

Classification of titanium dioxide published in EU Official Journal

The European Union [published](#) on 18 February 2020 a delegated regulation classifying titanium dioxide (TiO₂) as a category 2 suspected carcinogen by inhalation under EU Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures.

This classification follows the opinion of the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) and is not based on any new scientific evidence or new understandings about potential harms. The text attempts to constrain the classification to a hazard associated with the inhalation of excessive volumes of unbound TiO₂ dust. This theoretical dust hazard is not new and critically it is not specific to TiO₂ but applies to more than 300 substances.

The Titanium Dioxide Manufacturers Association (TDMA) disagrees with the classification and has consistently made its views known throughout the regulatory discussion since 2017.

The opinion of the RAC itself is clear in stating that there are no robust carcinogenicity studies. The rat study relevance is unclear given the differences between rat and human lung function. Moreover, the RAC's opinion is contrary to the available data of more than 24,000 workers demonstrating there is no link between cancer in humans and exposure to TiO₂. TiO₂ has been safely used for over 100 years in a very broad array of beneficial products, many of which will now have to carry a hazard label despite there being no inhalation risk to consumers.

The EU attempted to limit the classification of TiO₂ to powders and the regulatory text refers to “powder TiO₂ and mixtures placed on the market in powder form containing 1% or more of TiO₂ which is in the form of, or incorporated in, particles”. Liquid and some solid mixtures are not classified, but specific warning statements and labels need to be applied to those that contain more than 1% of TiO₂. The classification further acknowledges that this hazard only occurs under prolonged inhalation exposure to very small TiO₂ particles at an extremely high concentration (Note W).

Unfortunately, the text of the entry introduces several new concepts and terms without providing any meaningful definitions or interpretative guidelines, opening the door to various interpretations. In addition, there is no precedent upon which stakeholders in the TiO₂ industry can rely in implementing the classification's requirements. The classification also introduces uncertainties in the treatment of waste containing TiO₂ that will need to be addressed and clarified.

The EU's decision will enter into force 18 months after the publication in the EU's Official Journal, and this time will be needed to attempt to address ambiguities created by the text.

