPLK) is used in both human and veterinary medicinal products, for example, to treat digestion problems and as a constituent of poultices. It can also be used as an excipient in personal care products and in a number of dietary products, plasters, foot-powders and in the specialised treatment of some lung disorders.

The current production volume of kaolin in the EU is 4 million t/y and its consumption is around the same. The market for kaolin in the EU is worth €300 million/y.

***Bentonite***

Bentonite is an absorbent aluminium phyllosilicate clay consisting mostly of montmorillonite. It contains up to **2%** $TiO_2$ by weight. It finds a variety of uses, including (IMA Europe, undated):

- **Foundry**: bonding material in the preparation of moulding sand for the production of iron, steel and non-ferrous casting;
- **Pelletising**: binding agent in the production of iron ore pellets;
- **Construction and Civil Engineering**: thixotropic, support and lubricant agent in diaphragm walls and foundations, in tunnelling, in horizontal directional drilling (HDD) and pipe jacking. Also used in Portland cement and mortars;
- **Environmental Markets**: wastewater purification. Bentonite is the active protective layer of the Geosynthetic Clay Liners;
- **Drilling**: mud constituent for oil- and water-well drilling;
- **Oils / Food Markets**: removal of impurities in oils where its adsorptive properties are crucial in the processing edible oils and fats (soya / palm / canola oil). In drinks such as beer, wine and mineral water and in products like sugar or honey, bentonite is used as a clarification agent;
- **Agriculture**: animal feed supplement, as a pelletising aid in the production of the animal feed pellets, as well as a flowability aid for unconsolidated feed ingredients such as soy meal. It is also used as an ion-exchanger for improvement and conditioning of the soil. When thermally treated, it can be used as a porous ceramic carrier for various herbicides and pesticides;
- **Pharmaceuticals, Cosmetics and Medical Markets**: filler in pharmaceuticals and antidote in heavy metal poisoning. Personal care products such as mud packs, sunburn paint, baby and face powders, and face creams may all contain bentonite;
- **Detergents**: laundry detergents and liquid hand cleansers/soaps;
- **Paints, Dyes and Polishes**: thickening and/or suspension agent in varnishes, and in water and solvent paints.
- **Cat Litter**;
- **Paper**: used in pitch control, de-inking for paper recycling and the manufacture of carbonless copy paper; and
- **Catalyst**: employed in the alkylation processes to produce fuel additives.

The current production volume of bentonite in the EU is 3 million t/y and its consumption is ca. 2.7 million/y. The market for bentonite in the EU is worth €600 million/y.

***Perlite***

Perlite is an amorphous volcanic glass that has a relatively high water content, typically formed by the hydration of obsidian. It is naturally occurring and has the unusual property of greatly expanding when heated sufficiently. It is an industrial mineral and a commercial product useful for its light weight after processing. Perlite may contain **0.2%** by weight $TiO_2$. It finds a variety of uses, including (The Perlite Institute, undated):

- Lightweight formed products;
- High temperature insulation;
- Simulated stone, masonry and wood products;
- Perlite volcanic glass as a hollow microsphere filler;
- Lightweight fillers for glass/reinforced polyester;
- Perlite volcanic glass as a glass flake filler;
- Perlite concrete;
- Filtration;
- Non-evacuated cryogenic and low temperature services;
- Well cements; and
- As an absorbent or carrier.

The current production volume of perlite in the EU is 0.65 million t/y and its consumption is around the same. The market for perlite in the EU is worth €120 million/y.

***Mica***

Mica is a mineral name given to a group of minerals that are physically and chemically similar. They are all silicate minerals, known as sheet silicates (because they form in distinct layers). Micas are fairly light and relatively soft, and the sheets and flakes of mica are flexible. Mica is heat-resistant and does not conduct electricity. There are 37 different mica minerals. The most common include: purple lepidolite, black biotite, brown phlogopite and clear muscovite (Minerals Education Coalition, undated). Mica may contain up to **2%** by weight $TiO_2$.

It finds wide application, including (IMA Europe, undated):

- **Automotive**: mica is used in the production of bitumen foils that are attached onto the inner vehicle frame structures to dampen vibrations;
- **Brake pads and clutches**: mica is added to frictional systems to impart better heat transfer in conjunction with noise reduction;
- **Decoratives**: mica can be found in various products such as decorative paints, ceramics, decorative concrete, post cards, wallpapers;
- **Drilling**: mica is used as a mud constituent for oil well drilling;
- **Fibre cement**: mica is used in highly engineered fibre cement to impart dimensional stability either in moisturising conditions or in passive fire protection;
- **Fire extinguishers**: mica provides anti-caking & flowability;
- **Foundries**: mica is used for coatings in iron casting and to a limited extent in aluminium production casting;
- **Paints and coatings**: mica is used in external renderings and anti-corrosive paints;
- **Paper coatings**: mica is used in packaging products as it provides protection from the water or grease associated with the food;
- **Plastics**: mica acts as a reinforcing additive in the packaging industry and in the automotive industry;

- **Plasterboard and joint compound**: mica is used primarily as an anti-cracking and reinforcing additive;
- **Pearlescent pigments**: mica can provide a pearlescent effect once it has been coated with $TiO_2$ or $Fe_2O_3$;
- **Rubber**: mica is used either as a demoulding agent during the vulcanisation process, or as an anti-sticking powder when several rubber pieces are stacked together; and
- **Welding rods**: mica brings added value both during the rod manufacturing step (easing the extrusion) and the welding itself. During welding, the platy structure acts like a shield protecting the molten steel from ambient air oxidation and moisture.

The current production volume of mica in the EU is 90,000 t/y. The market for mica in the EU is worth €40 million/y.

***Diatomite***

The term diatomite is applied both geologically and commercially to the nearly pure sedimentary accumulation of diatom frustules—the microscopic skeletons of unicellular aquatic algae belonging to the class of golden brown algae, Bacillariophyceae. The sediments are fine-grained, highly siliceous, and consist primarily of amorphous opaline silica with only minor amounts of organic residue, secondary minerals, and co-deposited nondiatomaceous or crystalline clastic debris. Synonyms in current usage include diatomaceous earth and kieselguhr (Minerals Education Coalition, undated - b). Diatomite may contain up to **0.7%** by weight $TiO_2$ and finds a variety of applications, such as (IMA Europe, undated):

- **Filter aids**: because of its high degree of porosity combined with its low density and inertness, diatomite makes an excellent filtration medium, used for antibiotics, beer, chemicals, edible oils and fats, fruit juices, glucose, pharmaceuticals, solvents, sugar, vitamins, water, wine, and many others;
- **Functional mineral additives**: the versatility of diatomite as a functional filler, in part as a result of its unique particle shape, has led to its widespread use in a number of applications such as paints, plastics, paper, insulating bricks, and dental mouldings;
- **Carriers for active Ingredients and diluents**: typical applications include: pesticide carriers and catalyst carriers; and
- **Aggregates**: the aggregates are used as absorbents in a number of applications including floor sweeping, the clean-up of hazardous wastes, oil and grease absorbents, and soil amendments.

The current production volume of diatomite in the EU is 0.1 million t/y and its consumption is 0.13 million t/y. The market for diatomite in the EU is worth €40 million/y.

***Ball clays***

Ball clay (also known as plastic clay) is an extremely rare mineral found in very few places around the world. Ball clays usually contain three dominant minerals: from 20-80% kaolinite, 10-25% mica, and 6-65% quartz. In addition, there are other 'accessory' minerals and some carbonaceous materials present. The wide variation both in mineral composition and in the size of the clay particles, results in different characteristics for individual clay seams within a deposit (IMA-NA, undated). Ball clays may contain up to **2%** by weight $TiO_2$. Their applications include (IMA Europe, undated):

- **Sanitaryware**: ball clay provides plasticity and workability;
- **Tableware**: ceramic tableware utilises plastic clay to provide high plasticity and a good white-fired colour, combined with kaolin, feldspar and quartz;

- **Wall and floor tiles**: combined with feldspar, kaolin and quartz, plastic clays are utilised for their plasticity and bonding properties;
- **Glazes and slips**: plastic clays are also used in the production of coatings for ceramic products;
- **Refractory clays**: ball clays are used in refractory products such as kiln insulation and furniture;
- **Construction ceramics**: building materials such as bricks, clay pipes and roof tiles all contain plastic clay;
- **Electrical porcelain insulators**: plastic clays are used in the electrical porcelain components that provide insulation from high voltage currents;
- **Chemical applications**: plastic clays are used as fine fillers and extenders in polymers, adhesives, plastics, fertilisers and insecticides; and
- **Sealants**: plastic clays are also widely used for lining landfill waste disposal sites, and for sealing over them once completed.

The current production volume of ball clays in the EU is 12 million t/y and its consumption is around the same. The market for ball clays in the EU is worth €400 million/y.

***Vermiculite***

Vermiculite is a member of the phyllosilicate, or sheet silicate, group of minerals. It has the unique ability to expand to many times its original volume when heated - a property known as exfoliation. The majority of applications call for vermiculite in its exfoliated form (IMA Europe, undated - b).

Vermiculite contains **0.5%** by weight $TiO_2$ and finds a variety of applications including (IMA Europe, undated)

- **Animal feedstuffs**: vermiculite is used as a support and carrying medium for a range of nutrients such as fat concentrates, vitamin preparations and molasses;
- **Bitumen coated screeds**: vermiculite, coated with a bituminous binder, can be used as a dry, lightweight roof and floor screed;
- **Lightweight concretes**: vermiculite concretes may be used for in situ roof and floor screeds and in the fabrication of pre-cast products. Vermiculite concretes can also be used around back boilers and as a fire back support material;
- **Vermiculite plasters**;
- **Loose-fill insulation**: loose-fill vermiculite can be used between joists in lofts for house insulation;
- **Boards, panels and premixed coatings**: these coatings have been used in the petrochemical industry and tunnel construction;
- **Refractory and high temperature insulation**: vermiculite for refractory and high temperature insulation is normally bonded with alumina cements, fire clays and silicates to produce a wide range of vermiculite products which, depending on type and application, can withstand hot face temperatures of up to 1,100 °C;
- **Steelworks and foundries**: vermiculite is used for hot topping molten steel to reduce heat loss from ingots and ladles and generally as a loose-fill insulator;
- **Silicate bonded shapes and blocks**: pressed vermiculite block insulation can be used in high temperature kilns, furnaces, combustion plants, boilers, wood burning stoves and night storage heaters; and
- **Automotive industry**: vermiculite is now used extensively in the friction lining industry (e.g. brake and clutch linings) as a safe alternative to asbestos;
- **Horticulture:** vermiculite is well established as a growing medium; and
- **Packaging materials**: exfoliated vermiculite is a useful packaging medium.

Currently, ca. 18,000 tonnes of vermiculite are produced each year in the EU (in Bulgaria) (USGS, 2016b). No data are available on the value of the market in the EU.

***Refractory materials***

*Presence of titanium dioxide in materials used in the refractory industry*

$TiO_2$ is also present, up to 4%, in a number of naturally occurring minerals that are used in the refractory industry including refractory calcined clay (chamotte), calcined bauxite, brown fused alumina, andalusite, zircon silicate, synthetic mullite, refractory clay, as well as kaolin and bentonites that were discussed above (Cerame-Unie, 2016; German Refractory Association, 2016)[63].

*Impacts from the proposed classification for titanium dioxide*

The proposed classification would create the need to further reduce dust exposure during raw material handling and product manufacture. This would be achieved through the use of individual respirator systems to control exposure in warehouses and manufacturing facilities' LEV covering the entire production process. In addition, a high proportion of refractory shapes and monolithics (unshaped refractories) would contribute hazardous waste from any unused arisings from production processes. The additional cost (estimated at €100,000 per plant), if passed on to customers, would result in significant price increases for the downstream user industries (steel, aluminium, cement, glass, ceramics, and any other energy intensive sector) and the recycling of refractories[64] would also be impacted.

Elimination of $TiO_2$ from the manufacturing process is not a realistic proposition, as such a high proportion of raw materials would be affected, that it is difficult to imagine how cost effective alternatives could be found to meet user industry demand. Not only is $TiO_2$ an impurity in a wide range of naturally occurring mineral raw materials used in refractory products, the unique balance of rheological behaviour and refractoriness of the clays used makes them vital to the means of operation in many other types of products. According to the European Refractory Producers Federation, if $TiO_2$ were eliminated from aluminous refractories, only high purity alumina, calcined, sintered or fused would be possible. This would be costly and not possible due to market inability to source such pure alumina.

High purity synthetic aggregates, without $TiO_2$ as an impurity, would work in some applications, but production costs would increase because of this aggregate change and possibly because of higher processing temperatures. Although high purity general refractory products already exist, depending on the specific application, such purer products do not always perform as well as natural aggregates – frequently increasing consumption and associated costs. In addition, they would need validating across the applications and more specialised products would need individual evaluation. A re-qualification period of 10 years could be envisaged.

Finally, refractory articles sold to downstream users have no intended release and are not normally classified and labelled. However, the presence of the new carcinogen might appear on the safety



[63] $TiO_2$ can also be found in metal working slags. A range of 0.5 to 1% is typical in blast furnace slags. Quoted quantities are 35 million t/y for blast furnaces in the EU. Although X-ray fluorescence analysis might detect titanium in a sample which is conventionally reported as $TiO_2$, in some materials the titanium might be present as titanates. Any classification change needs to be clear on what it applies to.

[64] Refractory bricks (which are used to build the walls of the furnace) are taken out at the end of the lifetime and then crushed and used as a secondary raw material in the refractory industry or in other industries.

data sheet which might increase user resistance - even though the $TiO_2$ is not readily available for inhalation.

The European Refractory Producers Federation brings together 160 members located in Austria, Belgium, the Czech Republic, France, Germany, Italy, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and the UK. These companies would be affected by the proposed classification and it is estimated that the proposed classification would impact 40% to 50% of all refractory products (Cerame-Unie, 2016). With regard to the tonnage of potentially impacted refractories, the European Refractory Producers Federation estimates that $TiO_2$ occurs as an impurity in nearly all silica-based refractories and about 80% of the high alumina refractories. According to statistics held by the Federation, this amounts to 1.3 million t/y manufactured in the EU.

The value of the EU refractory market in 2014 was ca. €4.8 billion/y; therefore, a simple analogy would suggest that €2-2.5 billion worth might be affected by the proposed classification for $TiO_2$. In 2014, the industry employed over 17,000 workers[65].

***Abrasives***

$TiO_2$ is present as an impurity in raw materials used in the abrasives industry. According to the Federation of European Producers of Abrasives (FEPA), the abrasives industry represent an annual turnover of €3.5 billion in Europe, of which €2.5 billion are ceramic abrasives. There are 150 relevant production plants in European countries employing ca. 20,000 workers.

***Zircon***

Zircon is a mineral belonging to the group of nesosilicates and it is natural zirconium silicate, $ZrSiO_4$. Ilmenite ($FeTiO_3$), rutile ($TiO_2$) and zircon minerals are mined together as co-products. The downstream processing of zircon, however, leaves $TiO_2$ as an impurity at **0.1-0.5%** by weight in the zircon. Therefore, the proposed classification for $TiO_2$ would impact on the industry as classification rules mean that zircon would carry the same classification as $TiO_2$.

Ceramics account for the single largest share of demand with about 50%[66] as a whitening agent in the body of porcelain tiles, followed by refractory and foundry (30%)[67], followed by zirconia, zirconium chemicals and metal. Minor uses include friction materials, welding rods and zirconium alloys.

There are 10 EU-based companies involved in the marketing of zirconium products in the EU alongside a smaller number of non-EU companies. The most important countries in this market include France, Spain, Italy, Germany and the UK.

The proposed classification would increase the regulatory burden on the zircon industry, as described for other minerals above. The worst-case scenario (e.g. following a restriction on $TiO_2$)

65 Figures based on a visual assessment of statistics available at http://www.pre.eu/ (accessed on 28 October 2016).

66 Information available at http://www.zircon-association.org/Websites/zircon/images/Resources/EICF_160417_presentation_web.pdf (accessed on 28 October 2016).

67 Foundry applications are mostly relevant to China.

would be major loss of market share to imported, technically inferior but unclassified alternatives, leading to a significant reduction in demand and plant closures / loss of direct employment in the industry. It is worth noting that the $TiO_2$ feedstock demand is the principal driver of zircon supply[68].

The volume of zircon consumed in the EU is estimated at 325 ktonnes/y (according to the USGS, no production takes place in the EU) and has a market value of just over US$300 million (or over €275 million) per year[69].

***Summary***

A summary of the key information on the aforementioned minerals is provided in **Table 4–22**. The total market value of these minerals and products exceeds €6.2 billion a year but it must be understood that downstream uses of these minerals are of a value much higher than what is shown in this table.

**Table 4–22: $TiO_2$ impurities and markets for selected minerals and products**

| Mineral | $TiO_2$ impurities (%) | EU production (million t/y) | EU market (million t/y) | Value of EU market (€billion/y) |
|---|---|---|---|---|
| Kaolin | >2.5 | 4 | 4 | 0.3 |
| Bentonite | >2 | 3 | 2.7 | 0.6 |
| Perlite | 0.2 | 0.65 | 0.65 | 0.12 |
| Mica | <2 | 0.09 | No data | 0.04 |
| Diatomite | <0.7 | 0.1 | 0.13 | 0.04 |
| Ball clays | <2 | 12 | 12 | 0.4 |
| Vermiculite | 0.5 | 0.018 | No data | No data |
| Refractory materials | <4 | 1.3 | No data | >2 |
| Abrasives (ceramic) | No data | No data | No data | 2.5 |
| Zircon | 0.1-0.5 | - | 0.325 | 0.275 |
| **Total** | **>14** | **>21** | **>20** | **>6.2** |

*Source: consultation*

## 4.7.2 Impacts on manufacturers and users of other poorly soluble powders

In Section 4.1.4, page 63 ("*Summary of carcinogenicity studies*") of the Proposal for Harmonised Classification and Labelling, it is concluded, "*In absence of mechanistic data to the contrary, the rat model is adequate to identify potential carcinogenic hazards of poorly soluble particles to humans, such as $TiO_2$*". As the carcinogenic effect in animal testing discussed in the French CLH proposal is not substance-specific but characteristic of respirable poorly soluble dusts, the CLH proposal for $TiO_2$ sets a precedent for a subsequent classification of all other poorly soluble powders regardless of each and every substance's human health carcinogenicity data. In this context, the proposed classification for $TiO_2$ would be a cause of significant problems in two key areas:

[68] Information available at http://www.zircon-association.org/Websites/zircon/images/Resources/EICF_160417_presentation_web.pdf (accessed on 28 October 2016).

[69] A value per tonne of just below US$1,000 per tonne has been obtained from http://www.zircon-association.org/Websites/zircon/images/Resources/EICF_160417_presentation_web.pdf (accessed on 28 October 2016). An exchange rate of US$1 = €0.917 has been used (as of 28 October 2016).

- All poorly soluble powders that could replace it (including minerals such as kaolin, chalk, talc, etc.) could be considered to exert carcinogenicity in a similar manner. As such, (a) there would be no realistic, feasible natural alternative for the replacement of $TiO_2$, and (b) the proposed classification would not offer any discernible additional protection to workers' health as $TiO_2$ as alternatives would have an equivalent carcinogenicity hazard profile; and

- The manufacture, handling and use of other poorly soluble powders, if similarly classified for carcinogenicity, would become more costly and burdensome in the EEA thus leading to further loss of competitiveness of EEA businesses.

A case study of potential impacts is provided for carbon black (and associated materials) below.

**Box 4-3: Case study – Potential impacts on the carbon black industry from the proposed classification for $TiO_2$**

Carbon black (EC No. 215-609-9, CAS No. 1333-86-4) is virtually pure elemental carbon in the form of colloidal particles that are produced by incomplete combustion or thermal decomposition of gaseous or liquid hydrocarbons under controlled conditions. Carbon black is mainly used as a reinforcing agent in tyres and other rubber products. A small percentage is used as a colourant in polymers for indirect food contact use. Carbon black is also in the top 50 industrial chemicals manufactured worldwide, based on annual tonnage, which currently stands at 8.1 million t/y[70].

There are four EU-based companies involved in the manufacture of carbon black and seven companies in total that place carbon black on the EU market. The most important EU Member States within the carbon black market are the Netherlands and Italy as they both host carbon black manufacturing plants. It is estimated that 2,600-3,200 workers are employed in the carbon black industry in the EU.

The EU market for carbon black had a volume of 2 million tonnes in 2014, of which rubber goods (mostly tyres) represented 88% of consumption, followed by plastics (5%), printing inks (4%), coatings and paints (1%) and other small applications such as activated carbon, concrete/bricks, papers/toners and road fillers (collectively accounting or 2%) (Jung & Bouysset, 2015).

As described above, the proposed classification for $TiO_2$ would potentially pave the way for the classification of carbon black and other substances, for example, fumed alumina (which is used in adhesives, sealants, chemical mechanical planarization and cosmetics) and activated carbon (which is used in a large variety of uses including as an industrial and consumer filtration medium for potable water and other consumable beverages). Such a classification would have a profound adverse impact on the use of the substances; it would make their handling and use in the EU more burdensome and costly and could lead to loss of competitiveness and loss of jobs both among manufacturers of these substances but also EU-based downstream users.

A carcinogenicity classification, if it resulted in the discontinuation of the use of these poorly soluble powders, would also have an impact on consumer welfare; as the majority of carbon black is used as a reinforcing agent in car and lorry tyres, it imparts important safety properties to the rubber of a tyre, specifically rolling resistance, durability and longevity. Simply stated, consumer and lorry tyres would be less safe and would wear out much sooner (i.e., ca. 10,000 miles lifespan) without the use of carbon black. On the other hand, activated carbon acts as a filtration medium and removes harmful impurities and unpleasant odours in potable water and other beverages. Its classification might restrict its use in food and beverage processing, possibly compromising food and beverage quality & safety.

Furthermore, given the EU's regulatory influence, this classification could be adopted by other countries and would greatly increase the possibility of product liability legal actions, and worker compensation claims.

*Source: information submitted by a leading carbon black manufacturer*

[70] Information available at http://www.carbon-black.org/index.php/what-is-carbon-black (accessed on 28 October 2016).

## 4.8 Impacts on the environment

Restricting or making the continued use of $TiO_2$ more burdensome could have considerable adverse impacts on the environment. This is elaborated with specific examples overleaf.

| Impact category | Relevant applications | Description |
|---|---|---|
| Imports of finished articles into the EEA | All | In many applications, cheaper, imported finished articles could replace more expensive EEA-made ones; as a result there would be an increase in $CO_2$ emissions from increased transportation of the articles into the EEA. |
| Alternatives and their impacts on the environment | All | **Obtaining sufficient volumes of alternatives**: the energy required to produce $TiO_2$ is high and, as such, the ecological footprint of its production is significant. However, the alternatives to $TiO_2$ are, like $TiO_2$, based on minerals that are extracted from the earth. A significant new investment and infrastructure would need to be put in place to meet the significantly increased demand for the alternatives. This would have its own significant ecological footprint, which would not be as optimised as has been currently achieved through the 90 years of experience of industrial use of $TiO_2$. In addition, the current $TiO_2$ extraction and processing activities (typically outside the EEA) would become redundant and significant volumes of equipment and construction waste from this decommissioning would be generated. |
| | All | **Adverse effects of alternatives**: some alternatives to $TiO_2$ are accompanied by an environmental hazard classification (e.g. heavy metals or zinc-based pigments). Substitution of $TiO_2$ with one of those substances might thus increase ecological pressure on the environment. With specific regard to cosmetics, an increased use of organic UV filters as $TiO_2$ substitutes would lead to higher volumes of them being released into the environment with potentially long-term adverse effects onto the flora and fauna. Spherical plastic particles that can be used as substitutes are products based on mineral oil and require significant amounts of energy to produce and convert for use and there are concerns about their release to the aquatic environment.<br><br>Alternatives to $TiO_2$ would need to be used at higher loadings and $TiO_2$-free articles would need to be replaced more often. Production of bulkier products (for example, paper products) would impact on packaging and delivery costs, therefore affecting the environmental footprint of some products. |

| Impact category | Relevant applications | Description |
|---|---|---|
| | Adhesives / Fibres / Paper | **Natural vs. petrochemical products**: gelatine glues that contain $TiO_2$ are a based on a by-product from animals and are a re-use of otherwise discarded material. The alternative would be hot melts which are more expensive and based on polymers that originate from the petrochemical industry. If these products were replaced, it would be by less environmentally friendly and would result in more costly and less recyclable products. On the other hand, if $TiO_2$ use in fibres were to be substituted, the poorer quality of the synthetic fibres would cause a shift to natural fibres. The global environmental impact would be much worse due to high land use, increased water and energy consumption, increased use of fertilisers and transport in the context of a projected increase of world population and limited technical closed loop recycling possibilities for natural fibres in comparison with the synthetic ones.<br><br>Particleboard based furniture often utilises manufacturing residues or reclaimed wood as raw material and therefore the combination of decor paper and particle board contributes to high resource efficiency and the establishment of a circular economy. Decor paper is produced using mainly forest cellulose and $TiO_2$. The pulp comes from forest managed in a sustainable way (certified by external third parties as FSC and PEFC) and it is a renewable and carbon neutral raw material. Plastic films that could replace this paper are based on fossil fuels. |
| Durability | All (examples: paints, coatings, plastics) | Because of the superior durability of $TiO_2$-based paints, coatings, plastics, etc. any alternative would lead to the generation of higher emissions, more waste and the need to re-paint/coat or replace more often. Maintenance of buildings would increase, raw materials would be used more frequently and replacement of wooden parts would become common practice. This would go against the principles of sustainable development. |

| Impact category | Relevant applications | Description |
|---|---|---|
| Air quality | Construction products | **Loss of $TiO_2$ would mean loss of photocatalytic applications**: $NO_x$ are one of the most critical groups of air pollutants in urban areas. One of the options to reduce the concentration of these pollutants in the air is to create photocatalytically active surfaces in appropriate locations and $TiO_2$ is, so far, the only photocatalyst providing the needed characteristics. In Directive 2008/50/EC, the European Union set upon local authorities a maximum limit of 40 µg nitrogen dioxide/$m^3$ in the ambient air at the local authority level and defined potential fines for authorities which fail to meet that limit (as an annual average). In July 2015, the European Commission reprimanded Germany for persistently exceeding the limit for many years[71]. If the federal, state and local governments continue to fail in taking sufficient action to reduce pollution of these harmful gases, there may be proceedings, and following that high fines may also be imposed on individual cities and local authorities (up to €50,000 per day and location is the possible penalty).<br><br>Similarly, the use of photocatalysis in $TiO_2$-containing products leads to environmentally friendly and sustainable decomposition of harmful gases and solids indoors (such as nicotine and tar). Various harmful substances are not simply collected in filter materials (which must be disposed as more or less dangerous waste) but decomposed to harmless compounds. There is currently no comparable technology.<br><br>Any significant restriction of the use of $TiO_2$ as a photocatalyst would bring to the end the widespread use of photocatalysis as an environment-friendly and sustainable technology for air cleaning. |
| | Fibres | **Automotive applications**: if synthetic fibres for wet laid processes cannot be produced any more with a suitable quality due to the elimination of $TiO_2$ from fibre processing, they would not be available for filter products for the automotive industry. Maintenance intervals/mileages would have to decrease to a level unseen for decades and there would be higher engine oil consumption / material consumption/maintenance costs during a car's life. |
| | Catalysts | **Impact from loss of catalysts used to prevent atmospheric emissions**: inability to produce SCR catalysts could have adverse environmental impacts and a significant number of these SCR catalysts used globally are manufactured in the EEA. Particularly in countries outside the EEA with lower fuel quality, users would not be able to use SCR technologies for automotive applications and alternative technologies are sensitive to low fuel quality. This might delay the implementation of SCR technologies in such countries for years. |

71 Information available at http://www.fr-online.de/wirtschaft/stickoxid-und-feinstaub--europameister-im-luft-verpesten-,1472780,34274106.html (accessed on 23 October 2016).

| Impact category | Relevant applications | Description |
|---|---|---|
| Energy consumption, efficiency and management | Paints & coatings, plastics | **Electricity consumption and heating**: if the availability of white and bright architectural paints on the market diminished, a higher consumption of electricity could be expected due to the use of darker colours in the home/office. In relation to exterior coatings, a negative impact would be expected on the heat management of buildings due to reduced light reflectivity. White colours contribute to a global lowering of temperature because of their solar reflectance (cf. temperature of a white roof <50 °C and a dark one >80 °C); reducing the availability of light colours would probably result in more energy-demanding, resource inefficient air conditioning with, in the end, a potential impact on global warming. In addition, $TiO_2$ is used to make plastic roofing material and profiles (windows) which reflect light, thus causing buildings to heat up less in hotter climates. This reduces the need for air conditioning. Substitution of this roofing material with less effective material would thus increase energy consumption and $CO_2$ footprint.<br><br>Similarly, the reflectivity of road marking lines would be affected meaning that the white lines might not be as visible thus raising the need for more/better lighting on roads. The potential for a higher number of accidents would mean more delays on the roads and, in turn, this increased congestion would also have a negative environmental impact as more vehicles would be running for longer therefore creating more potentially harmful emissions into the atmosphere than would otherwise be produced. |
| | Inks | **Photovoltaic applications**: photovoltaic modules are covered with white ink films to increase efficiency. Without $TiO_2$-containing white inks it would not possible to achieve this effect, so efficiency would decline. |
| | Glass | **Glass applications**: if the EEA industry was unable to use $TiO_2$, there would be costs to the environment, as $TiO_2$-based glass offers significant benefits in sustainable construction materials – self-cleaning windows reduce maintenance and extend building lifetime, coatings reduce the need for heating and cooling of buildings which is responsible for a large amount of $CO_2$ emissions. |
| | Detergents | **$TiO_2$ and lower washing temperatures**: a key effect of incorporating enzymes in detergent products is that lower washing temperatures can be employed with consequent savings in energy consumption. Lifecycle analyses have shown that the use phase in the washing machine or dishwasher is the one that requires the most energy and hence also generates the most $CO_2$ emissions. Washing at the lowest possible temperature helps to cut $CO_2$ emissions, saves energy and helps the environment, as enzymes are readily and fully biodegradable. Therefore, in the event of classification of $TiO_2$ as Carc Cat 1B preventing its use in detergents, there would be negative impacts on the environment. |

| Impact category | Relevant applications | Description |
|---|---|---|
| Waste management and recycling | Plastics and fibres | **Impacts on plastics recycling**: reclassification of plastic waste as hazardous due to the presence of $TiO_2$ as a carcinogen would have an effect on the recycling of such waste. Unless a specific exemption is introduced in Annex III of the Waste Framework Directive (on the basis of the critical route of exposure being irrelevant to plastic waste), up to 1.25 million tonnes of recycled plastic products would be at stake. Their recycling prevents the release of an estimated 1.8-2.4 million tonnes of $CO_2$ equivalents per year, according to the EuPC, through the increased use of virgin resins.<br><br>Synthetic fibres allow good, proven and effective recycling techniques, such as mechanical recycling of PP family in the Engineering Plastic sector; mechanical recovery of PET that is applied in fibres production; chemical recycling of polyamide back to feedstock monomer; and new innovative techniques currently in progress. The proposed classification would make recycling of fibre waste more difficult, if not impossible if the waste is classified as hazardous. By way of example, using recycled PET polymer from PET bottles for fibres is a sustainable alternative to virgin PET polymer, with just 25% of the carbon footprint compared to virgin polymer use. If regulatory controls on $TiO_2$ became too burdensome, significant amounts of this high value secondary raw material would have to be exported to operations outside of the EEA. PET (and polyamide) recyclate is slightly discoloured due to the thermal history of the material. This discoloration is masked/reduced by $TiO_2$. If the continued use of $TiO_2$ would become unattractive (or at a later stage restricted), consumer acceptance for recycled fibre products (for example, in the bedding sector) would be reduced. |
| | Food packaging | If it is no longer possible to use $TiO_2$ in food packaging, then some information (which is presently provided by means of printing inks), would be delivered using adhesive paper labels. The mixing of materials would seriously hinder the ability of the current processes to recycle the packaging material. This could result in the growth of the non-recyclable waste fraction (which to date has been decreasing) and an increase in the amount of waste destined for landfill or energy recovery.<br><br>Furthermore, due to the lower shelf life caused by the lack of $TiO_2$, increased amounts of packed food will have to be disposed of. If more packaging materials are printed outside the EEA, due to the non-availability of $TiO_2$ based inks within Europe, then the carbon footprint of the packaging will increase as a result of longer transport routes. |

# 5 Conclusions

## 5.1 Why and how the proposed classification would impact the EEA

This report has explained that upon the adoption of the proposed hazard classification for $TiO_2$, five drivers of impacts on the EEA industry and EEA consumers would come into action:

1. There is existing legislation that restricts or otherwise controls the marketing and use of substances that are classified as Carc Cat 1B.

2. There is a lack of feasible alternatives for $TiO_2$ for the vast majority of its uses. Known alternatives are technically infeasible in the uses of concern. More specifically:

    a. There is no alternative on the market with technical properties, e.g. brilliance, colour strength, opacity, pearlescence and price-performance ratio, similar to $TiO_2$. The range of colour shades achievable (e.g. in paints) without $TiO_2$ is very narrow compared to the present range. Bright opaque colours would be unachievable.

    b. No known alternative can demonstrate the weatherability of $TiO_2$. This is based on $TiO_2$'s exceptional stability to heat, light and weathering plus its ability to absorb UV radiation, a critical property in the field of cosmetics, packaging and construction e.g. by preventing degradation of paint films and embrittlement of plastic articles.

    c. No known alternative holds approvals for use in certain consumer applications where authorisation of additives is required before use. Only approved white colours can be used in food and pharmaceuticals and $TiO_2$ is the only white pigment which is allowed for use as a colouring agent in its current food and pharmaceutical applications.

    d. Some applications must use $TiO_2$. No other substance could replace $TiO_2$ as a raw material in the production of Complex Inorganic Coloured pigments (e.g. rutile pigments). In its use as a photocatalyst, no real alternative exist with the same performance.

    Overall, there are no viable alternatives for delivering whiteness to polymeric or synthetic materials (paints, plastics, paper) and, in any case, other white pigments may be unavailable in sufficiently large volumes to replace the large volumes of $TiO_2$ currently used and may also pose a hazard to human health and/or the environment. Importantly, if $TiO_2$ was classified as a Carc Cat 1B substance, other white pigments (being poorly soluble powders themselves) would also meet the requirements for the same hazard classification.

3. Market developments would play a critical role. The direct impact of the proposed classification on consumer uses of $TiO_2$-based formulations would result in the collapse of EEA's $TiO_2$ manufacturing base and would have wider consequences that are difficult to predict. Manufacturing outside the EEA, where the carcinogenicity classification for $TiO_2$ would not apply, would become more competitive and thus more attractive. On the other hand, several large users of $TiO_2$ (for instance, leading paint manufacturers) have extensive global operations. Such users might consider the adoption of variable protection standards across operations both logistically unwelcome and reputationally risky and thus adopt

measures appropriate to a Carc Cat 1B substance across their global operations. Thus adverse impacts from the proposed classification might extend beyond the borders of the EEA.

4. Supply chains for $TiO_2$-containing formulations and articles are particularly long and diverse; for instance, paints containing $TiO_2$ are applied to myriads of surfaces/articles which, in turn, find their way in vast numbers of different complex end products. Whilst it may be impossible to quantify all impacts that would arise along such supply chains, it is clear that adverse impacts would magnify as the scope and the value of markets increases along those chains.

5. Industrial/professional user and consumer perceptions would play an important role. Irrespective of the route of exposure (which is critical in assessing risks from exposure to $TiO_2$), presence of a Carc Cat 1B in a vast number of processes and products placed on the market would be perceived by users in a negative way.

6. The classification of $TiO_2$ would pave the way to the potential classification of other substances, either because they are themselves poorly soluble (see Point 2 above) or because they contain $TiO_2$ impurities at a level that exceeds 0.1% by weight. This would generate adverse impacts along the respective supply chains.

## 5.2 Impacts on the manufacture and supply of titanium dioxide in the EEA

In total, there are 17 $TiO_2$ manufacturing plants in the EU plus one in Norway (as well as two known manufacturers in Ukraine). Germany, the United Kingdom, and Finland combined represent over 60% of EEA production capacity for $TiO_2$.

EEA production represents almost 20% of the total worldwide production and amounts to ca. 1,100 ktonnes/y. Of this, 67-68% is sold in the EEA and the rest is sold to customers outside the EEA. The total value of the $TiO_2$ manufactured in EU plus Norway is estimated at ca. €2.66 billion and the **Gross Value Added to the EEA economy is estimated at €473 million**. The breakdown of $TiO_2$'s applications shows that paints, coatings, inks, plastics and paper account for 98% of total demand for the substance, with paints and coatings accounting for more than half of the total. The remaining 2% covers a wide range of minor but specialist applications (with each one still potentially accounting for thousands of tonnes of $TiO_2$).

The range of impacts envisaged for $TiO_2$ manufacturers in the EEA include:

- **Capacity underutilisation**: this report estimates that the direct regulatory impact on consumer uses of $TiO_2$ from the proposed classification of Carc Cat 1B would be the loss of an estimated 25% of current total $TiO_2$ demand in the EEA. Further decline in the demand for $TiO_2$-containing articles as a result of negative perceptions among consumers, as well as losses associated with an inability to meet the criteria of ecolabelling schemes and supply chain requirements, would mean that market losses would likely exceed one-third of current total $TiO_2$ demand in the EEA. When impacts on the manufacturing cost, profitability and competitiveness of industrial users of $TiO_2$ in the EEA are taken into account, it would appear likely that 50% or perhaps more of total current demand for the substance could be lost;

- **Loss of production of ancillary products**: $TiO_2$ manufacturing plants also produce by-products such as titanium chemicals, iron salts, sulphates, inorganic acids, aluminium substances, etc. If demand for and production of $TiO_2$ declines, production (and associated sales) of these by-products would also decline; and

- **Higher cost of waste management**: if $TiO_2$-containing waste (with a $TiO_2$ content above 0.1% by weight) were to be classified as hazardous waste, the cost and complexity of management of this waste would dramatically increase.

Due to the high fixed costs in the manufacture of the substance, a substantially high capacity utilisation is required to ensure profitability for each plant. The aforementioned loss of demand for $TiO_2$ (in the range of 25-50%, if not more), coupled with the recent poor financial performance of the industry would result in the collapse of the $TiO_2$ manufacturing base in the EEA and the shutdown of several manufacturing plants in the EEA. Due to the shift to non-EEA sourcing of $TiO_2$, this could potentially lead to (short term) shortages and (short- and longer term) price increases.

The $TiO_2$ manufacturing industry in the EA currently employs an estimated **8,150 workers** and is responsible for the **creation of ca. 22,800 support jobs** within the domestic economies of the relevant EEA Member States. Many, indeed the majority, of these jobs would be at risk if $TiO_2$ plants were to shut down.

## 5.3 Impacts on the supply of feedstock and raw materials and energy to titanium dioxide manufacture in the EEA

There is no mining of titanium ore in the EU but there is an ilmenite mine in Norway as well as an ore processor generating $TiO_2$ slag also in Norway. These two companies are believed to currently sell most of their outputs to European customers. The collapse of the $TiO_2$ market in the EEA arising from the adoption of the proposed classification could have significant negative consequences for the two companies who would be forced to seek customers outside the EEA. The rest of the significant volumes of feedstock required by EEA manufacturers of $TiO_2$ are sourced from overseas suppliers.

As far as suppliers of other raw materials and energy are concerned, a total annual trade of ca. 4 million tonnes of chemicals and an annual demand for over 7,500 GWh of energy would be at stake. Closure of $TiO_2$ manufacturing plants in the EEA would result in significant loss of turnover for the suppliers of feedstock, raw materials, consumables, utilities as well suppliers of all purchased services required to maintain and operate those manufacturing facilities.

## 5.4 Impacts on downstream users of titanium dioxide in the EEA

There are four areas where impacts may arise for downstream users:

- Compliance with horizontal legislation;
- Restrictions on the marketing and use of formulations and products that contain substances classified as Carc Cat 1A/1B;
- Adverse market, supply chain and competition dynamics; and
- Employment impacts.

### 5.4.1 Impacts from compliance with horizontal legislation

The key legislative instruments of relevance to the use of a Carc Cat 1B substance include the CLP Regulation, Council Directive 1989/391/EEC and Directive 2004/37/EC (the Carcinogens and

Mutagens at Work Directive), and the Waste Framework Directive 2008/98/EC and associated instruments (Regulation 1357/2014, and Decision 2000/532/EC). Specific impacts might include the following:

- **Reformulation of products**: legislation on worker health protection requires that companies using the substance should consider is substitution by alternative substances. To start with, $TiO_2$ concentrations of 0.1% by weight could not achieve the desired technical characteristics in all relevant formulations. With particular regard to paints and coatings, in recent years, concerted efforts have been made towards the replacement of $TiO_2$ in paint formulation in response to its then high market price. Those efforts failed as it was only possible to substitute a small proportion of the overall $TiO_2$ loading if performance standards were to be met.

  For applications where $TiO_2$ is an indispensable raw material, e.g. the manufacture of Complex Inorganic Pigments, its replacement is de facto impossible. For certain other applications, e.g. as a UV filter in cosmetics and the packaging for pharmaceuticals, and as a white food colourant and a pharmaceutical excipient, there are no approved alternatives that could match the performance of $TiO_2$.

  $TiO_2$ is used in a vast number of products. By way of a single example, $TiO_2$ is used in the great majority of coloured pharmaceutical and dietary supplement tablets and capsules, either as a sole colourant or in combination with other pigments to produce a range of colours. Reformulation to remove $TiO_2$ would clearly be an enormous (and very costly) task.

  Downstream users of $TiO_2$ have, therefore, consistently argued that reformulation to technically acceptable $TiO_2$-free products is not possible. If the technical characteristics of the new formulations were to be disregarded, the time required for reformulation would be significant[72] and the costs would be very large due to the testing and trialling required (for pharmaceuticals alone, testing the stability of the formulations would necessitate an unprecedented volume of tests), the increased volumes of less efficient pigments needed (e.g. 20-50% higher for ZnS) and the need for new additives (e.g. new UV absorbers/blockers in construction plastics)[73];

- **Improved workplace conditions for the protection of workers' health**: if the substance cannot be replaced, users would need to ensure the minimisation of exposure to the substance and thus closed systems should be used. Where this is not possible, exposure should be reduced as far as feasible. Consultation suggests that the majority of users would need to implement additional measures in the workplace in order to meet these new requirements. Costs could rise to **up to €20 million per site** for the implementation of completely closed systems for the handling and use of $TiO_2$. If closed systems were not to be used, improvements to ventilation and air extraction would still require an investment of **hundreds of thousands of Euros**. The median cost estimated by respondents to the questionnaire is **€75,000**. Notably, in some cases $TiO_2$ can be used in the form of slurry to eliminate exposure to powders. However, the price of slurry is €200-250/tonne higher compared to powder. Even for a minority of users who believe

[72] Examples from consultation: (a) consumer paints: 5-10 years; (b) industrial paints: 5-20 years; (c) consumer inks: 2-5 years; (d) printer toners: 2-10 years; (e) industrial inks: 5 years; (f) cosmetics: 3-8 years; (g) fibres: over 2 years.

[73] Quantified estimates from consultation: (a) paints: up to €60 million; (b) plastics: €4-10 million; (c) consumer inks: €0.05-5 million; (d) industrial inks: €5 million; (e) pigments: €0.05-4 million; (f) fibres: €0.5-2 million.

that they would not need to implement measures beyond what is currently in place, additional monitoring campaigns costing thousands of Euros per year would be required; and

- **$TiO_2$ waste classified as hazardous**: a waste that would contain $TiO_2$ in a concentration above 0.1% by weight would be classified as hazardous (HP 7). This would cause significant process implications where post-industrial waste is recycled into the process (e.g. paints) but would also significantly increase waste disposal costs. Available estimates for the cost of segregation of $TiO_2$ waste and treatment as hazardous are in the range of **€0.1-0.35 million per site**. In cases where $TiO_2$-containing waste is currently a marketable by-product (e.g. polyester fibre waste currently used as secondary raw material), the proposed classification would cause the loss of this market. The classification of waste as hazardous would also have a very detrimental effect on post-consumer recycling. For instance, recycling of plastics from long life applications currently accounts for 600-700 ktonnes per year and rising. All of those streams could be potentially affected since it would not be feasible to segregate materials containing $TiO_2$ (the large majority) from others. Nevertheless, in light of the very low probability of inhalation exposure to $TiO_2$ powder from the handling and disposal of wastes, industry would likely petition Member States to invoke Article 7(3) of the Waste Framework Directive and thus classify such wastes as non-hazardous and avoid the adverse business impacts described here.

### 5.4.2 Impacts from restrictions on the marketing and use of titanium dioxide-containing formulations and products

The proposed classification would result in a restriction on the marketing and use of certain consumer formulations and products. These include:

- **Applications automatically restricted under Entry 28 of Annex XVII of the REACH Regulation:**
  - *Paints, coatings, adhesives, sealants, fillers, etc. for DIY use;*
  - *Inks, artists' paints, school and recreation paints, correction fluids for consumer use;*
  - *Detergents*;

- **Applications where exemptions are theoretically possible**:
  - *Cosmetics*: their placing on the market would be restricted under the provisions of the Cosmetics Regulation;
  - *Food and feed*: use of $TiO_2$ as additive E171 would be challenged;
  - *Pharmaceuticals*: similar to food applications, use of $TiO_2$ as additive E171 would be challenged;
  - *Medical devices*: the placing of devices containing $TiO_2$ on the market would be restricted under the provisions of the newly agreed Medical Devices Regulation;
  - *Biocides*: their placing on the market would be restricted under the provisions of the Biocidal Products Regulation; and
  - *Toys*: their placing on the market would be restricted under the provisions of the Toy Safety Directive.

Among those applications for which exemptions and derogations are possible, there is uncertainty as to whether such exemptions might be granted. Consultation and literature review would suggest the cosmetics and biocides might be the most challenging. Food, pharmaceuticals and medical devices are expected to have a higher probability of an exemption on the basis of low/non-existent consumer exposure via inhalation and the lack of approved alternative colourants.

The economic descriptors of the affected applications are shown in **Table 5–1**. The impacts are dominated by the market for DIY paints and coatings, which is worth **€3.5 billion per year**. It must be understood that the total value of all consumer markets lost would be much higher but specific data for DIY construction products, cosmetics, food, pharmaceutical, biocide and detergent applications are not available.

Even if an exemption could be secured under the provisions of relevant legislation, the cost of achieving this could be substantial. Examples suggested by downstream users include:

- Cost for cosmetics under the Cosmetic Products Regulation: over €1 million; and
- Testing required to demonstrate that $TiO_2$ in fibres used in toys is completely bound and strongly encapsulated in the polymer: €1-1.5 million.

**Table 5–1: Summary of key metrics of markets affected by restrictions on the marketing and use of $TiO_2$-based products**

| Application area | Potentially affected turnover | GVA | Number of companies | Share of SMEs | Number of workers | Downstream markets |
|---|---|---|---|---|---|---|
| Paints & coatings | Arch: €6.2 billion/y of which €3.5 billion/y for DIY products Ind: €8.2 billion/y | €5 billion | 800 | 85% | 110,000 | Value: €750 billion Workers: 1,000,000 (30,000 DIY retail) |
| Inks | >€3.3 billion | Included in paints & coatings | >150 | >85% | Included in paints above | Value: €200 billion Workers: >50,000 |
| Construction products | €0.55 billion/y | No data | Adhesives & sealants: 450 | >>50% | Adhesives & sealants: 41,000 | No data |
| Cosmetics | Total sector: €77 billion | Total sector: €8 billion | Ingredients: 100 Cosmetic products: 5,000 Distribution: 120,800 | 92% | Total sector: 152,000 | GVA: €21 billion Workers: 1,600,000 |
| Food, feed and packaging | No data | No data | No data | No data | No data | No data |
| Pharmaceuticals | Total sector: €192 billion | No data | Total sector: 1,900 | No data | Total sector: 725,000 | No data |
| Medical devices | No data | | | | | |

## 5.4.3 Impacts from adverse market, supply chain and competition dynamics

Impacts on EEA-based downstream users of $TiO_2$ from changes in the markets would be extensive and multifaceted. In brief, they can be described as follows:

- **Loss of market due to loss of competitiveness as a result of increased compliance costs**: it was described above that complying with the requirements of the Carcinogens and Mutagens at Work Directive could have an investment cost ranging from thousands to millions of Euros as well as an ongoing cost (e.g. for workforce monitoring). In addition, certain consumer products would have to be removed from the market. Consequently:

- The increased cost of regulatory compliance might need to be passed on to customers downstream;
- For companies for which consumer products are a major part of their portfolio, the removal of these products from the EEA market would lead to a fundamental shift in their cost/benefit base; and
- Companies currently manufacturing consumer products may not have the production volumes running through their factories to cover their overheads.

If EEA-based products were to become more costly to manufacture, it would be unavoidable for them to become less competitive relative to non-EEA made products both within and outside the EEA market. For bulk producers, price sensitivity is key and the proposed classification could severely harm them. In addition, for obvious reasons, the manufacture of finished articles outside the EEA would become less costly and burdensome and thus more appealing.

Although relocation of the production of important $TiO_2$-containing products, such as DIY and professional architectural paints, might not appeal across the board as it is mainly a regional activity, over time under the constant pressure of market needs, a shift of the value chain to locations outside the EEA could be expected, for reasons of proximity and integration with suppliers (unless non-EEA jurisdiction quickly follow the EEA example and introduce their own hazard classification for $TiO_2$);

- **Loss of market due to loss of competitiveness as a result of reformulation**: it has been explained that reformulation is not a realistic proposition in the vast majority of $TiO_2$'s applications. If, however, reformulation was pursued under pressure from regulation and the supply chain, the cost of manufacturing would increase as a result of the investment cost of reformulation (see details above) and the lower efficiency of alternative pigments. Small companies in particular could not easily absorb the costs of reformulation so would need to pass these on to customers, thus rendering their products more expensive and their market position less competitive. Furthermore, replacement of $TiO_2$ would result in poorer quality products which would affect the faith of customers in the $TiO_2$-free products;

- **Loss of market due to supply chain requirements**: in some cases, the supply chain cannot accept the use of Carc Ca 1A/1B substances even if, strictly, this is allowed by regulation. Typical examples include:

  - *Negative lists and supply chain prohibitions*: under the EuPIA Exclusion Policy and Council of Europe Resolution ResAP (2005)2 the proposed classification would de facto prohibit the use of $TiO_2$-based printing inks (although exemptions might be considered); under their Global Automotive Declarable Substance List (GADSL) automotive OEMs would require that the substance is not contained in products supplied to them;

  - *Inability to meet requirements of ecolabelling and green procurement schemes*: manufacturers who are currently placing on the market products that have been awarded an environmental label (e.g. the Ecolabel or a national one such as the Blue Angel in Germany) would no longer be able to retain this, if $TiO_2$ remained in their formulations. In addition, the proposed classification would trigger substitution of $TiO_2$-containing products (e.g. plastics) from public procurement (infrastructure, public building, supplies for public administration) but also from some commercial sectors;

- **Loss of market due to negative perceptions along the supply chain**: $TiO_2$ would be stigmatised and, thus, even if it legally could be used, it could be de facto banned, particularly in consumer applications/products. Inclusion of a substance classified as a carcinogen and labelling disclosing such presence might not be acceptable to many users further downstream in many sectors that produce finished items, articles or components. Brand owners would likely put significant pressure on the upstream supply chain to replace $TiO_2$. This would also attract negative publicity and undue attention from the media, NGOs, professional users and the end consumer, even where the $TiO_2$ inhalation risk is zero, thus adding further pressure towards avoiding the use of $TiO_2$-based products even where such action is unwarranted. It would also be confusing for consumers (in this example, patients) to be informed that an ingredient used in so many different medicinal products is actually a carcinogen; similarly, presence of a carcinogen in clothing, underwear, sports clothing, etc. would raise alarm among consumers; and

- **Loss of market as a result of follow-up action by other jurisdictions**: similar regulatory action, in the form of hazard classification of $TiO_2$ as a Carc Cat 1B in other global regions could follow. Whilst this would allow for a more level playing field between EEA businesses and their non-EEA counterparts, both in the EEA and outside the EEA, it would further impact upon exports of EEA-made products to overseas markets.

Within the EEA, the increased regulatory burden could also drive consolidation in the industry, leading to less competition. SMEs would be most vulnerable in the face of such a trend. SMEs have limited capabilities (R&D, marketing, equipment) for protecting their workers and formulating feasible alternatives. Large companies producing a wide range of products would be better placed to cope with a loss of $TiO_2$-containing products compared to smaller businesses which concentrate on smaller product portfolios.

It is worth mentioning that there are specific applications of $TiO_2$ that would affect particular parts of the EEA. This is the case with ceramic pigments applications which are critical to the ceramic tiles industry. This industry is particularly strong, but also particularly dependent on $TiO_2$, in certain regions of Spain and Italy.

Finally, it should be understood that adverse impacts would not only affect the users of $TiO_2$ but would permeate the supply chain. Many examples can be provided here, e.g. DIY stores would lose a very significant proportion of their sales to DIY enthusiasts; packaging manufacturers would be forced to redesign packaging structures (which could impair established recycling processes); and manufacturers of laser printers would lose business as $TiO_2$-based toners would be removed from the market, and so forth.

## 5.4.4 Impacts on employment

It is not possible to quantify the potential impacts on employment in the EEA. However, it is clear that the number of workers potentially affected is particularly large. For instance, 110,000 workers are involved in the manufacture of paints and printing inks in the EEA and the number of workers involved in the application of paints (at construction sites, industrial production lines, etc.) is estimated to be around 1 million. In the plastics sector, 1.5 million workers are involved in the manufacture of plastics with an estimated 4.5 million workers handling and using the plastics further downstream. Based on the assumption that between 25% and 50% of EEA demand for $TiO_2$ may be lost following the adoption of the proposed classification, the number of jobs potentially lost could be of the order of tens to hundreds of thousands across the EEA.

## 5.5 Impacts on actors outside the titanium dioxide supply chains

Many industrial minerals contain $TiO_2$ as a natural impurity up to 4% by weight. This means that if $TiO_2$ were to be classified as Carc Cat 1B, all these industrial minerals would also have to be classified as Carc Cat 1B. This would significantly affect their handling, processing and use. Information available suggests that EEA markets for minerals of **a combined volume that exceeds 20 million tonnes per year and a combined market value of over €6.2 billion per year** would be impacted.

In addition, the proposed classification for $TiO_2$, if adopted, would set a precedent for the subsequent hazard classification of other poorly soluble powders regardless of each and every substance's human health carcinogenicity data. This (a) effectively renders the known alternative white pigments unsuitable as replacements for $TiO_2$, and (b) would make the manufacture, handling and use of such poorly soluble powders more costly and burdensome in the EEA, thus leading to further loss of competitiveness of EEA businesses along the relevant supply chains.

## 5.6 Impacts on consumers

Given that $TiO_2$ is present in a multitude of products that surround consumers in their daily lives, the potential impacts from the proposed classification would be significant and far-reaching:

- **Loss of consumer choice and reduction of product availability**: irrespective of where DIY paints, coatings, adhesives, sealants, artists' colours, detergents and other formulations are made, they would be removed from the consumer market to a very great extent. If one takes the NCS catalogue[74] as an example, out of the 1950 NCS colours in total only 125 are currently produced without $TiO_2$. The presence on the market of several other regulated products such as cosmetics, medical devices, toys, food and its packaging, pharmaceuticals – even textiles – would also be under threat. Many consumer articles (e.g. plastics, ceramics, glass, etc.) would become more costly to manufacture in the EEA with an impact on their pricing and therefore their production may be affected, scaled back, relocated outside the EEA or discontinued;

- **Increased costs and loss of performance**: as professional decorators and builders would be the only ones who would be legally permitted to work with $TiO_2$-based mixtures, consumers' costs would increase significantly, as they would have to pay more for materials and labour. By way of example, a member of the public may currently purchase the DIY paint needed for painting the walls and ceiling of a 120-130 $m^2$ apartment for, say, €50. A professional painter would charge more than €500, if not more. Reformulated products would be more costly and the reduced durability of painted/pigmented products would increase the maintenance and replacement costs for the individual consumer, the public sector, local authorities, housing associations and national health systems (due to the increase in the cost of pharmaceuticals);

- **Loss of satisfaction and welfare**: EEA consumers would face the loss of a great proportion of the colour palette, poorer aesthetics, duller home and office interiors and exteriors and the worsening of the quality, durability and performance in several products. For instance, $TiO_2$-free alternative DIY paints, coatings and construction products would have neither the durability nor the 'brilliant white' appearance of existing paints. Higher paint thicknesses would be required to achieve the same opacity / hide the paint that is being overcoated. In addition, paint would probably need to be applied in three or four layers, not the current one to two applications.

[74] NCS is an international colour system for design, architecture, production, research and education.

Painted walls would need to be refurbished more regularly due to damage and discolouration. Thus, painting jobs would take longer, would need to be done more often, and homeowners and tenants would be disappointed with the final results compared with what can currently be achieved with $TiO_2$-based paints. Due to the cost associated with hiring a professional decorator (see above), the standard of decoration in homes across the EEA would decline and this would mostly affect people on low incomes.

DIY work, use of artists' paints and recreational/school products are popular activities for the public, including children, across the EEA. The message that the classification of $TiO_2$ would convey is that such activities involving white and bright colours are potentially harmful and thus should be avoided. This would impact upon the creativity of children and adults alike.

Cosmetic formulations would also perform worse than consumers are used to. Sunscreens would require increased dosages of alternatives (e.g. ZnO) thus their formulations would cost more, and would be undesirably whiter on the skin. Without $TiO_2$ as a whitening pigment, make-up products and other skin cosmetics would be less efficient;

- **Adverse effects on public health**: elimination of $TiO_2$ from certain products could have adverse effects on public health. Examples of this include bright safety coatings for the road marking industry, display information on packaging that is important to the consumer (e.g. food ingredients, safety), UV filters used in the packaging of foodstuffs, cosmetics and light-sensitive pharmaceuticals, and intumescent products and coatings.

  Of particular importance is the use of $TiO_2$ as a UV filter in sunscreens. Under the Cosmetic Products Regulation there are only two mineral UV filters authorised: $TiO_2$ and ZnO. ZnO contributes mainly to UVA protection and has poorer performance against UVB radiation in contrast to $TiO_2$ which is a major contributor to high SPFs. Replacement of $TiO_2$ would mostly affect children's products and formulations for people with sensitive skin as the formulators would need to use chemical UV filters which are preferred for these sensitive groups. A lower level of skin protection from the sun, especially from a young age, could have a very detrimental health effect with the development of a higher number of skin cancer cases later in life.

## 5.7 Impacts on the environment

Restricting or making the continued use of $TiO_2$ more complex, burdensome and costly could have considerable adverse impacts on the environment. The key underlying reasons include:

- The large volumes of alternatives that would be required for the substitution of $TiO_2$ – the extraction of alternatives would be accompanied by an increased environmental footprint;

- The adverse environmental hazard profile of certain alternatives;

- The unrivalled efficiency of $TiO_2$ and the durability of $TiO_2$-containing products – use of alternatives would result in the generation of higher emissions, generation of larger volumes of waste and the need to re-paint/coat or replace articles more often;

- The unique catalytic and photocatalytic properties of $TiO_2$ which allow for environment-friendly and sustainable technologies for indoor and outdoor air cleaning;

- The contribution of $TiO_2$ to better energy efficiency and management in the fields of construction, photovoltaics and clothes washing (cf. use of detergents) and the role of white and bright paints and coatings in a lighter and brighter living and working environment;

- The likely increase of imports of finished $TiO_2$-containing articles into the EEA following the adoption of the proposed classification that would lead to increased releases of greenhouse gases from transportation; and

- The adverse impacts on the circular economy from making the re-use and recycling of materials such as plastics and packaging more difficult due to the presence of a carcinogen in concentrations greater than 0.1% by weight.

## 5.8 Potential benefits to health from the proposed classification for titanium dioxide

As a final point in this analysis, it is appropriate to compare the extensive adverse impacts from the adoption of the proposed classification against the likely benefits to human health that would arise.

With regard to worker exposure, it is worth noting that the concentrations where specifically rats begin to show symptoms in toxicological experiments are significantly higher than the occupational exposure limits currently in place under many national jurisdictions[75]. Therefore, the adoption of the proposed classification would not result in a discernible improvement to workers' health beyond what is achieved as a result of compliance with the existing legislative framework across the EEA. On the contrary, it would introduce the requirement to further minimise exposure (as substitution would not be feasible) and thus result in a significant and unnecessary increase in compliance costs.

Furthermore, as $TiO_2$ is typically embedded in matrices (in the wider sense of the term, i.e. paints, coatings, plastics, fibres, pigment formulations, ceramic articles, enamels, glass elastomers, etc.), any concern over worker exposure should be confined to the handling and use of the substance in its powder form, i.e. at the stage of manufacture and where $TiO_2$ is used as a powdered raw material. The proposed classification disregards this distinction and would apply regardless of the form in which $TiO_2$ is used or is present; as such, it would cause adverse effects on the EEA industry without any benefits to workers' health by virtue of the complete (or near complete) lack of inhalation exposure to $TiO_2$ when the substance is embedded in a matrix.

On the other hand, as regards consumer exposure to $TiO_2$, possibilities for inhalation exposure to $TiO_2$ are exceedingly limited:

- The substance is not available to consumers (or indeed professional users) in the form of powder with very few exceptions;

- Dusts that contain $TiO_2$ may also be generated during the removal and disposal of products that contain $TiO_2$, for example, when sanding old paint, but under those conditions $TiO_2$ is embedded into a matrix (e.g. within paint dust particles); and

- Inhalation to aerosols might theoretically also occur in some very limited cases (e.g. spraying of liquid products) but $TiO_2$ is again embedded into a matrix.

[75] Online searches confirm that OELs currently in force are 10 $mg/m^3$ or lower (see http://limitvalue.ifa.dguv.de/, accessed on 6 November 2016).

In all cases, inhalation exposure is infrequent and the levels of potential exposure are very much lower than those shown to generate a toxic response in rat experiments. On this basis, the proposed classification would not contribute towards the protection of consumer health.

Taking the above into account and considering the unintended adverse consequences that would arise for the supply chains of both $TiO_2$ and of other poorly soluble powders, as well as for consumers in the EEA, it can be concluded that the proposed classification would lead to a scale of socio-economic impacts entirely disproportionate to (a) any perceived risk to human health, and (b) any human health benefits that could theoretically be attributed to the proposed harmonised classification. Workplace measures dictated by the existing legislation on occupational safety and health can provide a more cost-efficient approach to risk reduction which would also fit in with the requirements and aspirations of the EU's 'better regulation' agenda.

# 6 Comparison of impacts for carcinogenicity classifications of category 1B and 2

## 6.1 Comparison of regulatory provisions

### 6.1.1 Provisions of EEA-wide regulatory framework

In preparation

### 6.1.2 Other provisions

In preparation

## 6.2 Impacts of a Carcinogenicity Category 2 classification of the manufacture and use of titanium dioxide

### 6.2.1 Impacts on the titanium dioxide supply chain

In preparation

## 6.3 Impacts on actors outside the titanium dioxide supply chains

In preparation

## 6.4 Impacts on consumers

In preparation

# 7 References


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# 8 Annex 1: Legislation of relevance to the proposed hazard classification

## 8.1 Legislative requirements

### 8.1.1 Classification and labelling

**Table 8–1: Key parameters of relevant legislation – Classification & labelling**

| Key parameters | | Details |
|---|---|---|
| Relevant legislative instruments | | Regulation 1272/2008/EC |
| Description of potential impact | | It would affect the labelling of $TiO_2$ as placed on the market and products containing $TiO_2$. It would require changes to labelling and SDS of mixtures. Packaging may need to be changed |
| Applicability (multiple sectors vs. single sector) | | Multiple |
| Potential adverse impact on:<br>- Industry (I)<br>- Professionals (P)<br>- Consumers (C) | | I/P |
| Driver of impact on society | Hazard | ✓ |
| | Risk (incl. availability of alternatives) | |
| Immediacy of potential impact | | As soon as harmonised classification is adopted and CLP Regulation is updated. This could take 18 months or more |
| Realistic potential for a restriction on the use of $TiO_2$ | | Possible but unlikely – but it would increase compliance costs |

### 8.1.2 Carcinogens at work

| Table 8–2: Key parameters of relevant legislation – Carcinogens at Work | | |
|---|---|---|
| **Key parameters** | | **Details** |
| Relevant legislative instruments | | Framework Directive - Council Directive 1989/391/EEC<br>Directive 2004/37/EC – Carcinogens and Mutagens at Work |
| Description of potential impact | | **Directive 2004/37/EC**: Employers should consider the use of alternative substances. If the substance cannot be replaced, closed systems should be used. Where this is not possible exposure should be reduced. Employers have to make certain information available to the competent authority if requested (activities, quantities, exposures, number of exposed workers, preventive measures) |
| Applicability (multiple sectors vs. single sector) | | Multiple (incl. manufacture) |
| Potential adverse impact on:<br>- Industry (I)<br>- Professionals (P)<br>- Consumers (C) | | I/P |
| Driver of impact on society | Hazard | |
| | Risk (incl. availability of alternatives) | ✓<br>If no alternatives available, use of $TiO_2$ could continue with improved worker health protection measures (as/where necessary) |
| Immediacy of potential impact | | As soon as harmonised classification is adopted and CLP Regulation is updated. Industry may have some time before the official adoption of the CLH to conduct risk assessments |
| Realistic potential for a restriction on the use of $TiO_2$ | | Only if technically feasible safer alternatives could be identified; this is not the case with $TiO_2$. However, adherence to requirements would be burdensome |

### 8.1.3 Waste

**Table 8–3: Key parameters of relevant legislation – Waste Framework**

| Key parameters | | Details |
|---|---|---|
| Relevant legislative instruments | | Directive 2008/98/EC<br>Regulation 1357/2014<br>Decision 2000/532/EC<br>Basel Convention |
| Description of potential impact | | The properties that render wastes hazardous are defined in Annex III to Directive 2008/98/EC. According to Annex III, when a waste contains a substance classified as a carcinogen under CLP and exceeds or equals one of the concentration limits shown in Table 6 to the Annex, the waste shall be classified as hazardous by HP 7.<br>A Carc. Cat 1B classification for $TiO_2$ would mean that a concentration that exceeds 0.1% would render any $TiO_2$-containing waste hazardous.<br>However, under Article 7(3) or Directive 2008/98/EC, where a Member State has evidence to show that specific waste that appears on the list as hazardous waste does not display any of the properties listed in Annex III, it may consider that waste as non-hazardous waste. The Member State shall notify the Commission of any such cases without delay and shall provide the Commission with the necessary evidence. In the light of notifications received, the list shall be reviewed in order to decide on its adaptation.<br>It is worth noting that in October 2016 the Industry, Research and Energy Committee (ITRE) of the European Parliament voted in favour of amendments to the Directive including the addition of the following to Article 9, "- *reduce the content of hazardous substances in materials and products by setting targets and encourage communication about hazardous substances in the supply chain*".<br><br>The transboundary movement of wastes that contain $TiO_2$ (if classified as Carc cat. 1B and falling under UN Class 9) would also become more complex under the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal |
| Applicability (multiple sectors vs. single sector) | | Multiple (incl. manufacture) |
| Potential adverse impact on:<br>- Industry (I)<br>- Professionals (P)<br>- Consumers (C) | | I/P/(C) |
| Driver of impact on society | Hazard | ✓ |
| | Risk (incl. availability of alternatives) | |
| Immediacy of potential impact | | As soon as an article or mixture becomes waste after the harmonised classification is adopted and CLP Regulation is updated |
| Realistic potential for a restriction on the use of $TiO_2$ | | Uncertain whether regulatory burden would be so high as to lead to $TiO_2$ being abandoned, especially if an exemption can be secured |

### 8.1.4 Industrial Emissions

| Table 8–4: Key parameters of relevant legislation – Industrial Emissions | | |
|---|---|---|
| **Key parameters** | | **Details** |
| Relevant legislative instruments | | Directive 2010/75/EC – Industrial Emissions (IPPC)<br>Regulation 1357/2014<br>Decision 2000/532/EC |
| Description of potential impact | | The list of polluting substances in Annex II includes "*Substances and mixtures which have been proved to possess carcinogenic or mutagenic properties or properties which may affect reproduction via the air*"<br>Member States shall ensure that the permit includes all measures necessary for compliance with the requirements of Articles 11 and 18. Those measures shall include among others:<br>(a) emission limit values for polluting substances listed in Annex II, and for other polluting substances, which are likely to be emitted from the installation concerned in significant quantities, having regard to their nature and their potential to transfer pollution from one medium to another |
| Applicability (multiple sectors vs. single sector) | | Multiple (incl. manufacture) |
| Potential adverse impact on:<br>- Industry (I)<br>- Professionals (P)<br>- Consumers (C) | | I |
| Driver of impact on society | Hazard | ✓ |
| | Risk (incl. availability of alternatives) | (✓) |
| Immediacy of potential impact | | Depends on speed at which installation emission permits are updated |
| Realistic potential for a restriction on the use of $TiO_2$ | | Unlikely |

### 8.1.5 REACH Regulation

| Table 8–5: Key parameters of relevant legislation – REACH Restrictions for consumer products | |
|---|---|
| **Key parameters** | **Details** |
| Relevant legislative instruments | Regulation 1907/2006/EC – Annex XVII |
| Description of potential impact | Annex XVII to Regulation (EC) No 1907/2006, in its entries 28 to 30, (semi-automatically) prohibits the sale to the general public of substances that are classified as CMR categories 1A or 1B or of mixtures containing them in a concentration above specified concentration limits. The substances concerned are listed in Appendices 1 to 6 to Annex XVII (through a Commission Regulation).<br><br>There is also a so-called 'fast-track' restriction procedure. Article 68(2) stipulates that for a substance on its own, in a preparation or in an article which meets the criteria for classification as carcinogenic, mutagenic or toxic to reproduction, category 1A or 1B, and could be used by consumers and for which restrictions to consumer use are proposed by the Commission, Annex XVII shall be amended in accordance with the procedure referred to in Article 133(4). Under this procedure, the European Commission has published a preliminary list of CMR Cat. 1A and 1B substances it proposes to restrict for use in textile consumer articles. The list contains 286 chemicals potentially present in textile articles and clothing, including phthalates, flame retardants and pigments. Following a period of consultation, the latest information suggests that the European Commission will aim to limit the scope to articles that may come into direct contact with the skin and include the substances from the list of the CMRs subject to the public consultation that are most relevant for such articles. A wider scope and inclusion of additional CMRs will be considered in a second step. The Commission is going to establish 4 lists of CMR 1A/1B substances (European Commission, 2016):<br>- Substances that are potentially present in clothing and are relevant for the restriction;<br>- Substances that are less likely to be present in clothing or less likely to be released, to be further assessed in a second step;<br>- Substances that are not present in clothing; and<br>- Substances that were not present in the initial list, suggested during the public consultation, to be further assessed in a second step.<br><br>Articles to be considered in a second step might include floor coverings, carpets, upholstery, clothing accessories and leather articles.<br><br>It is also understood that the Commission is looking to present a proposal to "fast-track" a restriction of CMR substances in construction products.<br><br>Restrictions under Annex XVII of REACH do not apply to (a) medicinal or veterinary products; (b) cosmetic products, (c) certain fuels and oil products; and (d) artists' paints covered by Regulation (EC) No 1272/2008 |
| Applicability (multiple sectors vs. single sector) | Multiple |
| Potential adverse impact on:<br>- Industry (I)<br>- Professionals (P)<br>- Consumers (C) | I/C |

**Table 8–5: Key parameters of relevant legislation – REACH Restrictions for consumer products**

| Key parameters | | Details |
|---|---|---|
| Driver of impact on society | Hazard | ✓ |
| | Risk (incl. availability of alternatives) | ✓<br>Lack of suitable alternatives, exposure conditions and socio-economic aspects may be considered in granting derogations |
| Immediacy of potential impact | | When substances receive a harmonised classification for the first time as CMR and are included in an ATP of the CLP Regulation, the European Commission prepares a draft amendment to include these substances in the Appendices of REACH Annex XVII. The amendment then has to be adopted in accordance with Article 68(2) of REACH, before the new substances are covered by entries 28-30.<br>(NB. inclusion to the list of 286 chemicals potentially present in textile articles and clothing may be avoided if exposure can be ruled out on technical grounds) |
| Realistic potential for a restriction on the use of $TiO_2$ | | In principle, yes, for the substance and its mixtures (>0.1% wt.) |

**Table 8–6: Key parameters of relevant legislation – REACH Restrictions for non-consumer products**

| Key parameters | | Details |
|---|---|---|
| Relevant legislative instruments | | Regulation 1907/2006/EC – Annex XVII |
| Description of potential impact | | Harmonised classification as Carc Cat 1B opens up possibilities for future proposals for restrictions to be submitted by Member States or ECHA (European Commission) following a Risk Management Options Assessment (RMOA) |
| Applicability (multiple sectors vs. single sector) | | Multiple |
| Potential adverse impact on:<br>- Industry (I)<br>- Professionals (P)<br>- Consumers (C) | | I/P/(C) |
| Driver of impact on society | Hazard | |
| | Risk (incl. availability of alternatives) | ✓<br>Restrictions proposals need to consider alternatives and balance of benefits vs. costs |
| Immediacy of potential impact | | Depends on timing of restrictions proposals; unclear as to whether interested Member States (or the Commission) would first wait for the official update to the CLP Regulation |
| Realistic potential for a restriction on the use of $TiO_2$ | | Possible, but not outright; industry input possible |

| Table 8–7: Key parameters of relevant legislation – REACH Authorisation | | |
|---|---|---|
| **Key parameters** | | **Details** |
| Relevant legislative instruments | | Regulation 1907/2006/EC – Annex XIV |
| Description of potential impact | | Possible future proposal for inclusion to Candidate List, following a Risk Management Options Assessment (RMOA). Potential subsequent listing in Annex XIV requires that continued use beyond the sunset date receives an Authorisation (unless use is specifically exempt) |
| Applicability (multiple sectors vs. single sector) | | Multiple |
| Potential adverse impact on:<br>- Industry (I)<br>- Professionals (P)<br>- Consumers (C) | | I/P/(C) |
| Driver of impact on society | Hazard | ✓<br>Listing on the Candidate List focuses on hazard profile |
| | Risk (incl. availability of alternatives) | ✓<br>Prioritisation, scope of Applications for Authorisation and outcome of applications will depend on existence of alternatives and balance of benefits vs. costs |
| Immediacy of potential impact | | Depends on timing of (a) SVHC proposal, (b) prioritisation of the substance into Annex XIV, (c) granted Sunset/latest Application Dates. The process does allow for a considerable amount of time for generating an Application. However, the mere listing of the substance on the Candidate List could result in negative perceptions along the supply chain |
| Realistic potential for a restriction on the use of $TiO_2$ | | Possible, but not outright; industry can make inputs to the process and has control over the contents of Applications |

### 8.1.6 Cosmetics

| Table 8–8: Key parameters of relevant legislation – Cosmetics | |
|---|---|
| **Key parameters** | **Details** |
| Relevant legislative instruments | Regulation 1223/2009/EC<br>SCCS Opinion SCCS/1516/13 (22 April 2014)<br>Regulation (EU) 2016/1143 |
| Description of potential impact | **Regulation 1223/2009/EC**: $TiO_2$ is included in three 'positive lists' of the Cosmetics Regulation:<br>- Annex IV (List of colourants allowed in cosmetic products), entry 143;<br>- Annex V (List of preservatives allowed in cosmetic products), entry 52; and<br>- Annex VI (List of UV filters allowed in cosmetic products) entries 27 and 27a with a concentration limit of 25%.<br>According to Article 15 substances classified as CMR substances of category 1A, 1B, or 2 under Part 3 of Annex IV to Regulation (EC) No 1272/2008 are banned for use in cosmetic products. Exceptions to this general rule are possible where all of the following are fulfilled:<br><u>Category 1A or 1B</u><br>- They comply with the food safety requirements as defined in Regulation (EC) No 178/2002;<br>- There are no suitable alternative substances available, as documented in an analysis of alternatives;<br>- The application is made for a particular use of the product category with a known exposure; and<br>- They have been evaluated and found safe by the Scientific Committee on Consumer Safety (SCCS) for use in cosmetic products. This must take into account exposure to these products, overall exposure from other sources and vulnerable population groups.<br><u>Category 2</u><br>- They have been evaluated and found safe by the Scientific Committee on Consumer Safety (SCCS) for use in cosmetic products. This must take into account exposure to these products, overall exposure from other sources and vulnerable population groups.<br><br>Specific labelling in order to avoid misuse of the cosmetic product shall be provided in accordance with Article 3 of this Regulation, taking into account possible risks linked to the presence of hazardous substances and the routes of exposure. The Commission shall amend the Annexes to this Regulation within 15 months of the inclusion of the substances concerned in Part 3 of Annex VI to Regulation (EC) No 1272/2008<br><br>**SCCS Opinions**: in April 2014, the SCCS concluded that the use of $TiO_2$ nanomaterials with the characteristics as indicated below, at a concentration up to 25% as a UV-filter in sunscreens, can be considered to not pose any risk of adverse effects in humans after application on healthy, intact or sunburnt skin. This, however, does not apply to applications that might lead to inhalation exposure to $TiO_2$ nanoparticles (such as powders or sprayable products) (Scientific Committee on Consumer Safety, 2014). As of August 2016, two further $TiO_2$-related opinions are pending, one on coatings for $TiO_2$ nano-forms used as a UV filter in dermally applied cosmetic products and another on $TiO_2$ nano-forms when used as UV-Filter in sunscreens and personal care spray products at a concentration up to 5.5% |

| Table 8–8: Key parameters of relevant legislation – Cosmetics | | |
|---|---|---|
| **Key parameters** | | **Details** |
| Applicability (multiple sectors vs. single sector) | | Single |
| Potential adverse impact on:<br>- Industry (I)<br>- Professionals (P)<br>- Consumers (C) | | I/P/C |
| Driver of impact on society | Hazard | |
| | Risk (incl. availability of alternatives) | ✓<br>SCCS needs to assess new information and decide on fate of substance |
| Immediacy of potential impact | | The immediate effect of the proposed classification would be an initiation of a risk management procedure that can result in a ban on the use of the substance. Timing of impacts would depend on timing of SCCS assessment and opinion. The SCCS risk assessment is itself based on the submitted evidence by the cosmetic industry. Preparing of a dossier to support a request for an exemption can only be prepared after the RAC opinion on the CLH proposal. In principle, the SCCS process can be long with several iterations (and the opinion may become available after the date of entry into application of the harmonised CMR classification under the CLP Regulation), however $TiO_2$ is a substance with a large body of scientific and toxicological evidence that is familiar to the Committee |
| Realistic potential for a restriction on the use of $TiO_2$ | | Probable – industry needs to demonstrate that exposure of consumers is sufficiently low and provide information on alternatives (although some/much of it is already available from previous regulatory defence efforts) |

### 8.1.7 Toy Safety

**Table 8–9: Key parameters of relevant legislation – Toy Safety**

| Key parameters | | Details |
|---|---|---|
| Relevant legislative instruments | | Directive 2009/48/EC<br>European Standard EN71-3:2013 |
| Description of potential impact | | **Directive 2009/48/EC**: CMR substances shall not be used in toys but exceptions exist:<br>(a) these substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in the Community legal acts referred to in Section 2 of Appendix B for the classification of mixtures containing these substances;<br>(b) these substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as specified in the first subparagraph of Article 10(2);<br>(c) a decision in accordance with Article 46(3) has been taken to permit the substance or mixture and its use, and the substance or mixture and its permitted uses have been listed in Appendix A.<br>That decision may be taken if the following conditions are met:<br>(i) the use of the substance or mixture has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure;<br>(ii) there are no suitable alternative substances or mixtures available, as documented in an analysis of alternatives; and<br>(iii) the substance or mixture is not prohibited for use in consumer articles under Regulation (EC) No 1907/2006.<br>A Carc. Cat 1B harmonised classification would affect the use of the substance in toys, including in toy cosmetics – see Cosmetics Regulation<br><br>**EN71 Standard**: sets out requirements toys must meet in order to be sold in the EU. Included in these requirements are extraction limits for metals in toys and toy components, but extraction limits are not provided for individual raw materials used in the manufacturing of toys or their components, such as titanium dioxide. The manufacturer of any toy product has the responsibility to ensure that the finished article complies with the Standard including the migration limits relevant to the intended condition of use. The standard defines three different toy categories, and migration limits for 19 elements are specified for each category. Titanium is not listed.<br><br>Note that children's paints fall under toys (while artists' paints fall under paints and coatings) |
| Applicability (multiple sectors vs. single sector) | | Multiple |
| Potential adverse impact on:<br>- Industry (I)<br>- Professionals (P)<br>- Consumers (C) | | I/C |
| Driver of impact on society | Hazard | |
| | Risk (incl. availability of alternatives) | ✓<br>The Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) needs to assess new information and decide on fate of substance |
| Immediacy of potential impact | | The Commission shall mandate the relevant Scientific Committee to re-evaluate those substances or mixtures as soon as safety concerns arise and |

| Table 8–9: Key parameters of relevant legislation – Toy Safety | |
|---|---|
| **Key parameters** | **Details** |
| | at the latest every five years from the date that a decision in accordance with Article 46(3) was taken.<br>SCHEER must provide their opinion on the use of CMR in toys following the same rules of procedure as the SCCS (in cosmetics document). Under Article 46(3) the formal decision on the authorisation of CMRs in toys is taken by the Commission after they have been evaluated by the relevant scientific committee. These measures are adopted in accordance with the regulatory procedure with scrutiny referred to in Article 47(2). The timeframe for SCHEER opinion is decided upon by the Chairman of the Committee and so is not a standard.<br><br>The EN Standard might take some time before it is amended to potentially include $TiO_2$ |
| Realistic potential for a restriction on the use of $TiO_2$ | Possible – industry needs to demonstrate that exposure of children is sufficiently low/zero |

## 8.1.8 Food contact materials

| Table 8–10: Key parameters of relevant legislation – Food Contact Materials | |
|---|---|
| **Key parameters** | **Details** |
| Relevant legislative instruments | Framework Regulation (EC) No 1935/2004 – Food Contact materials<br>Regulation (EC) No 2023/2006 - Good Manufacturing Practice for Materials and Articles intended to come into Contact with Food<br>Plastics - Regulation EU/10/2011 - Plastics in Materials and Articles<br>Plastics - Regulation 282/2008/EC - Recycled Plastic Materials and Articles<br>Active and Intelligent Materials - Regulation (EC) No 450/2009 - Active and intelligent materials and articles |
| Description of potential impact | **Framework Regulation 1935/2004**: according to its Article 3, materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could: (a) endanger human health; or (b) bring about an unacceptable change in the composition of the food; or (c) bring about a deterioration in the organoleptic characteristics thereof.<br>For the groups of materials and articles listed in Annex I and, where appropriate, combinations of those materials and articles or recycled materials and articles used in the manufacture of those materials and articles, specific measures may be adopted or amended in accordance with the procedure referred to in Article 23(2). Annex I includes the following materials and articles (in bold those potentially relevant to $TiO_2$):<br><br>1. Active and intelligent materials and articles<br>**2. Adhesives**<br>**3. Ceramics**<br>4. Cork<br>**5. Rubbers**<br>**6. Glass**<br>7. Ion-exchange resins<br>8. Metals and alloys<br>**9. Paper and board**<br>**10. Plastics**<br>**11. Printing inks**<br>12. Regenerated cellulose<br>**13. Silicones**<br>**14. Textiles**<br>15**. Varnishes and coatings** (e.g. can coatings)<br>16. Waxes<br>17. Wood<br><br>**Regulation 2023/2006 (GMP)**: this Regulation lays down rules on good manufacturing practice for materials and articles intended to come into contact with food. It introduces general rules for all business operators in the supply chain, and specifies that quality assurance and control systems are established and implemented. All printing inks intended for use on food packaging are in the scope of this Regulation. Its Annex introduces detailed rules, which relate to processes involving the application of printing inks to the non-food contact side of a material or article. |

| Table 8–10: Key parameters of relevant legislation – Food Contact Materials | |
|---|---|
| **Key parameters** | **Details** |
| | **Regulation EU/10/2011 (Plastics Regulation incorporating the Union list)**: coated and printed plastic materials and articles are covered by the scope of the Plastics Regulation. Plastics held together by adhesives are also covered by its scope. However, substances used only in **printing inks, adhesives and coatings** are not included in the Union list because these layers are not subject to the compositional requirements of the Plastics Regulation. The only exceptions are substances used in coatings which form gaskets in closures and in caps. The requirements for printing inks, adhesives and coatings are intended to be set out in separate specific Union measures. Until such measures are adopted, they are covered by national law[76]. If a substance used in a coating, a printing ink or an adhesive is listed in the Union list, the final material or article has to comply with the migration limit of this substance, even if the substance is used in the coating, printing ink or adhesive only.<br>Even though **colourants** fall under the definition of additives, they are not covered by the Union list of substances. Colourants used in plastics are covered by national measures. Certain colourants, in particular, cadmium pigments, are regulated by EU legislation on chemicals and listed in Annex XVII of the REACH Regulation. They have to comply with the general safety requirements of Article 3 of the Framework Regulation (EC) No 1935/2004 and are subject to risk assessment in line with Article 19 of the Plastics Regulation.<br>Recital 27 of the Plastics Regulation indicates that CMR substances should not be used in food contact materials or articles without previous authorisation and should therefore not be covered by the functional barrier concept; authorised substances are included in the Union list.<br>$TiO_2$ is currently an authorised substance, under entries 610, 805 and 873 in Table 1 of Annex I, for use as an additive or polymer production aid. No $TiO_2$-specific migration limits are provided hence, in accordance with Article 11, a generic specific migration limit of 60 mg/kg applies and in accordance with Article 12 an overall migration limit for plastic materials of 10 milligrams of total constituents released per $dm^2$ of food contact surface ($mg/dm^2$) applies.<br>Article 15 (3) states that when new scientific data are available the declaration of compliance shall be renewed; however the new classification (based on pre-existing toxicological data) may not qualify as 'new scientific data'.<br><br>**Regulation 282/2008/EC**: only authorised monomers and additives should be added to the recycled plastics and their migration limits should also be respected by recycled plastic food contact materials. Use of $TiO_2$ in recycled plastic would be unlikely to be authorised, if no longer on the Union List.<br><br>**Regulation (EC) No 450/2009**: the Regulation defines active materials and articles as those which may deliberately incorporate substances, which are intended to be released into food. On the other hand, intelligent packaging systems provide the user with information on the conditions of the food and should not release their constituents into the food. CMR substances cannot be used in such materials and packaging even if not in direct contact |

76 A brochure by Chemours provides a useful overview of relevant national legislation (Chemours, 2016c).

| Table 8–10: Key parameters of relevant legislation – Food Contact Materials | | |
|---|---|---|
| **Key parameters** | | **Details** |
| | | with food or the environment surrounding the food and even if they are separated from the food by a functional barrier.<br><br>**Notes**: in relation to ceramic materials used for food contact, Directive 84/500/EEC (as amended by Directive 2005/31/EC) applies. However, this specifically regulates the migration of lead and cadmium from ceramic food contact materials and does not include provisions relevant to carcinogens in general. Consultation suggests that this Directive may be subject to revision and replacement by a Regulation in the future.<br><br>Another food contact material that is regulated in the EU is regenerated cellulose film intended to come into contact with foodstuffs which is subject to provisions of Directive 2007/42/EC. According to Article 3, regenerated cellulose films shall be manufactured using only substances or groups of substances listed in Annex II to the Directive subject to the restrictions set out therein. Substances other than those listed in Annex II may be used when these substances are employed as colouring matter (dyes and pigments) or as adhesives, provided that there is no trace of migration of the substances into or onto foodstuffs, detectable by a validated method. Consultation and research has not confirmed the relevance of these food contact materials to $TiO_2$ |
| Applicability (multiple sectors vs. single sector) | | Multiple |
| Potential adverse impact on:<br>- Industry (I)<br>- Professionals (P)<br>- Consumers (C) | | I/C |
| Driver of impact on society | Hazard | |
| | Risk (incl. availability of alternatives) | ✓<br>The European Food Safety Agency (EFSA) needs to assess new information and decide on whether to authorise the continued use of the substance |
| Immediacy of potential impact | | Classification of $TiO_2$ as Carc Cat 1B may trigger a re-evaluation of an authorisation. Such re-evaluation may be initiated under Article 11(5) or Article 12 (1) of the Framework Regulation by the business operator using an authorised substance, the Commission, a Member State or the European Food Safety Authority under Article 12 (3). In this context, it should be stressed that Article 11(5) of the Regulation obliges a business operator using an authorised substance or materials or articles containing the authorised substance to "*immediately inform the Commission of any new scientific or technical information, which might affect the safety assessment of the authorised substance in relation to human health*" |
| Realistic potential for a restriction on the use of $TiO_2$ | | Unclear – inhalation exposure would appear to be irrelevant.<br>It is understood that national legislation may be in place (for instance on paper, board, coatings) and action may be taken under national rules. Council of Europe Resolutions and EuPIA's Exclusion Policy would also apply (see Sections 7.2.1 and 7.2.2 below) |

### 8.1.9 Food and feed additives

**Table 8–11: Key parameters of relevant legislation – Food Additives**

| Key parameters | | Details |
|---|---|---|
| Relevant legislative instruments | | Regulation 1333/2008<br>Regulation 1129/2011<br>Regulation 738/2013<br>Regulation 231/2102 |
| Description of potential impact | | **Regulation 1333/2008**: Permitted additives can be found within the Annexes of the Regulation. Notably, only food colours listed in Annex II to this Regulation may be used for the purpose of decorative colouring of eggshells and for the stamping of eggshells. The last Commission Regulation to introduce new food categories where use of $TiO_2$ (E171) is permitted was new food categories where E171 is allowed was Commission Regulation (EU) No 738/2013. This notes that $TiO_2$ is not liable to have an effect on human health, it is not necessary to seek the opinion of the European Food Safety Authority.<br>Nevertheless, $TiO_2$ has been re-evaluated by EFSA in accordance with Commission Regulation (EU) No 257/2010 (European Food Safety Authority, 2016). The conclusion has been that available toxicological data do not indicate adverse effects via oral ingestion. While EFSA was unable to set an Acceptable Daily Intake (ADI) for$TiO_2$ because of data limitations, using the margin of safety approach, they concluded that dietary exposure does not pose health concerns. The experts highlighted, however, the need for new research to fill data gaps on potential effects of titanium dioxide on the reproductive system (European Food Safety Authority, 2016b).<br>A Carc. Cat. 1B classification may lead to the review of the evaluation and potentially the removal from the list of approved food additives or the setting of a stringent ADI.<br><br>**Regulations 1129/2011 & 738/2013**: in the EU, $TiO_2$ (E171) is listed in Annex II of Regulation 1333/2008/EC as a permitted colour in foodstuff at *quantum satis* and it is presumed to be safe<br><br>**Regulation 231/2102**: this Regulation specifies purity criteria |
| Applicability (multiple sectors vs. single sector) | | Single (but with indirect links to cosmetics and pharmaceuticals) |
| Potential adverse impact on:<br>- Industry (I)<br>- Professionals (P)<br>- Consumers (C) | | I/C |
| Driver of impact on society | Hazard | |
| | Risk (incl. availability of alternatives) | ✓ |
| Immediacy of potential impact | | Timing would depend on the completion of the review of the new scientific data |
| Realistic potential for a restriction on the use of $TiO_2$ | | Possible but unlikely – only calcium carbonate (chalk, E170) is an approved white colourant and it cannot meet the performance of $TiO_2$. Also, inhalation exposure risks are clearly limited |

| Table 8–12: Key parameters of relevant legislation – Additives in Animal Feed Additives | | |
|---|---|---|
| **Key parameters** | | **Details** |
| Relevant legislative instruments | | Regulation 1831/2003 |
| Description of potential impact | | $TiO_2$ is present in Annex I under Category 2 (colourants), Functional Group a with the entry: "*Titanium dioxide (anatase & rutile structure) as colouring agents authorised for colouring foodstuffs by Community rules [Dogs; Cats]*" |
| Applicability (multiple sectors vs. single sector) | | Single |
| Potential adverse impact on:<br>- Industry (I)<br>- Professionals (P)<br>- Consumers (C) | | I/C |
| Driver of impact on society | Hazard | |
| | Risk (incl. availability of alternatives) | ✓ |
| Immediacy of potential impact | | Timing would depend on the completion of the review of the new scientific data for food additives |
| Realistic potential for a restriction on the use of $TiO_2$ | | Possible but unlikely – no other white pigment appears to be listed |

## 8.1.10 Colouring matters for medicinal products

| Table 8–13: Key parameters of relevant legislation – Colouring matters for Medicinal Products | |
|---|---|
| **Key parameters** | **Details** |
| Relevant legislative instruments | Directive 2001/83/EC<br>Regulation 1901/2006<br>Directive 2009/35/EC<br>Regulation 1333/2008 (see above) |
| Description of potential impact | **Directive 2001/83/EC**: It is a legal requirement according to Directive 2001/83/EC on the Community code relating to medicinal products for human use as amended that excipients which are used must comply with the relevant European Pharmacopoeia (PhEur) monograph.<br><br>**Regulation 1901/2006**: Regulation 1901/2006 on medicinal products for paediatric use includes a Commission Statement with which the Commission requested the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency to draw up an opinion on the use of these categories of substances as excipients of medicinal products for human use, on the basis of Articles 5(3) and 57(1)(p) of Regulation (EC) No 726/2004.<br>The CHMP delivered its opinion in October 2007; this states, "*In the event that CMR toxicity has been identified for an excipient, the rule is to avoid and replace this excipient. In the rare cases where this would not be possible, the use of such CMR excipients in a medicinal product would only be considered after careful evaluation of the benefits of the medicinal product in the target patient population versus the potential risks (…) any risk identified for an excipient and in particular a CMR substance, would be acceptable only on condition that this excipient cannot be substituted with a safer available alternative, or that the toxicological effects in animal models are considered not relevant for humans (e.g. species specific, very large safety ratio), or where the overall benefit/risk balance for the product outweighs the safety concern with the product. Overall, the use of any excipient with a known potential toxicity, and which could not be avoided or replaced, would only be authorised if the safety profile was considered to be clinically acceptable in the conditions of use, taking into account the duration of treatment, the sensitivity of the target population and the benefit-risk ratio for the particular therapeutic indication*" (European Medicines Agency, 2007)[77].<br>**Directive 2009/35/EC**: Directive 2009/35/EC gives specifications on colouring matters for medicinal products. Only the colouring matters listed in Annex II to Regulation 1333/2008 may be used to colour medicinal products for human and veterinary use. A Carc. Cat 1B classification would result in the review and potential de-authorisation of $TiO_2$ |



[77] Interestingly, the opinion also states, "*For non-genotoxic rodent carcinogens (which are known to be around 50% of molecules tested in life span rodent carcinogenicity studies) only those for which the mechanism of tumorigenesis (including the route of administration) has been identified as relevant for man, should be carefully considered before a decision is taken to include them in a pharmaceutical product. It is important to highlight that many of the substances positive in the carcinogenicity studies are specific rodent carcinogens with no relevance to humans. In addition, the 'safety ratios' (e.g. the relation between the exposures that were tumorigenic in rodents and those to be reached in patients) should be taken into consideration*" (European Medicines Agency, 2007).

| Table 8–13: Key parameters of relevant legislation – Colouring matters for Medicinal Products | | |
|---|---|---|
| **Key parameters** | | **Details** |
| Applicability (multiple sectors vs. single sector) | | Single |
| Potential adverse impact on:<br>- Industry (I)<br>- Professionals (P)<br>- Consumers (C) | | I/C |
| Driver of impact on society | Hazard | |
| | Risk (incl. availability of alternatives) | ✓ |
| Immediacy of potential impact | | Depends on the type of variation required for the existing Authorisation dossiers (European Commission, 2013):<br>- A replacement of the excipient would require a variation Type IAIN which requires immediate notification;<br>- Qualitative or quantitative changes in one or more excipients that may have a significant impact on the safety, quality or efficacy of the medicinal product requires a major variation Type II; or<br>- A reduction of the shelf life of the finished product as packaged for sale would require a variation Type IAIN which requires immediate notification.<br>It would also be dependent on food additives legislation. Timing would depend on the completion of the review of the new scientific data for a removal of $TiO_2$ from the Annex of Regulation 1333/2008 |
| Realistic potential for a restriction on the use of $TiO_2$ | | Possible but might be unlikely – only calcium carbonate (chalk, E170) is an approved white colourant and it cannot meet the performance of $TiO_2$. Also, inhalation exposure risks are clearly limited (while calcium from $CaCO_3$ would be absorbed by ingestion). |

## 8.1.11 Medical devices

Table 8–14: Key parameters of relevant legislation – Medical Devices

| Key parameters | | Details |
|---|---|---|
| Relevant legislative instruments | | Directive 93/42/EEC (amendment agreed in June 2016) |
| Description of potential impact | | The endorsed text for the new medical devices Regulation includes a 0.1% concentration limit for category 1A and 1B CMRs and endocrine disrupting chemicals (EDCs) in devices that:<br>- Are invasive and come into direct contact with the body; or<br>- (Re)administer, transport or store medicines, body liquids or other substances, including gases, to/from the body.<br>Devices would only be permitted to contain such substances, at a level above this limit, if a justification is provided. This would have to be based on:<br>- An analysis and estimation of potential patient or user exposure;<br>- An analysis of alternative substances, materials or designs;<br>- Arguments to justify why any possible substitutes or design changes are "inappropriate to maintain the functionality, performance and the benefit-risk ratios of the product"; and<br>- Where available, the latest scientific committee guidelines |
| Applicability (multiple sectors vs. single sector) | | Multiple |
| Potential adverse impact on:<br>- Industry (I)<br>- Professionals (P)<br>- Consumers (C) | | I/(C) |
| Driver of impact on society | Hazard | |
| | Risk (incl. availability of alternatives) | ✓ |
| Immediacy of potential impact | | As soon as harmonised classification is adopted and CLP Regulation is updated, unless justification for ongoing use is submitted (timing uncertain) |
| Realistic potential for a restriction on the use of $TiO_2$ | | Possible but unlikely – lack of alternatives and inhalation exposure risks are clearly limited |

## 8.1.12 Construction products

| Table 8–15: Key parameters of relevant legislation – Construction products | |
|---|---|
| **Key parameters** | **Details** |
| Relevant legislative instruments | Construction Products Regulation (EU) 305/2011 |
| Description of potential impact | In line with Article 4(1) of the Regulation, the manufacturer must draw up a Declaration of Performance (DoP) when placing on the market a construction product which is covered by a harmonised standard, or for which a European Technical Assessment has been issued. A copy of the DoP must be further supplied with every product which is made available on the market.<br>The Regulation also provides in Article 6(5) that the information referred to in Article 31 (requirements for safety data sheets), or Article 33 (duty to communicate information on substances in articles), of the REACH Regulation shall be provided together with the DoP. This information therefore accompanies the construction product in all steps of the supply chain till the final end user (contractor, worker and consumer).<br>Article 3(3) also allows the Commission to decide for which essential characteristics manufacturers shall declare the performance of the product and the Commission can also determine threshold levels. This is not applied today, but could be in the future. Combined with Article 6(5), this may have the effect to exclude some products from the market.<br>Its recital No. 25 also stresses that "*the specific need for information on the content of hazardous substances in construction products should be further investigated*", which may influence any future revision of the Regulation.<br>The classification of $TiO_2$ as a Carc. Cat. 1B would mean that safety data sheets would need to be supplied for mixtures that contain more than 0.1% $TiO_2$. Also, if the substance is named as a Substance of Very High Concern or ends up in Annex XIV, information will also need to be provided to users of construction articles that contain $TiO_2$ in a concentration above 0.1% by weight |
| Applicability (multiple sectors vs. single sector) | Construction products |
| Potential adverse impact on:<br>- Industry (I)<br>- Professionals (P)<br>- Consumers (C) | I/(P)/(C) |
| Driver of impact on society: Hazard | ✓ |
| Driver of impact on society: Risk (incl. availability of alternatives) | |
| Immediacy of potential impact | As soon as harmonised classification is adopted and CLP Regulation is updated (mixtures) and after the adoption of $TiO_2$ as a SVHC (articles). Any future extension of the REACH Regulation to cover new substances will automatically apply also to the obligation of construction products manufacturers to disseminate the relevant information, thus keeping pace with scientific progress |
| Realistic potential for a restriction on the use of $TiO_2$ | Unlikely |

### 8.1.13 Biocides

**Table 8–16: Key parameters of relevant legislation – Biocides**

| Key parameters | | Details |
|---|---|---|
| Relevant legislative instruments | | Regulation EU/528/2012 |
| Description of potential impact | | Active substances classified as Carc. Cat 1B shall not be authorised unless they meet one of the criteria set out in Article 5 (2): (a) the risk to humans, animals or the environment is negligible; (b) the active substance is essential to prevent or control a serious danger to human health, animal health or the environment; or (c) not approving the active substance would have a disproportionate negative impact on society.<br>Article 19(4) of the Regulation states that a biocidal product shall not be authorised for use by the general public where:<br>(a) it meets the criteria according to Directive 1999/45/EC for classification as:<br>— toxic or very toxic,<br>— a category 1 or 2 carcinogen (now Carc Cat 1A/1B),<br>— a category 1 or 2 mutagen (now Muta Cat 1A/1B), or<br>— toxic for reproduction category 1 or 2 (now Repro Cat 1A/1B),<br>unless it would result in disproportionate negative impacts for society when compared to the risks to human health |
| Applicability (multiple sectors vs. single sector) | | Multiple |
| Potential adverse impact on:<br>- Industry (I)<br>- Professionals (P)<br>- Consumers (C) | | I/C |
| Driver of impact on society | Hazard | |
| | Risk (incl. availability of alternatives) | ✓ |
| Immediacy of potential impact | | The Biocidal Products Committee (BPC) has to make their decision 270 days after the receipt of the eMSCA evaluation |
| Realistic potential for a restriction on the use of $TiO_2$ | | Unlikely – $TiO_2$ is not a biocide itself; lack of alternatives and inhalation exposure risks are clearly limited |

## 8.1.14 Electrical and electronic equipment

| Table 8–17: Key parameters of relevant legislation – WEEE and RoHS | | |
|---|---|---|
| **Key parameters** | | **Details** |
| Relevant legislative instruments | | Directive 2011/65/EU<br>Directive 2012/19/EU |
| Description of potential impact | | The RoHS Directive suggests that as soon as scientific evidence is available, and taking into account the precautionary principle, the restriction of other hazardous substances (including nanomaterials)) and their substitution by more environmentally friendly alternatives which ensure at least the same level of protection of consumers should be examined.<br>Following a Carc. Cat 1B classification for $TiO_2$, particularly, if regulatory activities ensue under the REACH Regulation, there may be a possibility that a Member State may submit a proposal for including the substance in Annex II of the RoHS Directive |
| Applicability (multiple sectors vs. single sector) | | Multiple |
| Potential adverse impact on:<br>- Industry (I)<br>- Professionals (P)<br>- Consumers (C) | | I/C |
| Driver of impact on society | Hazard | |
| | Risk (incl. availability of alternatives) | ✓ |
| Immediacy of potential impact | | Timing would depend on how soon a proposal for an Annex II entry is submitted by a Member State |
| Realistic potential for a restriction on the use of $TiO_2$ | | Possible but inhalation exposure risks are clearly limited |

## 8.1.15 Tobacco products

| Table 8–18: Key parameters of relevant legislation – Tobacco products | | |
|---|---|---|
| **Key parameters** | | **Details** |
| Relevant legislative instruments | | Directive 2014/40/EU<br>Decision (EU) 2016/787 |
| Description of potential impact | | **Directive 2014/40/EU**: the Directive sets out additional enhanced reporting obligations for additives included in a priority list in order to assess, inter alia their toxicity, addictiveness and CMR properties, including in combusted form. Manufacturers or importers need to prepare reports on the available scientific literature on the effects of each listed additive. The information received shall assist the Commission and Member States in taking the decisions pursuant to Article 7, including a prohibition on the marketing of tobacco products containing additives that have CMR properties in unburnt form or increase the CMR properties of a tobacco product at the stage of consumption to a significant or measureable degree.<br><br>**Decision (EU) 2016/787**: the Decision set out the priority list of additives and includes $TiO_2$ into the list. The Decision applies from 1 January 2017 and manufacturers and importers will be required to submit enhanced reports in respect of the first set of identified additives by 1 July 2018.<br><br>It can be envisaged that the proposal for a harmonised classification of Carc Cat 1B would need to be taken into account in the generation of the enhanced report for the $TiO_2$ and might have an indirect role in making the substance more susceptible to future regulatory action (a ban) |
| Applicability (multiple sectors vs. single sector) | | Single |
| Potential adverse impact on:<br>- Industry (I)<br>- Professionals (P)<br>- Consumers (C) | | I/C |
| Driver of impact on society | Hazard | |
| | Risk (incl. availability of alternatives) | ✓<br>Enhanced report will need to look into both hazard and exposure to estimate the risk of tobacco smokers |
| Immediacy of potential impact | | By 1 January 2018 the enhanced report will need to be submitted; the CLH process will not have finished before then |
| Realistic potential for a restriction on the use of $TiO_2$ | | Only a potential indirect effect |

## 8.1.16 Important notes and summary

It is important to point out that several pieces of relevant legislation would certainly impose a regulatory burden on the $TiO_2$ supply chain and the outcome of such efforts made cannot be predicted with any certainty. Possible regulatory consequences include:

- **REACH Authorisation**: as noted above, were $TiO_2$ to be added to the Annex XIV Authorisation List, barring any exemptions secured by interested parties, a very significant number of companies would be required to secure an Authorisation or at least would need to be covered by an Authorisation held upstream in their supply chain for their specific use(s) of $TiO_2$. The effort required for a successful Application for Authorisation would be significant even if applicants have strong arguments in relation to the lack of feasible alternatives and the socio-economic benefits from continued use. The outcome of these applications cannot be predicted;

- **Need for quick action to secure derogations**: there are application areas where a Carc Cat 1B hazard classification would cause major problems but where rapid, successful action by interested parties could mitigate impacts. Typical examples are the cosmetics, toys, biocidal products, food, pharmaceuticals applications where a risk assessment would need to be undertaken to take into account the new classification. For instance:

  - For cosmetics, securing derogations could be a challenging task as there are only 15 months between the CLH being added to Annex VI of the CLP and the Cosmetics Regulation annexes being updated with a review of the existing authorisations for $TiO_2$ (a preservative, colourant and UV filter) by the SCCS. Therefore, the time for obtaining an SCCS opinion on safe use is very short. It is understood that it can take up to 2 years to prepare an SCCS dossier. If cosmetics companies would be interested in safeguarding the use of $TiO_2$, they would need to prepare a dossier for the SCCS opinion as soon as possible;

  - As regards biocides, any active substance must be approved at Union level if it is to be placed on the market and $TiO_2$ (more accurately, its reaction mass with silver chloride) would have to go through this process anyway. The problem lies in that Carc Cat 1A and 1B classifications are exclusion criteria for active substances and biocidal products. It is possible to get around this by proving that the risk to humans is negligible and there is no alternative. This would require significant effort and coordination by industry and the Biocidal Products Committee would have to make their decision 270 days after the receipt of the eMSCA evaluation.

It can also be envisaged that if the use of $TiO_2$ was severely restricted, the substance would likely be added to Annex I of Regulation (EU) No 649/2012 on export and import of hazardous chemicals. Given its CLH harmonised classification, export of the substance would be hindered.

Finally, it has been suggested by some stakeholders that the proposed classification would bring $TiO_2$ within the scope of the Seveso III Directive (Directive 2012/18/EU). Part 2 of Annex I to the Directive includes named dangerous substances and entry 33 within names specific carcinogens. However, the provisions for amendment of the Directive (Article 25) does not prescribe the possibility of amending Annex I. In any case, carcinogens are not the main focus of the Directive and only by specifically naming $TiO_2$ under Part 2 of Annex I could the Directive become applicable to the substance under the proposed hazard classification.

Finally, a further table, **Table 8–19**, presents the applicability of the different pieces of legislation to the general $TiO_2$ application areas identified earlier in this document. Red colour indicates relevance, while orange colour indicates potential relevance (if certain conditions are met) or specific areas where particularities exist; for instance, the CLP Regulation and the Authorisation provisions of the REACH Regulation apply to chemical inputs to food preparation and pharmaceuticals manufacture but not to the marketing and use of foodstuffs or medicines.

| Table 8–19: Relevance of different regulatory instruments to the applications of $TiO_2$ following a harmonised classification of Carc Cat 1B | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Relevant legislation** | **Type** | **Number** | **Manufacture and import of $TiO_2$** | **Paints** | **Plastics** | **Paper** | **Inks** | **Construction materials** | **Fibres** | **Catalysts** | **Food, feed and food contact materials** | **Pharmaceuticals** | **Cosmetics** | **Elastomers** | **Pigment manufacture** | **Ceramics** | **Glass** | **Medical devices** | **Detergents** | **Biocides** |
| CLP | Regulation | 1272/2008/EC | | | | | | | | | | | | | | | | | | |
| Carcinogens and Mutagens at Work | Directive | 1989/391/EEC | | | | | | | | | | | | | | | | | | |
| | Directive | 2004/37/EC | | | | | | | | | | | | | | | | | | |
| Waste Framework | Directive | 2008/98/EC | | | | | | | | | | | | | | | | | | |
| | Regulation | 1357/2014 | | | | | | | | | | | | | | | | | | |
| | Decision | 2000/532/EC | | | | | | | | | | | | | | | | | | |
| Industrial Emissions | Directive | 2010/75/EC | | | | | | | | | | | | | | | | | | |
| REACH | Regulation Annex XVII | 1907/2006/EC | | | | | | | | | | | | | | | | | | |
| | Regulation Annex XIV | 1907/2006/EC | | | | | | | | | | | | | | | | | | |
| Cosmetics | Regulation | 1223/2009/EC | | | | | | | | | | | | | | | | | | |
| | Regulation | (EU) 2016/1143 | | | | | | | | | | | | | | | | | | |
| Toy Safety | Directive | 2009/48/EC | | | | | | | | | | | | | | | | | | |
| | European Standard | EN71-3:2013 | | | | | | | | | | | | | | | | | | |

**Table 8–19: Relevance of different regulatory instruments to the applications of $TiO_2$ following a harmonised classification of Carc Cat 1B**

| Relevant legislation | Type | Number | Manufacture and import of $TiO_2$ | Paints | Plastics | Paper | Inks | Construction materials | Fibres | Catalysts | Food, feed and food contact materials | Pharmaceuticals | Cosmetics | Elastomers | Pigment manufacture | Ceramics | Glass | Medical devices | Detergents | Biocides |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Food Contact Materials | Regulation on Food Contact Materials | 1935/2004 | | | | | | | | | | | | | | | | | | |
| | Regulation Plastics in Materials and Articles | EU/10/2011 | | | | | | | | | | | | | | | | | | |
| | Regulation Recycled Plastic Materials and Articles | 282/2008/EC | | | | | | | | | | | | | | | | | | |
| | Regulation | (EC) No 450/2009 | | | | | | | | | | | | | | | | | | |
| Food Additives | Regulation | 1333/2008/EC | | | | | | | | | | | | | | | | | | |
| | Directive | 94/36/EEC | | | | | | | | | | | | | | | | | | |
| | Regulation | 231/2102 | | | | | | | | | | | | | | | | | | |
| | Regulation | 1831/2003/EC | | | | | | | | | | | | | | | | | | |

| Table 8–19: Relevance of different regulatory instruments to the applications of $TiO_2$ following a harmonised classification of Carc Cat 1B | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Relevant legislation | Type | Number | Manufacture and import of $TiO_2$ | Paints | Plastics | Paper | Inks | Construction materials | Fibres | Catalysts | Food, feed and food contact materials | Pharmaceuticals | Cosmetics | Elastomers | Pigment manufacture | Ceramics | Glass | Medical devices | Detergents | Biocides |
| Medicinal Products | Directive | 2001/83/EC | | | | | | | | | | | | | | | | | | |
| | Regulation | 1901/2006 | | | | | | | | | | | | | | | | | | |
| | Directive | 2009/35/EC | | | | | | | | | | | | | | | | | | |
| | Directive | 94/36/EC | | | | | | | | | | | | | | | | | | |
| Construction Products | Regulation | 305/2011 | | | | | | | | | | | | | | | | | | |
| Biocides | Regulation | EU/528/2012 | | | | | | | | | | | | | | | | | | |
| Medical Devices | Directive | 93/42/EEC (amendment agreed in June 2016) | | | | | | | | | | | | | | | | | | |
| Restriction of hazardous substances in electrical and electronic equipment | Directive | 2011/65/EU | | | | | | | | | | | | | | | | | | |
| | Directive | 2012/19/EU | | | | | | | | | | | | | | | | | | |
| Tobacco additives | Directive | 2014/40/EU | | | | | | | | | | | | | | | | | | |
| | Decision | (EU) 2016/787 | | | | | | | | | | | | | | | | | | |
| Other | | | | ✓ | ✓ | | ✓ | ✓ | ✓ | | ✓ | | | | | | | | | |

## 8.2 Other provisions

### 8.2.1 Food contact materials

***Introduction***

The Framework Regulation (EC) No. 1935/2004 includes a long list of materials and articles in its Annex I but, in practice, so far specific rules have been set out for a few of them. The following rules on food contact materials and articles apply:

- **Harmonised rules** on active and intelligent materials under Regulation (EC) No 450/2009, and plastics under Regulation 10/2011 (NB. as shown in **Table 8–10**, there is legislation on ceramics and regenerated cellulose film but these do not have a direct relevance to $TiO_2$);

- **Council of Europe (CoE) Resolutions on coatings, paper and board, and printing inks**. Although these CoE Resolutions are guidelines, they are used by most national competent authorities to check compliance of non-harmonised food contact materials and articles with Article 3 of the EU Framework Regulation. Several of these Resolutions are under review. This review work is confidential and it is understood that there is also a confidential draft CoE/EDQM Framework Resolution that concerns the use / presence of CMRs food contact materials and articles. The existing Resolutions are presented below; and

- **National rules on a variety of food contact materials and articles**. Pending the adoption of more specific EU measures, food contact materials must also comply with any relevant national legislation in different EU Member States. Literature suggests that specific pieces of national legislation on different types of materials are currently in place in 19 EU Member States (Baughan, 2015). Member States such as Finland and the Netherlands, for example, maintain national requirements for paper and board, while Germany has established Recommendations concerning paper and board for different end-uses (e.g., baking and filter papers). On 25 September 2016, the Belgian Federal Public Service (FPS) Public Health and Safety of the Food Chain and Environment released a Royal Decree on varnishes and coatings intended to come into contact with foodstuffs, which will enter into force on 1 January 2017. According to the decree, the following substances can be used intentionally to make coatings intended for food contact: those substances listed on the Annex I to Regulation (EU) No 10/2011 on plastics, those approved by a Member State, those approved by the European Food Safety Authority, those that do not migrate to a detectable amount in the food, and those that are not classified as CMR, and are not in nano-form (Food Packaging Forum, 2016).

  More generally, national regulations may include positive lists for substances, impurity specifications, and sanctioned test methods. For Member States without specific requirements for paper and board (e.g., the United Kingdom, Denmark, and Sweden), such materials are required to be safe, which can be established through references to national positive listings, EU Directives, evaluations by the EU Scientific Committee on Food (now the European Food Safety Agency), clearances in other jurisdictions (e.g., clearances under the U.S. Food and Drug Administration's food additive regulations), and CoE Resolutions (Misko, 2004).

***CoE Resolution on coatings***

In relation to coatings in food packaging, there is a Council of Europe (CoE) Resolution, namely, Framework Resolution ResAP(2004)1 on coatings[78] intended to come into contact with foodstuffs. The Resolution is not legally binding and applies to coatings which in the finished state are intended to come into contact or which are brought into contact with foodstuffs and are designed for that purpose. The following types of coating are covered (CoE, 2004):

- Coatings for metal packaging;
- Flexible packaging coatings; and
- Heavy-duty coatings.

In accordance with the Resolution, coatings should meet the following conditions:

- They comply with the requirements of the EU Framework Regulation;
- They are manufactured in accordance GMP;
- They do not transfer their constituents to foodstuffs in quantities exceeding $10mg/dm^2$ of surface area of material or article ($mg/dm^2$) (overall migration limit). However, this limit is 60 mg of the constituents released per kg of foodstuff (mg/kg) in the following cases:
    - Articles which are containers or are comparable to containers or which can be filled, with a capacity of not less than 500 ml and not more than 10 litres;
    - Articles which can be filled and for which it is impracticable to estimate the surface area in contact with foodstuffs; and
    - Caps, gaskets, stoppers or other similar devices for sealing;
- They do not transfer migrating components not listed in "*Technical document No. 1 – List of substances to be used in the manufacture of coatings intended to come into contact with foodstuffs*" which have MW < 1000 D in quantities which could endanger human health. These non-listed substances of MW < 1000 D should be subjected to appropriate risk assessment, taking into account dietary exposure as well as toxicological and structure activity considerations.

$TiO_2$ is listed in 'List 1 of additives' as an additive not subject to any restriction of specification. On the other hand, 'Silver chloride (20% w/w) coated onto titanium dioxide (80% w/w)' is listed in the Appendix to the 'List 1 of additives' and a restriction or specification for it are pending (CoE, 2009).

It should be noted that this Resolution as well as those discussed below apply to the States members of the Partial Agreement in the Social and Public Health Field; these include: Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

***CoE Resolution on paper and board***

Of relevance to paper and board is Council of Europe Resolution AP (2002)1. As above for coatings, the Resolution is not legally binding but serves as an important reference and applies to all food contact paper, including coated board and paper layers in multilayer materials, but excluding non-

[78] Coatings are defined as the finished material prepared mainly from organic materials applied to form a layer/film on a substrate in such a way as to create a protective layer and/or to impart certain technical performance.

wovens. Paper that is used in food contact articles but that is separated from the food by a functional barrier is outside the scope of the Resolution (Baughan, 2015). According to the Resolution, paper and board used for all food contact applications under normal or foreseeable conditions of use should meet the following conditions (CoE, 2002):

- Comply with the requirements of the EU Framework Regulation;
- Be manufactured in accordance with GMP;
- Be of suitable microbiological quality;
- Not release substances which have an antimicrobial effect on foodstuffs; and
- Comply with restrictions on the migration of lead, cadmium, mercury and pentachlorophenol.

Technical Document No. 1 contains the lists of additives which may be used in the manufacture of paper and board materials and articles intended to come into contact with foodstuffs. $TiO_2$ is present in List 1, the list of additives assessed, without any restriction or specification but rather with the indication “Acceptable” (CoE, 2009b).

***CoE Resolution on printing inks***

In 2005, the CoE Committee of Ministers of the Partial Agreement in the Social and Public Health Field adopted the Resolution ResAP (2005)2 on “Packaging Inks Applied to the Non-Food Contact Surface of Food Packaging”. As noted above, CoE Resolutions are not legally binding, but are considered as statements of policy for national policy makers of the Partial Agreement member states.

The Resolution imposes the following requirements (CoE, 2005):

- Printed materials and articles intended to come into contact with foodstuffs, should not, in their finished state and under normal and foreseeable conditions of use, transfer their constituents to foodstuffs in quantities which could endanger human health or bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics thereof, in accordance with Article 3 of Regulation (EC) No. 1935/2004;
- The substances in packaging inks should be selected in conformity with the requirements for the selection of packaging ink substances as set out in Technical Document No.1;
- The packaging inks should be manufactured in accordance with the guides for good manufacturing practice;
- The packaging inks should be applied in accordance with converters’ good manufacturing practices;
- The printed or overprinted varnished layer of finished printed material or article should not come into direct contact with food;
- Global and specific migration from the finished printed material or article should not exceed the relevant limits; and
- There should be no, or only negligible, visible set-off or migration from the printed or varnished non-food contact layer to the food contact surface.

Technical Document No.1 includes among its exclusion criteria CMR 1A/1B substances. Substances which, however, are classified as category 1A, 1B, or 2 but are evaluated by (a) Scientific Committee(s) and as a result can be used under the specified conditions, are admitted. No restriction is currently imposed on $TiO_2$.

***Impacts from the proposed classification***

It cannot be certain how the proposed classification would be taken up within these CoE Resolutions. It would appear that upon the substance being classified as Carc Cat 1B, it would fail the exclusion criteria for printing inks. As far as coatings and paper/board are concerned, the listings of $TiO_2$ might be reviewed as a consequence of its new hazard classification.

### 8.2.2 EuPIA Exclusion Policy for printing inks and related products

The European Printing Ink Association (EuPIA) could not support the aforementioned CoE Resolution as adopted, because it was believed not to be practicable. The substance inventory lists were not sufficiently comprehensive, and did not provide protection for consumer health or reflect current practices (EuPIA, 2012).

Independent of these legal initiatives and in the absence of specific EU legislation, EuPIA developed a Guideline setting out a mechanism for the selection of raw materials for food packaging inks. Raw materials are selected in accordance with the "Selection scheme for packaging ink raw materials" of the EuPIA Guideline and with specific purity requirements. The inks are formulated and manufactured taking into account many individual and varying parameters relating to the substrate, application and end use in order to minimise the potential for migration of ink components into food and to allow the final package to comply with the legal requirements of Regulation (EC) No 1935/2004 and other existing regulations. Packaging inks are formulated and manufactured in accordance with the EuPIA Good Manufacturing Practices (EuPIA, 2012b).

EuPIA has established an Exclusion Policy (which evolved from an earlier Exclusion List). The EuPIA Exclusion Policy applies to the manufacture and supply of all types of printing inks and related products, for use in any application and on any substrate. Although the EuPIA Exclusion Policy does not impose any legal obligations, it has the full support of all EuPIA members. Printing ink manufacturers who are not members of EuPIA are also invited and encouraged to apply the criteria of the Exclusion Policy (EuPIA, 2016).

Raw materials excluded by the Policy, and which must therefore be avoided in the formulation of printing inks, are those substances or mixtures classified in one or more of the CLP hazard classes/categories listed in Group A and Group B on the following page. CMR 1A/1B are to be found in Group A. Furthermore, the substances in Groups C to G (listed in Annex 1 of the Policy) are excluded regardless of whether or not they fall under the hazard criteria of Group A or B.

For specific technical and performance reasons it may be necessary, in an individual ink, to use a raw material that contains a substance classified according to Group A or B. This exception may only be applied where the concentration of the substance in the raw material is below the limits at which the raw material will be classified and labelled. A decision to use such a raw material should be made only:

- If no suitable alternative raw materials are available;
- After an appropriate risk assessment has been carried out on the ink manufacturing process;
- After a risk assessment has been carried out, in conjunction with the converter, on the application and end use of the printed product.

When a raw material currently used becomes included in one of the categories in this Exclusion Policy by reason of re-classification, by default EuPIA members are expected to substitute this material as soon as practicable. A time frame of six months is normally regarded as appropriate.

If, after technical investigation, it is found not to be possible to replace a raw material in the short term for a specific application, an exemption from substitution can be granted according to the following rules:

- For hazards listed in Group A, the explicit approval of the EuPIA Technical Committee is required. A list of exemptions approved under this procedure is provided in Annex 2 to the Policy; and

- For hazards listed in Group B (only), it shall be the responsibility of the individual member company to conduct a risk assessment and to demonstrate that safe use is assured (in their own manufacturing, in customers' operations and/or in the final printed product as appropriate).

### 8.2.3 CE marking

Those products which are subject to a CE mark have to undergo a conformity assessment which assesses the products characteristics and whether they meet EU harmonised standards before a EC Declaration of Conformity is issued. The CE mark will be given if the product meets the conformity assessment under the legislation it is subject to. Whilst there is no general rule for carcinogens for CE markings, the classification of $TiO_2$ as Carc Cat 1B would mean that some products might not be able to attain a CE mark. Relevant affected products may include:

- **Toys**: Directive 2009/48/EC on toy safety specifies in detail the essential requirements to be fulfilled by manufacturers, importers or distributors, to prove that their product complies with EU regulations and finally, to be able to affix the CE marking. Annex II to the Directive specifies the safety requirements products have to comply with. In accordance with this Annex, substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under Regulation (EC) No 1272/2008 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys (although derogations can be granted); and

- **Ecodesign of energy related products**: the Ecodesign Directive (2009/125/EC) is a framework Directive that sets the ecodesign requirements related to the environmental parameters that manufacturers have to meet in order for their products to carry the CE marking. The Directive calls for particular attention to the use of substances classified as hazardous to health and/or the environment according to Council Directive 67/548/EEC, the precursor to the CLP Regulation.

The active implantable medical devices Directive 90/385/EEC and the Directive 93/42/EEC on Medical Devices also make some generic references to chemical risks but no specific requirement on CMR substances in relation to the CE marking is made (but note that the Medical Devices Directive is to be replaced by a new Regulation soon).

### 8.2.4 Ecolabel

Article 6(6) of Regulation (EC) No 66/2010 on the EU Ecolabel stipulates that the EU Ecolabel may not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as toxic, hazardous to the environment, CMR, in accordance with the CLP Regulation, nor to goods containing substances referred to in Article 57 of the REACH Regulation. The EU Ecolabel is awarded to many categories of products, including:

- Personal care products;
- Cleaning products;
- Clothing and textiles;

- Footwear;
- Paints and varnishes;
- Electronic equipment;
- Coverings;
- Furniture and bed mattresses;
- Gardening products
- Household appliances;
- Lubricants;
- Certain household items (sanity tapware and flushing toilets and urinals); and
- Paper products.

For instance, Commission Decision 2014/312/EU establishing the ecological criteria for the award of the EU Ecolabel for indoor and outdoor paints and varnishes prescribes that the final product formulation, including all intentionally added ingredients present at a concentration of greater than 0.010%, shall not, unless expressly derogated in its Appendix, contain substances or mixtures classified as toxic, hazardous to the environment, respiratory or skin sensitisers, or carcinogenic, mutagenic or toxic for reproduction in accordance with the CLP Regulation.

### 8.2.5 OEKO-TEX® Standard

The OEKO-TEX® Standard 100 is a worldwide consistent, independent testing and certification system for raw, semi-finished, and finished textile products at all processing levels, as well as accessory materials used. The central focus of the OEKO-TEX® Standard 100 has been the development of test criteria, limit values and test methods on a scientific basis. Among the limit values, there is a list for dyestuffs and pigments classified as carcinogenic and this list would likely include $TiO_2$ following its proposed classification.

On the issue of $TiO_2$ in the textile sector, it has also been noted by stakeholders that in the spinning process of man-made fibres there is always some amount of waste generated which contains $TiO_2$ (used for delustering of the fibres). This type of waste is largely used in EU (and worldwide) as an input material for other industries (e.g. engineering plastics and composite materials) and can be applied in automotive industry, machinery, household appliances, etc. The potential classification of $TiO_2$ as Carc Cat 1B consequently means a complete change of evaluation of the above goods by the final consumers.

# 9 Annex 2: Alternatives for titanium dioxide

## 9.1 Technical feasibility of alternatives

$TiO_2$ is used primarily as a pigment to scatter light, because it absorbs almost no incident light in the visible region of the spectrum. This pigment scatters light by three mechanisms: reflection from the surface of a crystal, refraction within a crystal, and diffraction, whereby light is bent as it passes near a crystal. Reflection and refraction are maximised by increasing the difference between the refractive index of the pigment and that of the polymer matrix or other material in which it is dispersed (Gázquez, et al., 2014).

$TiO_2$ (PW6) is the universal choice for white pigments. It is suitable for almost every usage and requirements; compared to $TiO_2$ all other white pigments have indisputable disadvantages or they are limited in their applicability.

A list of white pigments is presented in **Table 9–2**. Among them, zinc compounds such as zinc oxide, and zinc sulphide (within lithopone) as well as carbonates and other mineral powders (kaolin, talc) find extensive use. However, $TiO_2$ has the highest refractive index among all known white pigments, as shown in **Table 9–1**. Rutile $TiO_2$ has a refractive index that exceeds 2.7, while other popular white pigments such as zinc oxide (ca. 2), lithopone, kaolin, chalk and talc (all less than 2) have much lower index numbers. The high refractive indices of rutile and anatase $TiO_2$ result in high light scattering properties, as a result relatively low levels of $TiO_2$ pigment are required to achieve a white opaque coating, in comparison to alternative white pigments.

**Table 9–1: Density and refractive indices of selected white pigments**

| CI numbers | Pigment | Density | Refractive Index |
|---|---|---|---|
| PW1 | Lead white | 6.70-6.86 | 1.94-2.09 |
| PW3 | Lead sulphate | 6.12-6.39 | 1.878; 1.883; 1.895 |
| PW4 | Zinc oxide | 5.47-5.65 | 2.00-2.02 |
| PW5 | Lithopone | 4.3 | 2.3 (ZnS); 1.64 ($BaSO_4$) |
| PW6 – Rutile | Titanium dioxide | 3.75-4.3 | 2.71 - 2.72 |
| PW6 – Anatase | Titanium dioxide | 3.9 | 2.54-2.55 |
| PW10 | Barium carbonate | 4.3 | 1.529; 1.676; 1.677 |
| PW11 | Antimony trioxide | 5.67-5.75 | 2.18-2.35 |
| PW12 | Zirconium oxide | 2.40 | |
| PW18 | Chalk | 2.7-2.95 | 1.486 (1.510); 1.645 |
| PW18 | Magnesite | 3.0 | 1.508; 1.510; 1.700 |
| PW19 | Kaolin (Speswhite) | 2.16-2.63 | 1.558; 1.565; 1.564 |
| PW20 | Mica | 1.58-1.61 | |
| PW21 – PW22 | Barytes | 4.3-4.6 | 1.636; 1.637; 1.648 |
| PW24 | Aluminium hydroxide | 2.42-2.45 | 1.568-1.587 |
| PW25 | Gypsum | 2.32-2.36 | 1.520; 1.523; 1.530 |
| PW26 | Talc | 2.5-2.8 | 1.539; 1.589; 1.589 |
| PW27 | Silica/Quartz | 2.2-2.65 | 1.40-1.55 |

*Sources: http://cameo.mfa.org/images/c/cd/Download_file_536.pdf (accessed on 18 August 2016), ASTM (1995); Zorll (2000)*

| Table 9–2: Overview of white pigments | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Colour Index generic name** | **C.I. Common or Historical Name** | **C.I. Constitution Number** | **Chemical Composition** | **Colour Description** | **Opacity 1 = opaque 4 = trans.** | **Light Fastness I = excellent IV=Fugitive** | **Hazard classification** |
| PW1 | Lead white | 77597 | Basic lead carbonate<br>CAS No: 1319-46-6 | Silvery white | 1-2 | I | **Not harmonised**<br>Acute Tox. 4 (H302)<br>Acute Tox. 4 (H332)<br>Repr. 1A (H360)<br>STOT RE 2 (H373)<br>Aquatic Chronic 1 (H410) |
| PW2 | Lead sulphate white | 77633 | Basic lead sulphate<br>CAS No: 12397-06-7 | Greyish to white | 2 | I | **Not classified** (but likely to have a profile similar to other lead pigments) |
| PW3 | Basic lead sulphate white | 77630 | Lead sulphate<br>CAS No: 7446-14-2 | Greyish to white | 2 | I | **Not harmonised**<br>Acute Tox. 4 (H302)<br>Acute Tox. 4 (H332)<br>Repr. 1A (H360)<br>STOT RE 2 (H373)<br>Aquatic Acute 1 (H400)<br>Aquatic Chronic 1 (H410) |
| PW4 | Zinc oxide white | 77947 | Zinc oxide<br>CAS No: 1314-13-2<br>CAS No: 91315-44-5 | Translucent white | 2 | I | **Harmonised**<br>Aquatic Acute 1 (H400)<br>Aquatic Chronic 1 (H410) |
| PW5 | Lithopone | 77115 | Barium sulphate (28 - 30%) and zinc sulphide (68 - 70%) with trace amounts of zinc oxide<br>CAS No: 7727-43-7<br>CAS No: 1314-98-3 | White | 1-2 | I | 7727-43-7: **Not classified**<br>1314-98-3: **Not classified** |
| PW6 | Titanium white | 77891 | Titanium dioxide:<br>CAS No: 13463-67-7 | Purest white | 1 | I | **Not classified** |
| PW7 | Zinc sulphide white | 77995<br>77975 | Zinc sulphide<br>CAS No: 1314-98-3 | White to yellowish | 1-2 | I | **Not classified** |

| Table 9–2: Overview of white pigments | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Colour Index generic name** | **C.I. Common or Historical Name** | **C.I. Constitution Number** | **Chemical Composition** | **Colour Description** | **Opacity 1 = opaque 4 = trans.** | **Light Fastness I = excellent IV=Fugitive** | **Hazard classification** |
| PW8 | Strontium sulphide | 77847 | Strontium sulphide<br>CAS No: 1314-96-1 | Phosphorescent | - | - | **Not harmonised**<br>Met. Corr. 1 (H290)<br>Acute Tox. 3 (H301)<br>Skin Corr. 1A (H314)<br>Eye Dam. 1 (H318)<br>Aquatic Acute 1 (H400) |
| PW10 | Barium carbonate | 77099 | Barium carbonate<br>CAS No: 513-77-9 | Powder white | 3 | - | **Harmonised**<br>Acute Tox. 4 (H302) |
| PW11 | Antimony white | 77052 | Diantimony trioxide<br>CAS No: 1309-64-4 | Powder white | 1 | I | **Harmonised**<br>Carc. 2 (H351) |
| PW12 | Zirconium oxide | 77990 | Zirconium oxide<br>CAS No: 1314-23-4 | - | - | - | **Not classified** |
| PW13 | Barium tungstate | 77128 | Barium wolframate<br>CAS No: 7787-42-0 | White | - | I | **Not harmonised**<br>Acute Tox. 4 (H302)<br>Acute Tox. 4 (H332) |
| PW14 | Bismuth oxychloride | 77163 | Bismuth chloride oxide<br>CAS No: 7787-59-9 | Silvery white with pearlescent or iridescence properties | - | - | **Not classified** |
| PW15 | Tin oxide | 77861 | Tin dioxide<br>CAS No: 18282-10-5 | White to grey with slight pearlescent sheen | 1 | I | **Not classified** |
| PW16 | Lead silicate | 77625 | Lead monosilicate<br>CAS No: 10099-76-0 | White | **1** | - | **Not classified** (but likely to have a profile similar to other lead pigments) |

| Table 9–2: Overview of white pigments | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Colour Index generic name** | **C.I. Common or Historical Name** | **C.I. Constitution Number** | **Chemical Composition** | **Colour Description** | **Opacity 1 = opaque 4 = trans.** | **Light Fastness I = excellent IV=Fugitive** | **Hazard classification** |
| PW17 | Bismuth subnitrate | 77169 | Basic bismuth nitrate<br>CAS No: 1304-85-4 | Pearlescent white; Microcrystalline powder | 1 | II | **Not classified** |
| PW18 | Chalk | 77220 + 77713 | Natural calcium carbonate with magnesium carbonate as an impurity<br>CAS No: 471-34-1<br>CAS No: 546-93-0 | White to cream/blue/ grey off white | 1-4 | I | 471-34-1: **Not classified**<br>546-93-0: **Not classified** |
| PW18 | Precipitated chalk | 77220 | Pure calcium carbonate<br>CAS No: 471-34-1 | White | 1-4 | I | **Not classified** |
| PW18: 1 | Dolomite | 77220:1 + 77713:1 | Calcium magnesium carbonate<br>CAS No: 83897-84-1 | White to pale pink to yellowish white | 1-4 | I | **Not harmonised**<br>Skin Irrit. 2 (H315)<br>Eye Dam. 1 (H318)<br>STOT SE 3 (H335) |
| PW19 | Kaolin | 77004<br>77005 | White clay rock, mostly natural hydrated aluminium silicate with impurities of magnesium, iron carbonates, ferric hydroxide, mica, quartz-sand, etc.<br>CAS No: 1332-58-7 | Bright white; can have blue, green, red, orange or brown undertones | 1-4 | I | **Not classified** |
| PW20 | Mica | 77019 | Hydrous aluminium potassium silicate<br>CAS No: 12001-26-2 | Translucent pearlescent or shimmering off-white | 4 | I | **Not classified** |
| PW21 | Barium sulphate (synthetic) | 77120 | Synthetic barium sulphate<br>CAS No: 7727-43-7 | White | 2-3 | I | **Not classified** |

**Table 9–2: Overview of white pigments**

| Colour Index generic name | C.I. Common or Historical Name | C.I. Constitution Number | Chemical Composition | Colour Description | Opacity 1 = opaque 4 = trans. | Light Fastness I = excellent IV=Fugitive | Hazard classification |
|---|---|---|---|---|---|---|---|
| PW22 | Barytes (natural barium sulphate) | 77120 | Natural barium sulphate<br>CAS No: 7727-43-7 | White to off white | 2-3 | I | **Not classified** |
| PW23 | Alumina blanc fixe | 77122 | Aluminium hydrate, barium sulphate; coprecipitate of ca. 25% aluminium hydroxide and 75% barium sulphate<br>CAS No: 21645-51-2<br>CAS No: 7727-43-7 | White Crystalline powder | - | I | 21645-51-2: **Not classified**<br>7727-43-7: **Not classified** |
| PW24 | Aluminium hydroxide | 77002 | Aluminium hydroxide<br>CAS No: 21645-51-2 | Translucent white powder | 3-4 | I | **Not classified** |
| PW24 | Gibbsite (natural form of aluminium hydroxide) | - | Natural aluminium hydroxide with varying amounts of basic aluminium sulphate<br>CAS No: 21645-51-2 | Brown tinted Translucent Flakes | 4 | I | **Not classified** |
| PW25 | Gypsum | 77231 | Hydrated calcium sulphate<br>CAS No: 91315-45-6<br>CAS No: 10101-14-4 | White | 1-3 | I | **Not classified**<br>(calcium sulphate, CAS No: 7778-18-9 is also not classified) |
| PW26 | Talc | 77718 + 77019 | Mixed hydrated silicate of magnesium with varying impurities of calcium, iron and other compounds<br>CAS No: 14807-96-6<br>CAS No: 8005-37-6 | Slightly off white to light grey | 1-3 | I | 14807-96-6: **Not classified** |
| PW27 | Silica | 77811 | Two types:<br>Hydrous = diatomaceous earth;<br>Anhydrous = silica<br>Silicon dioxide<br>CAS No: 7631-86-9 | White to off white | 1-4 | I | **Not classified** |

| Table 9–2: Overview of white pigments | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Colour Index generic name** | **C.I. Common or Historical Name** | **C.I. Constitution Number** | **Chemical Composition** | **Colour Description** | **Opacity 1 = opaque 4 = trans.** | **Light Fastness I = excellent IV=Fugitive** | **Hazard classification** |
| PW28 | Calcium silicate | 77230 | Calcium metasilicate;<br>Calcium silicate;<br>CAS No: 10101-39-0<br>CAS No: 10101-41-4<br>CAS No: 13397-24-5<br>CAS No: 26499-65-0 | White to light cream | 2-3 | I | 10101-39-0: **Not classified** |
| PW28 | Hydrated calcium silicate | 77230 | Hydrated calcium silicate | Bright White | 4 | I | As above |
| PW 30 | Lead phosphate | 77622 | Trilead bis(orthophosphate)<br>CAS No: 7446-27-7 | - | - | - | **Harmonised**<br>Repr. 1A (H360Df)<br>STOT RE 2 (H373)<br>Aquatic Acute 1 (H400)<br>Aquatic Chronic 1 (H410) |
| PW32 | Zinc phosphate | 77964 | Trizinc bis(orthophosphate)<br>CAS No: 7779-90-0 | White | 1 | I | **Harmonised**<br>Aquatic Acute 1 (H400)<br>Aquatic Chronic 1 (H410) |
| PW33 | Calcium sulphoalumina te | 77235 | Calcium sulphoaluminate | - | - | - | **Not classified** |

*Source: http://www.artiscreation.com/white.html#ci_pigment_white (accessed on 18 August 2016); ECHA C&L Inventory, https://echa.europa.eu/information-on-chemicals/cl-inventory-database (accessed on 18 August 2016)*

According to comments made by I&P Europe on the French proposal for the harmonised classification of $TiO_2$[79], "*to obtain the same effect in pigmented materials with alternative substances such as zinc oxide, aluminium oxide or barium sulphate, 4 to 6 times as much pigment (ZnO) or 10 to 14 times as much pigment ($Al_2O_3$ and $BaSO_4$) would need to be added, amounts which are so high that the high pigment concentration results at one hand in a loss again in scattering properties because of 'crowding' at the percolation point and at the other in a loss in physical performance of the product (due to loss in mechanical strength of the pigmented matrix or viscosity increased or solidification of liquid products)*" (see also **Figure 9–1** also reproduced from I&P Europe's submission to the public consultation).

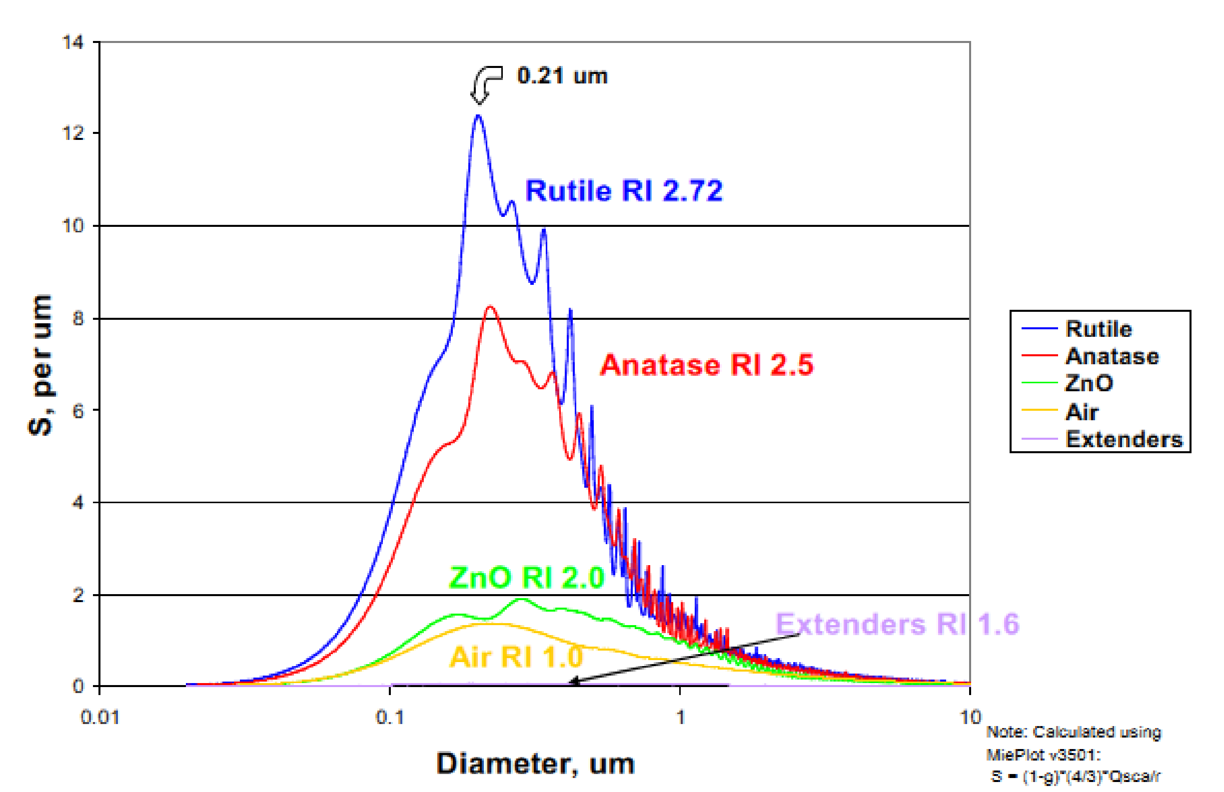


**Figure 9–1: Pigment scattering coefficients of $TiO_2$ and selected alternatives**
*Source: (Crowther & Johnson, undated)*

An important measure of a pigment's potential hiding power can be determined by a simple test whereby it is tinted with a standard black pigment, and assessed using an arbitrary scale. The tinting strength values for rutile titanium pigments range between 1550 and 1850 and for anatase between 1150 and 1350. The best of the other white pigments listed in **Table 9–1**, zinc sulphide, is only half as powerful as rutile (Gázquez, et al., 2014). Lower hiding powder exhibited by pigments other than $TiO_2$ could also be counterbalanced by deposition of thicker layers, but these layers are then more difficult / impossible to dry or cure, nor will they perform any longer the required functionalities. This could be particularly important in processes such as printing, but also more widely would impact upon the efficiency of any coating operation.

[79] Available at: https://echa.europa.eu/documents/10162/48252319-d727-42aa-8b3e-bb97cb218f0e (accessed on 22 August 2016).

Other important features of $TiO_2$ pigments are excellent resistance to chemical attack, good thermal stability and resistance to ultraviolet (UV) degradation. Rutile pigment is more resistant to UV light than anatase, and is preferred for paints, plastics, especially those exposed to outdoor conditions, and inks. On the other hand, anatase pigment has a bluer tone than the rutile type, is less abrasive and is used mainly in indoor paints and in paper, ceramics, rubber and fibre manufacture. Both rutile and anatase pigments can be made more resistant to photodegradation by coating the pigment particles, which also improves their dispersibility, dispersion stability, opacity and brightness (Gázquez, et al., 2014).

As a result, there is no white pigment that can match the opacity, hiding power, cost-efficiency, inertness and weatherability of $TiO_2$. It is important to note that several of the pigments identified above are mineral fillers widely considered to be suitable as extender pigments. Such pigments can be (and in some cases have been) used to partly replace $TiO_2$ in formulations, primarily for cost reasons. Their performance however cannot match that of $TiO_2$. These pigments have a relatively low refractive index of ca. 1.5. When the surrounding medium is air with a refractive index of 1.0, the difference in the two index values produces substantial light scattering, so that extender pigments appear white. However, when such alternative pigments are dispersed in other media, e.g. a paint binder which itself has a refractive index of ca. 1.5, they scatter light very poorly and appear much more transparent. Considering matrices such as paints, extender pigments may also have an adverse effect on other physical properties such as consistency, gloss (Zorll, 2000), stability and scrub resistance (film toughness) (Karakaş, et al., 2015). Whilst, on a case-by-case basis, $TiO_2$ might be technically possible to replace, particularly where technical requirements are not stringent, in order for opacity and hiding power to be acceptable, increased loadings of the alternatives may need to be used, thus imparting poor cost-efficiency on the alternatives.

A more recently developed technology is that of organic pigments, effectively, opaque polymer systems. These have been used in interior and exterior coatings as hollow-sphere polymeric pigment that allows paint manufacturers to reduce the raw material cost (i.e. the cost of $TiO_2$) of their formulations. For instance, such a commercial product claims to offer "*significantly increased light scattering efficiency while maintaining paint performance*", "*greater cost savings while providing equal hiding*", and "*a comparatively low binder demand* [so that] *the total PVC* [Pigment Volume Concentration] *can be slightly increased without sacrificing paint performance*" (Dow, 2010)[80]. However, this is not a solution if complete elimination of $TiO_2$ from the formulations is required; also, the integrity of the hollow spheres plays a significant role in the performance of such products (NB. products from other companies are available).

## 9.2 Hazard profile of alternatives

**Table 9–2** presented an overview of the hazard classification of alternative white pigments. It is acknowledged that other alternative systems may exist but, in terms of hazard profiles, the focus here is on alternative substances rather than materials.

The list of alternative white pigments includes several heavy metal compounds. Lead-based pigments in particular are by far more hazardous than $TiO_2$ and for this reason currently find very little use, if any, as they have been replaced by $TiO_2$. Zinc oxide and zinc phosphate have an unfavourable environmental hazard profile.



80 The specific product referred to here is claimed to be "*non-toxic in single acute oral, dermal, and inhalation exposure tests. Without proper safety precautions, it can be a mild skin and eye irritant*" (Dow, 2010).

Importantly, we must consider the mechanism through which the supposed toxicity of $TiO_2$ is manifested. As the carcinogenic effect in animal testing discussed in the French CLH proposal is not substance-specific but characteristic of respirable poorly soluble dusts, this can be expected to occur with most, if not all potential alternative substances too. Therefore, if it were accepted that $TiO_2$ is a carcinogen, all poorly soluble powders that could replace it (including minerals such as kaolin, chalk, talc, etc.) could be considered to exert carcinogenicity in a similar manner. This would especially be true if the substances in question were not so widely used as $TiO_2$ so that there is only limited experience with them. Consequently, at least every other organic and inorganic pigment would be a candidate for such a measure, especially fine particle sized pigment grades (Winkler, 2016). Overall, substitution of $TiO_2$ motivated by its classification as a Carc cat 1B substance by inhalation would not result in a discernible benefit to workers' health.

## 9.3 Availability of alternatives

Availability is another key concern over the vast majority of potential alternative pigments. Few pigments have a global consumption higher than $TiO_2$. Other white pigments such as zinc oxide and lithopone have a global market ca. 15-23 times smaller than $TiO_2$. In other words, there would simply be insufficient quantities of many of the alternative white pigments if $TiO_2$ were to be substituted in the EEA. **Table 9–3** presents an overview of the REACH registration status of the alternative white pigments. With the notable exceptions of zinc oxide, zinc sulphide, barium carbonate, and a number of minerals, the remaining pigments are registered in tonnage ranges far lower than that of $TiO_2$.

**Table 9–3: Registration tonnages for alternative white pigments**

| Colour Index generic name | C.I. Common or Historical Name | Chemical composition | REACH registration tonnage (t/y) |
|---|---|---|---|
| PW1 | Lead white | Basic lead carbonate<br>CAS No: 1319-46-6 | 10-100 |
| PW2 | Lead sulphate white | Basic lead sulphate<br>CAS No: 12397-06-7 | Not registered |
| PW3 | Basic lead sulphate white | Lead sulphate<br>CAS No: 7446-14-2 | Intermediate only |
| PW4 | Zinc oxide white | Zinc oxide<br>CAS No: 1314-13-2<br>CAS No: 91315-44-5 | <br>100,000 – 1,000,000<br>Not registered |
| PW5 | Lithopone | Barium sulphate (28 - 30%) and zinc sulphide (68 - 70%) with trace amounts of zinc oxide<br>CAS No: 7727-43-7<br>CAS No: 1314-98-3 | <br>10,000 – 100,000<br>100,000 – 1,000,000 |
| PW6 | Titanium white | Titanium dioxide:<br>CAS No: 13463-67-7 | 1,000,000 – 10,000,000 |
| PW7 | Zinc sulphide white | Zinc sulphide<br>CAS No: 1314-98-3 | 100,000 – 1,000,000 |
| PW8 | Strontium sulphide | Strontium sulphide<br>CAS No: 1314-96-1 | 10,000 – 100,000 |
| PW10 | Barium carbonate | Barium carbonate<br>CAS No: 513-77-9 | 100,000 – 1,000,000 |
| PW11 | Antimony white | Diantimony trioxide<br>CAS No: 1309-64-4 | 10,000+ |

| Table 9–3: Registration tonnages for alternative white pigments | | | |
|---|---|---|---|
| **Colour Index generic name** | **C.I. Common or Historical Name** | **Chemical composition** | **REACH registration tonnage (t/y)** |
| PW12 | Zirconium oxide | Zirconium oxide<br>CAS No: 1314-23-4 | 10,000 – 100,000 |
| PW13 | Barium tungstate | Barium wolframate<br>CAS No: 7787-42-0 | Not registered |
| PW14 | Bismuth oxychloride | Bismuth chloride oxide<br>CAS No: 7787-59-9 | Not registered |
| PW15 | Tin oxide | Tin dioxide<br>CAS No: 18282-10-5 | 1,000 – 10,000 |
| PW16 | Lead silicate | Lead monosilicate<br>CAS No: 10099-76-0 | Not registered |
| PW17 | Bismuth subnitrate | Basic bismuth nitrate<br>CAS No: 1304-85-4 | 100 – 1,000 |
| PW18 | Chalk | Natural calcium carbonate with magnesium carbonate as an impurity<br>CAS No: 471-34-1<br>CAS No: 546-93-0 | 1,000,000 – 10,000,000<br>1,000+ |
| PW18 | Precipitated chalk | Pure calcium carbonate<br>CAS No: 471-34-1 | 1,000,000 – 10,000,000 |
| PW18:1 | Dolomite | Calcium magnesium carbonate<br>CAS No: 83897-84-1 | 100,000 – 1,000,000 |
| PW19 | Kaolin | White clay rock, mostly natural hydrated aluminium silicate with impurities of magnesium, iron carbonates, ferric hydroxide, mica, quartz-sand, etc.<br>CAS No: 1332-58-7 | 100,000 – 1,000,000 |
| PW20 | Mica | Hydrous aluminium potassium silicate<br>CAS No: 12001-26-2 | Not registered<br>(Annex V exemption) |
| PW21 | Barium sulphate (synthetic) | Synthetic barium sulphate<br>CAS No: 7727-43-7 | 10,000 – 100,000 |
| PW22 | Barytes (natural barium sulphate) | Natural barium sulphate<br>CAS No: 7727-43-7 | 10,000 – 100,000 |
| PW23 | Alumina blanc fixe | Aluminium hydrate, barium sulphate; coprecipitate of ca. 25% aluminium hydroxide and 75% barium sulphate<br>CAS No: 21645-51-2<br>CAS No: 7727-43-7 | 1,000,000 – 10,000,000<br>10,000 – 100,000 |
| PW24 | Aluminium hydroxide | Aluminium hydroxide<br>CAS No: 21645-51-2 | 1,000,000 – 10,000,000 |
| PW24 | Gibbsite (natural form of aluminium hydroxide) | Natural aluminium hydroxide with varying amounts of basic aluminium sulphate<br>CAS No: 21645-51-2 | 1,000,000 – 10,000,000 |
| PW25 | Gypsum | Hydrated calcium sulphate<br>CAS No: 91315-45-6<br>CAS No: 10101-14-4 | Not registered<br>(Annex V exemption) |
| PW26 | Talc | Mixed hydrated silicate of magnesium with varying impurities of calcium, iron and other compounds<br>CAS No: 14807-96-6<br>CAS No: 8005-37-6 | Annex V exemption |

| Table 9–3: Registration tonnages for alternative white pigments | | | |
|---|---|---|---|
| **Colour Index generic name** | **C.I. Common or Historical Name** | **Chemical composition** | **REACH registration tonnage (t/y)** |
| PW27 | Silica | Two types:<br>Hydrous = diatomaceous earth;<br>Anhydrous = silica<br>Silicon dioxide<br>CAS No: 7631-86-9 | Annex V exemption |
| PW28 | Calcium silicate | Calcium metasilicate;<br>Calcium silicate;<br>CAS No: 10101-39-0<br>CAS No: 10101-41-4<br>CAS No: 13397-24-5<br>CAS No: 26499-65-0 | Annex V exemption |
| PW28 | Hydrated calcium silicate | Hydrated calcium silicate | Not registered (Annex V exemption) |
| PW 30 | Lead phosphate | Trilead bis(orthophosphate)<br>CAS No: 7446-27-7 | Not registered |
| PW32 | Zinc phosphate | Trizinc bis(orthophosphate)<br>CAS No: 7779-90-0 | 10,000 – 100,000 |
| PW33 | Calcium sulphoaluminate | Calcium sulphoaluminate | No data |



Finally, availability also needs to reflect the approval status of the different pigments. $TiO_2$ holds approvals which other pigments do not. For instance, $TiO_2$ is the only white pigment which is allowed for use as a colouring agent in pharmaceuticals. For foodstuff, the only other approved colourant is calcium carbonate (E170) but is used in different applications to $TiO_2$ (see also discussion below as well as in Section **Errore. L'origine riferimento non è stata trovata.**); any other alternative pigment, if there is one to be found, would have to go through a long authorisation process for food additives. This process would take years. Similarly, $TiO_2$ has specific approvals for use in cosmetics products[81] and packaging (plastic) materials.

## 9.4 Information from consultation

**Table 9–4** summarises information on specific alternatives that has been collected during the first round of consultation with downstream users. This information confirms that no alternative appears feasible as a substitute for $TiO_2$. The table also includes some information available on the ECHA website from the public consultation on the proposed classification for $TiO_2$. It is worth noting that an assessment of alternatives specific relevant to plastics has been provided by EuPC and has been incorporated into Section 4.5.2.

81 Zinc oxide is approved for use in UV sun screens but it contributes mainly to UVA protection in contrast to $TiO_2$ which protects against UVB radiation and is a major contributor to high Sun Protection Factors (SPF).

| Table 9–4: Overview of characteristics of potential alternatives identified through consultation | | |
|---|---|---|
| **Potential alternative** | **Assessment of the alternatives** | **Example applications** |
| Zinc oxide (ZnO)<br>*EC / List no.: 215-222-5*<br>*CAS no.: 1314-13-2* | ZnO is generally suitable only for 'niche' applications, such as hobby and artistic use or cosmetics.<br>**Technical feasibility**:<br>- ZnO has worse refractive index and durability, thus a much higher amount is needed due to lower covering ability and opacity (opacity is 5 times lower);<br>- ZnO has worse weatherability and stability against yellowing (in plastics) due to lack of UV stability compared to $TiO_2$;<br>- ZnO can cause thickening when used in water based paints;<br>- In sun-care products nano ZnO is permitted now in the EU and in some other regions around the world but is not as easy to formulate with and fewer grades are available. ZnO contributes mainly to UVA protection (in contrast to $TiO_2$ which is a major contributor to the SPF) and has poorer performance against UVB radiation; sunscreens would require increased dosages thus their formulations would cost more, and would be undesirably whiter on the skin;<br>- In other cosmetics, ZnO is not as good for coverage of the skin and it cannot produce pearl effect pigments; only $TiO_2$ can be used for such applications<br>**Economic feasibility**:<br>- ZnO is lower cost but less efficient than $TiO_2$, thus not cost effective;<br>- ZnO's price depends on zinc price and this can be volatile;<br>**Availability**:<br>- ZnO is readily available but in tonnages far lower than $TiO_2$;<br>**Risk reduction**:<br>- Harmonised classification of H400/H410 (aquatic toxicity 1, acute and chronic) means that it has been replaced by $TiO_2$ in many applications;<br>- Zinc is subject to migration limits under Annex II of the Plastics Regulation 10/2011, and can therefore not be used in unlimited quantities | Cosmetics<br>Plastics<br>Paints<br>Coil coatings<br>Sealants<br>Wallcoverings |

| Table 9–4: Overview of characteristics of potential alternatives identified through consultation | | |
|---|---|---|
| **Potential alternative** | **Assessment of the alternatives** | **Example applications** |
| Zinc sulphide (ZnS)<br>*EC / List no.: 215-251-3*<br>*CAS no.: 1314-98-3* | In a very few applications ZnS is used instead of $TiO_2$, whenever the abrasion of $TiO_2$ is too high. However it is accompanied by several disadvantages:<br>**Technical feasibility**:<br>- ZnS is inferior for colour and opacity properties and is not suitable for thin thickness applications (such as 1-3 µm in printing inks);<br>- ZnS requires higher dosages;<br>- ZnS degrades upon exposure to UV light, leading to darkening of the pigment (in plastics it causes "zinc burn"); and<br>- ZnS shows poor weathering properties (hydrolysis)<br>**Availability and economic feasibility**:<br>- As there is only one producer in the world, the whiteness and opacity is lower and the price is several times higher, ZnS is no alternative for the majority of $TiO_2$ applications. Price would likely rise further if $TiO_2$ became unavailable<br>**Risk reduction**:<br>- According to the notifications provided by companies to ECHA in REACH registrations no hazards have been classified, but there are concerns over releases of zinc to the environment;<br>- ZnS may be undesirable due to the presence of sulphur. It is also known to display biocidal (antimicrobial) properties in its nano-form<br>- Zinc is subject to migration limits under Annex II of the Plastics Regulation 10/2011, and can therefore not be used in unlimited quantities | Wallcoverings<br>Paints & coatings<br>Printing inks<br>Plastics |
| Barium sulphate ($BaSO_4$)<br>*EC / List no.: 231-784-4*<br>*CAS no.: 7727-43-7* | $BaSO_4$, as well as other fillers such as talc and kaolin (see below), can replace certain amounts of $TiO_2$ in formulations, but never the entire loading of $TiO_2$.<br>**Technical feasibility**:<br>- $BaSO_4$ produces a good white shade, but has very poor opacity. Similarly, limestone fillers are brighter white than the average quarried product, but cannot approach the impact of $TiO_2$;<br>- $BaSO_4$ has a very high specific gravity and has a tendency to form a hard settlement in (paint) cans;<br>**Economic feasibility**:<br>- It is less costly than $TiO_2$ but due to poor hiding power a higher dosage is required thus resulting in a higher cost than $TiO_2$ (a ten-times higher loading is required to obtain a nearly comparable result);<br>**Availability**:<br>- Market availability is good but still far lower than $TiO_2$;<br>**Risk reduction**:<br>- According to the notifications provided by companies to ECHA in REACH registrations no hazards have been classified. However, it contains a heavy metal which industry is generally moving away from (still, $BaSO_4$ has a low water solubility);<br>- Barium is subject to migration limits under Annex II of the Plastics Regulation 10/2011, and can therefore not be used in unlimited quantities | Paints<br>Road marking paints<br>Plastics<br>masterbatches |

| Table 9–4: Overview of characteristics of potential alternatives identified through consultation | | |
|---|---|---|
| **Potential alternative** | **Assessment of the alternatives** | **Example applications** |
| Lithopone: mixture of barium sulphate and zinc sulphide ($BaSO_4/ZnS$)<br>*EC / List no.: 231-784-4/ 215-251-3*<br>*CAS no.: 7727-43-7/ 1314-98-3* | Also known as C.I. Pigment White 5, lithopone is a mixture of inorganic compounds, widely used as a white pigment powder. It is composed of a mixture of barium sulphate and zinc sulphide.<br>**Technical feasibility**:<br>- Lithopone is essentially an extender. It can be used as cheaper alternative, but only for low cost end products;<br>- Lithopone offers only $^2/_3$ of $TiO_2$'s opacity/hiding power and not the same level of whiteness;<br>- It is unsuitable for exterior use (paints) due to relatively poor weatherability;<br>- It offers no resistance to UV radiation and thus inferior lightfastness;<br>**Economic feasibility**:<br>- It is moderately expensive;<br>**Availability**:<br>- Market availability is good but still far lower than $TiO_2$;<br>**Risk reduction**:<br>- Components not classified for hazards, but there are concerns over releases of zinc and heavy metals to the environment | Paints<br>Coil coatings<br>Wallcoverings |
| Kaolin (white clay or China clay, $Al_2Si_2O_5(OH)_4$)<br>*EC / List no.: 310-194-1*<br>*CAS no.: 1332-58-7* | As discussed for $BaSO_4$ above, kaolin can replace certain amounts of $TiO_2$ in a formulation, but never the whole amount of $TiO_2$.<br>**Technical feasibility**:<br>- Lower technical performances (opacity), i.e. less whitening capacity compared to $TiO_2$;<br>- White dispersions contain a reduced amount of $TiO_2$, but also contain glycols and reduce the solids content leading to shrinkage (in sealants);<br>- Dispersions need agitation to prevent settling;<br>- Calcined kaolin has improved whiteness but still can only be used as a $TiO_2$ extender rather than a full replacement;<br>- In gelatine glues, it is possible to use kaolin. This however gives different colour, rheology and viscosity. Especially where colour and viscosity are key, $TiO_2$ should be used. In dispersion glues (which are similar to paints), $TiO_2$ gives a form of white colour so it can be used as a base for colouring. Neither kaolin nor any other alternative can be used;<br>**Economic feasibility**:<br>- No data;<br>**Availability**:<br>- No data (but see discussion on the wide availability of this mineral);<br>**Risk reduction**:<br>- According to the classification provided by companies to ECHA in CLP notifications this substance causes serious eye irritation and causes skin irritation | Rubber<br>Adhesives<br>Sealants<br>Paints & coatings<br>Road marking paints |

**Table 9–4: Overview of characteristics of potential alternatives identified through consultation**

| Potential alternative | Assessment of the alternatives | Example applications |
|---|---|---|
| Calcium carbonate ($CaCO_3$) and Precipitated Calcium Carbonate (PCC)<br>*EC / List no.: 207-439-9*<br>*CAS no.: 471-34-1* | Calcium carbonate is used as $TiO_2$ extender to reduce, but not eliminate, the presence of $TiO_2$.<br>**Technical feasibility**:<br>- Lower technical performances (opacity is 5 times lower), i.e. less whitening capacity compared to $TiO_2$, it may be used in isolation to form a rudimentary white paint;<br>- Calcium carbonate also tends to be greyish white versus $TiO_2$ which is a bright white;<br>- Poor application properties (especially for thin layers, e.g. in printing inks), low gloss and poor wet and dry hiding characteristics;<br>- No UV resistance performance;<br>- Low stability in the presence of acids (see also food applications below);<br>- $CaCO_3$ is not easy to spray on capsules as the spray solution becomes very thick / viscous and clogs up the equipment<br>- Calcium carbonate (E170) is also authorised under the EU Additives Regulation (EC) No 1333/2008 at Annex II for use as a Group II food colour which may be used in most foods at *quantum satis* and it is considered to be safe. However its value as a food colour is limited because it has poor or no functionality in many food applications: (a) As well as being a much less effective white colour than $TiO_2$, it will readily react with any acids present in foods to generate carbon dioxide and a (possibly soluble) calcium salt with no white colouring properties; (b) It could not be used as a colour in any foods with low pH as it would neutralise the acid present, adversely affecting the product flavour, quality and possibly shelf life; (c) It also could not be used as a white colour in cake batters, scone doughs, etc. since it would interfere with the raising agent system; (d) Calcium carbonate could not be used as a replacement to produce white glitter powders since E555 (Potassium aluminium silicate - mica) is only authorised for use as a carrier for titanium dioxide (and E172 iron oxides which produce red/brown colour glitter powders); (e) It is normally used in foods to function as an acidity regulator, anticaking agent, stabiliser or nutrient source (of dietary calcium) rather than as a colour. It is also used as a firming agent in many canned or bottled vegetable products.<br>**Economic feasibility**:<br>- Less costly than $TiO_2$;<br>**Availability**:<br>- Widely available in quantities larger than $TiO_2$;<br>**Risk reduction**:<br>- According to the classification provided by companies to ECHA in REACH registrations this substance causes serious eye damage, causes skin irritation and may cause respiratory irritation;<br>- The use of $CaCO_3$ also has a potential health impact since the calcium would contribute to the total intake of calcium in a day (through foodstuff, food supplements or pharmaceuticals). Some individuals are affected adversely by increased calcium intake. $TiO_2$ is not absorbed in the GI tract, so has no adverse health impact | Decorative paints<br>Flooring and wall paints<br>Rubber<br>Cosmetics<br>Food<br>Pharmaceuticals |

| Table 9–4: Overview of characteristics of potential alternatives identified through consultation | | |
|---|---|---|
| **Potential alternative** | **Assessment of the alternatives** | **Example applications** |
| Trilead bis(carbonate) dihydroxide (white lead $2PbCO_3 \cdot Pb(OH)_2$)<br>*EC / List no.: 215-290-6*<br>*CAS no.: 1319-46-6* | White lead was used in the past, but is no longer used, because of its heavy metal content.<br>**Technical feasibility**:<br>- It is an effective white pigment with excellent whiteness and opacity;<br>**Economic feasibility**:<br>- No data;<br>**Availability**:<br>- Very low;<br>**Risk reduction**:<br>- According to the classification provided by companies to ECHA in REACH registrations. this substance may damage fertility or the unborn child, is very toxic to aquatic life with long lasting effects, is harmful if swallowed, is harmful if inhaled and may cause damage to organs through prolonged or repeated exposure | Paints<br>Wallcoverings |
| Zirconium oxide ($ZrO_2$)<br>*EC / List no.: 258-784-7*<br>*CAS no.: 53801-45-9* | $ZrO_2$ can be used as opacifying agent in frits | Frits |
| Cerium Oxide (CeO)<br>*EC / List no.: 234-374-3*<br>*CAS no.: 11129-18-3* | Both are less efficient and more expensive as heat stabilisers with limited availability | Silicone rubber |
| Carbon black (C)<br>*EC / List no.: 215-609-9*<br>*CAS no.: 1333-86-4* | | |
| Antimony oxide ($Sb_2O_3$)<br>*EC / List no.: 215-175-0*<br>*CAS no.: 1309-64-4* | **Technical feasibility**:<br>- Good opacity and hiding power but worse than $TiO_2$. The substance is also expensive and quite soft, making it unsuitable for areas prone to wear and tear;<br>**Risk reduction**:<br>- According to the harmonised classification and labelling (CLP00) approved by the European Union, this substance is suspected of causing cancer (H351) | Paints<br>Coil coatings |
| Aluminium oxide ($Al_2O_3$)<br>*EC / List no.: 215-691-6*<br>*CAS no.: 1344-28-1* | $Al_2O_3$ like $TiO_2$ may be used in Selective Catalytic Reduction (SCR) catalysts. Compared $Al_2O_3$, $TiO_2$ has the technical advantage that it is a sulphur-resistant carrier material. In addition, process efficiency would drop dramatically (in a range of 4 or 5). Strong investments would be required to maintain current production | Catalysts |
| Aluminium hydroxide ($Al(OH)_3$)<br>*EC / List no.: 244-492-7*<br>*CAS no: 21645-51-2* | Much lower opacity than $TiO_2$ or almost full transparency (depending on binder system) | Pigment formulations |

| Table 9–4: Overview of characteristics of potential alternatives identified through consultation | | |
|---|---|---|
| **Potential alternative** | **Assessment of the alternatives** | **Example applications** |
| Bismuth chloride oxide (BiClO)<br>*EC / List no. : 232-122-7*<br>*CAS no.: 7787-59-9*<br>Tin oxide ($SnO_2$)<br>*EC / List no.: 242-159-0*<br>*CAS no.: 18282-10-5* | Only suitable for special applications such as hobby and artistic use | Artists' paints |
| Organic UV filters | $TiO_2$ could be replaced in sunscreens by organic filters (avobenzone, EHT, Tinosorb® S and others).<br>**Technical feasibility**:<br>- Unstable to light and can complex leading to a reduction of UV protection;<br>- Some are vegetable extract and plant active but their efficacy and safety are not as good as $TiO_2$ (or ZnO);<br>**Economic feasibility**:<br>- Organic UV filters are costly;<br>**Availability**:<br>- Only a few manufacturers of these ingredients exist;<br>**Risk reduction**:<br>- These materials are synthetic and can penetrate the skin exposing the user to long-term unknown health risks<br>- May cause pollution when washed out in the sea | Cosmetics |
| Optical brighteners | The paper industry uses optical brighteners in order to reduce (but not eliminate) the consumption of $TiO_2$ | Paper |
| Alternative photocatalytic materials | **Semiconductors**: there are known semiconductors which show certain photocatalytic activities as well, but they are much costlier and they would show similar health risks due to their similar chemical and physical structures<br>**Air clearing devices**: photocatalytic surfaces containing $TiO_2$ might be replaced by air clearing devices; they come with a cost for acquisition, electricity and filter media, operating noise and waste production (e.g. used filter media)<br>**More frequent cleaning**: as to the self-cleaning properties of $TiO_2$-based surfaces, these might be replaced by cleaning materials and frequent cleaning efforts, with the disadvantages of running costs and potential environmental pollution<br>**Biocides**: as to the prevention against algae and mould, $TiO_2$-based products might be replaced by several biocides with harmful components, with the disadvantages of costs for application and maintenance, and environmental pollution | Photocatalysts |
| Opaque Polymer Systems | Widely marketed as $TiO_2$ extenders under various trade names, these are easy to handle, relatively cost effective, and have little impact on application properties. They are not capable of delivering an opaque paint system in isolation or in combination with any of the above technologies, thus they do not allow the complete replacement of $TiO_2$ | Paints |
| Steel | Steel is relevant to the hot water tank industry: all tanks are internally coated with porcelain enamel for water contact. Enamelled tanks might be replaced by steel tanks, however the use of stainless steel would be unaffordable | Porcelain enamels |

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