

TITANIUM DIOXIDE in Paint, Printing Inks and Artist colours The proposal by France to classify it as a carcinogen

An explanation for Members' customers for use by National Associations

- **What is titanium dioxide and why do we use it?**
 - Titanium dioxide (TiO₂) is a mineral, which is converted to be used as white pigment in various applications.
 - It is also used in the preparation of other colourants.
 - It is an essential raw material for the paint, coatings and ink industries, and is used in over 85% of our products. It provides key properties to the quality of our products, such as whiteness, opacity, brightness, protection from UV light, stability and durability. It is the most efficient and optimal way to provide an opaque white or coloured layer for decoration and protection for walls, metal objects, plastic films etc.
 - It is not only important for paint and printing ink but it is used in many other applications. The European Chemicals Agency ECHA¹ webpage indicates that it is present in many everyday articles².
 - There is no alternative that offers the same characteristics and advantages. .
- **Why are we talking about it?**
 - France through the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) has submitted a proposal to Europe under the CLP Regulation³ to classify TiO₂ (in all its forms) as a substance that has the potential to cause cancer in humans through inhalation (Category 1B) ;
 - ECHA opened a public consultation on this proposal on 31 May 2016, which will run for 45 days.
 - In 2009, the International Agency for Research on Cancer classified it as possibly carcinogenic to humans (*group 2B*) based on lung overload studies in rats.
 - As part of the implementation of the REACH Regulation, TiO₂ manufacturers provided various toxicological and epidemiological studies for the registration of this substance to the competent European authority (ECHA) in 2010. Robust information is available which concluded that specific classification (and therefore labelling) is not necessary for TiO₂. Our industry is convinced that the available evidence does not support the proposed classification proposal.

¹ European Chemical Agency responsible to coordinating the work under the chemical legislation REACH Regulation 2006/1907

² This substance can be found in products with material based on: plastic (e.g. food packaging and storage, toys, mobile phones), fabrics, textiles and apparel (e.g. clothing, mattress, curtains or carpets, textile toys), paper (e.g. tissues, feminine hygiene products, nappies, books, magazines, wallpaper), stone, plaster, cement, glass or ceramic (e.g. dishes, pots/pans, food storage containers, construction and isolation material), metal (e.g. cutlery, pots, toys, jewellery), wood (e.g. floors, furniture, toys), leather (e.g. gloves, shoes, purses, furniture) and rubber (e.g. tyres, shoes, toys)

³ Classification Labelling and Packaging of substances and mixtures Regulation 1272/2008

- There are studies available that show an effect in rats at high doses but this is not seen in other animal species such as the mouse and hamster. Most importantly, so far as we are aware, there is no evidence of effects in humans. The effect seen in the rat is believed to be a lung overload mechanism that is specific to the rat, which is not relevant for Human and not specific to TiO₂ i.e. similar effects would also be seen for other low solubility dusts.
- The vast majority of studies clearly show that TiO₂ is not carcinogenic to humans. The French Agency based its application on only two animal tests that were performed 20 to 30 years ago and which, moreover, brought contradictory findings. . Furthermore, the safety of TiO₂ is also confirmed by studies that stretched over several decades and involved ca. 20 000 workers at 15 production sites. No negative impacts on workers' health due to TiO₂ were found in these studies.
- **How could this affect our products?**
 - Besides the negative perception that the term 'carcinogen' brings, there would be legislative impacts on our products, including, for example, the potential of a ban on the sale of all TiO₂-containing products to the consumer.
 - Indeed, although the classification proposal is for TiO₂ as inhalable dust, it would affect liquid and paste-like products even though it is not available for exposure by inhalation from our products. This is the consequence of the EU chemical legislation, which is hazard based and not risk based. Nonetheless there is no evidence of risk in use of the products marketed by our sectors.
- **What can we do?**
 - CEPE, National Associations and Members will give input to the public consultation. Although it is in principle only opened to receive toxicological arguments on intrinsic properties, we will use that opportunity to send a first warning on the potential impact that such a classification would have on society and our industries.
 - The TiO₂ Manufacturers consortium (TDMA) will provide all required scientific arguments against the proposal and we are liaising and supporting TDMA, along with other industry associations
- **The next steps**
 - The French proposal will be discussed at EU level where all Member States' experts will be present. An official opinion from the RAC (the Risk Assessment Committee within ECHA) can be expected to be delivered by end 2017, early 2018. The opinion would then have to be endorsed by the EU Commission and be published.
 - We will work on further advocacy arguments to be shared with the appropriate authorities. CEPE has already provided input to the EU Commission's evaluation on whether the EU Chemical Legislation is fit for purpose and the case of TiO₂ was mentioned as an example of a chemical that could adversely suffer from unwanted and unnecessary consequences of a purely hazard based legislation.