

Status on the ongoing Classification and Labelling Harmonisation of TiO₂

16 March 2018

On 12 October 2017, the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) published its scientific [Opinion](#) recommending the classification of titanium dioxide (TiO₂) as a suspected carcinogen (cat. 2) by inhalation.

Since then, discussions have taken place between the European Commission, the Member States and interested parties on how the Opinion should be processed at a regulatory level given that this will likely set a precedent beyond TiO₂ and the CLP Regulation.

Simultaneously, the Titanium Dioxide Manufacturers Association (TDMA) has analysed the Opinion in depth and would like to emphasize the following important statements made by the RAC:

- There are no robust carcinogenicity studies in species other than rats (page 39 para 1).
- There are a number of open questions that are not clearly addressed in ECHA guidance documents (e.g. the use of rat data generated under conditions of lung overload for humans). These same uncertainties have also been raised by the European Commission in November 2017, as they submitted questions to the Competent Authorities for REACH and CLP (CARACAL).
- The carcinogenicity profile of TiO₂ is not a substance-specific intrinsic toxicity, and no primary genotoxicity is involved (see page 41, para 5). Instead, the carcinogenicity is a result of the physical “particle” effect (lung overload), common to many other substances described as “poorly soluble low toxicity particles” (PSLTs).

Given the uncertainty on some of the studies, TDMA is undertaking a major scientific programme that would address questions raised through this process so far. We are confident that when this state-of-the-art science programme is complete and presented, a different conclusion will be drawn.

The TDMA is committed to working with European and national authorities on this important matter to bring about meaningful and effective resolution of the regulatory questions raised by the RAC in their Opinion and reiterated by the European Commission.

About titanium dioxide

Titanium dioxide is by far the world’s highest volume and most versatile white pigment, and is used in the manufacture of a wide range of products including paints, coatings, plastics, paper and as a food colorant. In non-pigmentary form TiO₂ is used as a UV-filter in sunscreens and in many depollution technologies. Across the EU, the industry directly supports close to 23,000 jobs and hundreds of billions of Euros in added value. Titanium dioxide has been repeatedly examined and found safe by authorities around the world.

About TDMA

The Titanium Dioxide Manufacturers Association – TDMA - is a sector group of Cefic (the European Chemical Industry Council) and it represents the major producers of titanium dioxide (TiO₂) and acts as their responsible voice in Europe since 1974. TDMA promotes and defends the merits of titanium dioxide in all suitable applications by bringing forward evidence of its safety and efficacy. TDMA is a non-profit organisation and it has no commercial role. For all commercial enquiries, please refer to the websites of our members.

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