Titanium Dioxide
Forum Notes

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Titanium Dioxide Pigment (TiO$_2$) – Confidential

Introduction

The following document provides a summary of the WSL/BPF forum which presented an overview of the current European regulatory analysis of titanium dioxide (TiO$_2$) pigment. The document has been prepared by the forums speaker;

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Initial Consideration

Please consider when reading this document that no decision is yet final and communications with authorities continues across Europe. Industry cannot guarantee any outcome, yet it may provide input which could yet help influence the decision-making process and any future obligations which may enter into discussion. As the process and communications remain fluid, discretion is asked for regarding onward distribution of the information provided.

The information given is presented in good faith and is believed to be correct. This document makes no representation as to the accuracy and/or completeness of this information. This information is issued on the condition that the user will determine the safety and suitability of TiO$_2$-containing products for their purposes prior to use.
What Is Titanium Dioxide?

Titanium dioxide is a substance primarily manufactured for use as a pigment across a wide range of sectors on a global basis. Europe has a broad manufacturing base for TiO₂ covering seven companies across eighteen manufacturing sites within the European Economic Area (EEA). These sites have a manufacturing capacity of approximately 1,100 ktonnes per annum with 21% of this capacity manufactured directly in the UK.

The plastics industry is the second largest sector for consumption of TiO₂, accounting for approximately 25% of volume usage.

Why Use Titanium Dioxide in Plastics?

TiO₂ is a white pigment, which has no equal. In addition to its high levels of clean, bright whiteness, the substance affords other properties and benefits including;

✓ Excellent levels of opacity (covering capability, lack of transparency)
✓ Excellent outdoor weathering protection from harmful ultraviolet (UV) rays
✓ Chemical inertness
✓ Thermal stability
✓ Ease of application and stability during varied modes of end use process technique
✓ Non-flammable
✓ Colour retention aids recycling
✓ Non-toxic

The range of benefits listed above permit use in a variety of polymers, process types and many applications - which include for example; construction, automotive, marine, medical, fashion, furniture, leisure goods, electrical items, coatings and packaging to name but a few.
The use is not limited to white-coloured articles, for TiO$_2$ will often be used as a pigmentary base in a vast range of shades across the colour spectrum.

Concentration levels within a formulation will vary greatly depending upon final application and specific technical demands. Should you consider 1 tonne of TiO$_2$ may account for 20 tonne of plastics compound, this 20 tonne of compound may be converted into thousands of articles for which each in turn can be components used yet more complex final articles - the importance in application of the substance should therefore not be underestimated.

**Regulatory Process & Re-Classification – Background**

In 2013, TiO$_2$ was proposed for toxicological review by the French Member State Competent Authority known as ANSES. It was initially thought that the French may have been targeting nano-particles, which are falling under increasing scrutiny and as selected grades of TiO$_2$ are specifically manufactured as a nano-particle substance.

The volumes of TiO$_2$ specifically manufactured as nano-particles are very limited, accounting for circa 2% of manufactured volume and their use is limited to a small range of applications. Nano-particle forms are not used as pigments within the plastics industry, however a small percentage of content may fall under the nano-particle sizing band. In all cases, a distribution of size will occur as can the possibility of particle agglomeration.

A *nano-particle* TiO$_2$ would have an average (d50) particle size typically less than 0.10µm (100nm).

A *pigment grade* TiO$_2$ would have an average (d50) particle size typically in the range of 0.20 to 0.35µm (200 to 350nm).

Despite pigment grades falling above nano-particles by definition, it is generally considered that particles less than 10µm may be fine enough to be inhaled deep within the human respiratory system.

For comparison: how fine is 10µm?
Following a long term study by ANSES, in May 2016 they submitted a dossier of 159 pages to the European Chemicals Agency (ECHA) proposing that the hazard classification be changed from non-hazardous to –

**Class 1B Carcinogen via Inhalation**

**Hazard code H350i**

**Hazard Statement – May cause cancer via inhalation**

Their justification for this proposal centred upon toxicological studies that showed evidence of lung tumours in rats when exposed to inhaled quantities of TiO$_2$. Furthermore, as TiO$_2$ is used in many sectors, many of which may be later used by consumers, the volume and dispersive use was deemed high.

A public consultation was opened by ECHA enabling industry and other interested parties to submit their views as to the proposal. A submission was made and at a later date, the feedback from all entrants was obtained for analysis. The feedback consisted of 406 pages, with 311 submissions to the general response and 203 submissions with specific reference to carcinogenicity.

Of the 311, there was clear majority against or questioning the proposal. One submission was in support and twelve were listed as confidential.
On considering the response by region, the UK demonstrated positive levels of feedback to the consultation. It is however, advised that more companies consider submission during these periods within the regulatory process.

The response also demonstrated that whilst the regulation stems from European controls, lands far beyond the EU took interest and submitted views against or questioning the proposal.

On considering the response by sector, the plastics sector (as a consumer of circa 25% capacity) reflected the level of input in being the second largest identified market sector to submit responses.

Five Member States also made direct input to the public consultation with questioning of the classification. This questioning asked if a reduced severity should be considered (Class 2) and whether additional thought should be given to the manufacturing route (rutile vs. anatase), particle structure and surface coatings.
Prime Manufacturers Response

The primary manufacturers of TiO$_2$ joined together under one banner for the defence of TiO$_2$. The organisation is termed as the Titanium Dioxide Manufacturers Association (TDMA) and they are co-ordinated by Cefic in Brussels.

The TDMA set about a program of response which has included –

- Advocacy across Europe Member States
- Advocacy at EU Commission level
- Scientific study of use and risk management
- Epidemiology study of TiO$_2$ production plant workers
- Analysis of studies used to propose classification change
- Analysis of impact assessment

In November 2016, the TDMA organised a scientific forum to review several aspects of the process and toxicology. The forum was attended by approximately 100 interested parties, including ANSES.

The two-day forum discussed the following –

- Inhalation toxicology and carcinogenicity (poisons and cancer)
- Mechanism of action and pathology (cause and effect of disease)
- Occupational exposure limits
- Epidemiology (incidence and control of disease)
- Genotoxicity (damage to or mutation of DNA)

During the discussions, two of the primary studies used by ANSES were questioned.

The studies referred to are -


Both studies were performed on rats and questions were asked as to the relevance to humans.

Consideration was given to the basis that rats are more susceptible to respiratory issues than other rodent species and in one report female rats were used, which in turn can be questioned as being more susceptible than male rats. The levels of exposure were also questioned as levels included studies at excessive over exposure which created lung overload and is not considered representative of the levels found
in industry.

During both studies, evidence of an increased risk of lung tumour were identified, however the tumours were diagnosed as being caused via attrition, chronic inflammation of the tissue and oxidative stress. No chemical response was found and there was no indication of tumour via ingestion or dermal contact.

As the cause is considered mechanical rather than chemical, TiO$_2$ has been referred to as a Poorly Soluble Low Toxicity (PSLT) substance. Other fine particulate substances may also be considered as a PSLT and the potential TiO$_2$ reclassification may set a precedent for future chemicals classification if adopted.

The TDMA also undertook a review of epidemiology data relating to circa 24,000 workers based within the manufacturing of TiO$_2$ across Europe and the USA. The studies covered in excess of 50 years of human data; throughout, no evidence was identified to demonstrate a link between TiO$_2$ handling and increased risk of lung tumour in humans.

**UK Plastics Use by Industry – Workplace Exposure Limit**

When we consider use of TiO$_2$ in plastics, the use is primarily found in industrial environments. Industry is known to adopt high levels of risk management when handling powders and engineering aspects such as automation, area enclosure and dust extraction are commonplace across our industry. Furthermore, not all users handle TiO$_2$ in an inhalable format (e.g. masterbatch, compounds, dispersions etc.) and as such a blanket approach to classification may cause undue concern within the supply chain.

One mode of assessing dust levels within the working environment is via dust in air monitoring. The UK department, the Health and Safety Executive (HSE), has for many years approached many powder based materials with additional checks to control airborne powder and risk of inhalation. Titanium dioxide has (independent from the current proposals by ANSES) UK based Workplace Exposure Limits in place when this substance is handled in an industrial environment. The levels are found in the HSE document EH40/2005 and are –

- **Inhalable fraction** 10 mg/m$^3$ 8hour time weighted average
- **Respirable fraction** 4 mg/m$^3$ 8hour time weighted average

It is advised that all companies handling TiO$_2$ ensure compliance with the Workplace Exposure Limits and also consider a review of handling practice and worker protection to ensure exposure risk is managed to the highest levels.
European Risk Assessment Committee (RAC)

The RAC are a European committee of scientific experts who prepare opinions of ECHA relating to human health and environment. The RAC includes representatives from all European member states. Their discussions focus upon the hazard nature of a substance without reference to commercial implication.

1st June 2017 – the RAC reviewed TiO₂ and agreed the substance did not meet the hazard criteria for Class 1B classification.

8th June 2017 – the RAC reviewed TiO₂ and agreed the substance did meet the hazard criteria for Class 2 classification.

The proposal of the RAC was to re-classify TiO₂ with the hazard classification –

Class 2 Carcinogen via Inhalation

Hazard code H351 (inhalable)

Hazard Statement – Suspected of causing cancer via inhalation

Concern was raised by industry that whilst this offered a reduction of severity to the initial proposal, many will focus on the word cancer without examining the broader background to the classification.

Mid-September 2017 - the RAC adopted their opinion which was then formally published in October 2017.
RAC – Key Findings

Whilst the document is publicly available, the key findings identified include the following –

- TiO$_2$ was not shown to be a multisite carcinogen (i.e. affects lungs only)
- TiO$_2$ is a lung carcinogen especially in female rats
- There are no robust carcinogenicity studies in species other than rats
- Rat lung tumours only developed under inhalation exposure conditions associated with marked particle loading of macrophages
- Lung tumour development (mutagenicity in lung cells is considered to depend on chronic inflammation and oxidative stress) – reference made to the Alveolar Duct region of the respiratory system
- there is no experimental evidence for TiO$_2$ carcinogenicity for the oral or dermal route of application
- Alveolar clearance half-times measured in different studies at the exposure level of 250 mg/m$^3$ reached and exceeded 1 year..... represent excessive exposure which invalidates the results of the Lee et al.
- the carcinogenicity profile described for TiO$_2$ is not exclusively characteristic for TiO$_2$ but applies to a group of chemicals with similar toxicity profile addressed as “poorly soluble low toxicity particles”
- entry in Annex VI of CLP: “Titanium dioxide” (without a further physico-chemical description) is proposed to be used as chemical name (international chemical identification). The CAS number to be used is 13463-67-7
- If the substance is placed on the market as particles of the substance fulfilling the WHO fibre criteria or as particles with surface coating their hazardous properties must be evaluated in accordance with CLP Title II to assess whether a higher category (Carc. 1B or 1A) and/or additional routes of exposure (oral or dermal) should be applied

Continued Advocacy

Following the RAC adoption and formal release of their proposal, the TDMA initiated a further review meeting held (mid-October 2017). WSL/BPF were once more in attendance.

On 10$^{th}$ November 2017, a meeting was arranged with selected members of the UK Competent Authority team (HSE/BEIS).

The meeting was represented by industry from WSL/BPF, the BCF (British Coatings Federation) and the TDMA.
The discussion centred upon concerns of industry as to how classification change may impact upon industry, trade, technology and consumer choice.

During the meeting, results of the 2017 BPF survey on TiO₂ were presented and summarised as follows –

✓ Key processes, formats and final applications covered
✓ Circa 85% have used TiO₂ at their site in excess of 20 years
✓ Circa 45% have handled greater than 5,000t (70% >1,000t)
✓ Circa 70% of sites have at least one production staff member with over 20 years of service
✓ No site reports requiring respiratory medical treatment associated to TiO₂
✓ Circa 35% of sites primarily handle powder
✓ Circa 60% primarily zero dust formats
✓ Circa 60% of exposure is <1hour per day (90% <4hours)

The primary aim of the data was to demonstrate long term, safe use across the British plastics industry.

Additional discussion then included detailed reference of the risk management procedures found across UK industry combined with the lack of downstream consumer exposure due to the substance encapsulation within the polymer matrix.

The technical importance of TiO₂ combined with lack of suitable alternatives was raised as was concerns for perception within employees and downstream consumers which may require considered and timely communication management to prevent undue fears.

The discussions were well received and industry representatives considered the feedback unbiased, fair and constructive.

On 15th/16th November, a meeting of the European committee known as CARACAL took place. The CARACAL comprises of member state representatives and advises the EU Commission and ECHA on matters relating to REACH and CLP regulations.

Whilst no formal minutes are published by the CARACAL, it is understood that input from across Europe has been considered alongside the RAC proposal and a willingness to allow further review of use and implications will be considered.

Whilst no guarantee on any outcome can be certain, this is an opportunity for industry to offer additional input for review which may help aid the decision process of the authorities.
Currently, if adopted and without derogation, labelling obligations would apply to all raw and intermediate supply formats greater than 1% content up to point of article manufacture.

The next CARACAL meeting is scheduled for March 2018.

What input can the UK Plastics Industry provide?

1. Demonstration of voluntary guidance and safe use.
   Rather than simply state industry does a good job regarding safe handling, it will be beneficial to demonstrate a proactive stance as to self-questioning and re-assessment of current handling if nothing more than for confirmation of good practice. Whilst no individual site data will be submitted, a document will be prepared on behalf of the BPF to review Safe Handling Guidance specific for TiO₂. Should sites be willing to submit specific data, for example dust in air monitoring data, this will help demonstrate good control and risk management.

2. Substitution – proof
   Whilst it has been stated that no suitable alternatives exist, authorities have asked for demonstration rather than statement. A list of potential substitutes has been proposed which Industry would consider as not suitable - can we prove it?

   The list of ‘substitutes’ includes; zinc oxide, zinc sulphide, barium sulphate, talc, calcium carbonate, kaolin and dolomite.

   Industry must consider what evidence can be put forward to demonstrate these are not considered suitable substitutes.

   This may include aspects relating to; handling, processing, chemical interaction, hazard, colour, opacity, weathering etc.

   It may also include aspects relating to; price, availability, cost of change, certification, guarantees etc.

   Each polymer and application may vary but it is asked what studies can Industry do to help their own future?

   By way of singular example and in taking an application known to many households – uPVC window profiles
If the above ‘substitutes’ were considered, what would be the affect upon….. –

✓ Rheology
✓ Processing
✓ Thermal stability (Static/Dynamic)
✓ Colour
✓ Mechanicals
✓ Weathering
✓ Market acceptance
✓ Pricing (indicative via BPF)
✓ Availability
✓ Accreditation

3. **Consumer Risk**

Are we able to demonstrate a lack of consumer risk? For example, whilst we would consider TiO$_2$ encapsulated once converted into an article, can we demonstrate a lack of free dust when considering aspects such as an article being; sawn, cut, drilled, sanded etc.?

Dust in air analysis next to a saw upon an extrusion line, or cutting blade upon a coating line, may help demonstrate a lack of free inhalable TiO$_2$ dust.

*Are members of Industry able to submit such data?*

When you consider encapsulation, manufacturers of articles may also wish to consider potential of future questioning by downstream customers of articles. A final article will not require labelling however by way of example, are companies prepared if later asked ‘does this article contain any hazardous, toxic or carcinogenic substances?’ Advance preparation of suitable response may be beneficial.

4. **Non-dusting formats**

There may be interest in allowing possible derogation of labelling for non-powder formats e.g. masterbatch/compounds.
The CLP – Regulation states that: “Metals in massive form, alloys, mixtures containing polymers and mixtures containing elastomers do not require a label according to this Annex, if they do not present a hazard to human health by inhalation, ingestion or contact with skin or to the aquatic environment in the form in which they are placed on the market, although classified as hazardous in accordance with the criteria of this Annex.”

(CLP-Regulation, Annex I CLASSIFICATION AND LABELLING REQUIREMENTS FOR HAZARDOUS SUBSTANCES AND MIXTURES, paragraph 1.3.4.1.)

There is however, concern raised by authorities as to pellet breakdown during handling which may create dust and therefore can safe use be assured?

The CLP Regulation states:

Article 12 Specific cases requiring further evaluation

Where, as a result of the evaluation carried out pursuant to Article 9, the following properties or effects are identified, manufacturers, importers and downstream users shall take them into account for the purposes of classification:

(a) adequate and reliable information demonstrates that in practice the physical hazards of a substance or a mixture differ from those shown by tests

(b) conclusive scientific experimental data show that the substance or mixture is not biologically available and those data have been ascertained to be adequate and reliable

A pan European study is under discussion to assess masterbatch stability. This will be co-ordinated by the European plastics association, the EuPC. Additional details will be provided separately.

In addition to granular masterbatch/compounds, similar derogation may also be considered for liquid phase TiO₂.
Such derogation may include dispersions, pastes or plastisols with consideration of alignment alongside that of paints.

Primarily, such liquid phase materials are poured, dosed, pumped or spread.

Some concern has been raised to lower level volumes, which may be sprayed, or also spilt products, which may then dry and cause dust if brushed as waste.

Additional consideration is being given as to how best demonstrate safe use which could include dust in air monitoring and demonstration of long term drying times at ambient temperature enabling ease of cleaning.

With reference to points 1 to 4 above, any input from UK Industry may help support the future of TiO$_2$ and aid the decision process by authorities. It is asked if any sites are willing to support by offering data?

**Should any site have interest in supporting TiO$_2$ by such means, please contact Matt Davies (BPF) directly.**

**Email** - mdavies@bpf.co.uk

**Waste**

There remains some uncertainty as to the impact upon waste stream from the disposal of waste packaging through to granulation and reuse of articles. Discussion with authorities will continue however if Class 2 is adopted, TiO$_2$ will not fall under the Carcinogen and Mutagen Directive.

Further information will be provided once greater clarity is known.

**BPF Literature**

Additional literature is or will become available from the BPF via Matt Davies. Literature will include –

- ✓ TiO$_2$ briefing document for senior managers and Health and Safety personnel
- ✓ Guidance document to aid site specific preparation of employee communications
- ✓ Guidance document to enable self-assessment of handling practice for TiO$_2$
- ✓ TiO$_2$ flyer to offer simple communication of substance properties and
use in plastics

Timeline

The next CARACAL meeting will take place in March 2018

A review by the European Committee to discuss implementation of agreed actions could occur Summer 2018

If a re-classification is adopted, implementation could occur by Q2, 2020

Timelines cannot be assured as many factors may intervene over the coming months as new data is presented or priorities change within authorities.

Please consider, nothing is yet certain, the situation is being closely monitored, communications continue and any new data from Industry may help better clarify or amend the views within authorities.

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