Titanium Dioxide
Members’ Brief
September 2017
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Introduction

Following the European Chemical Agency’s (ECHA) Risk Assessment Committee (RAC) opinion that titanium dioxide (TiO₂) should be classified as a category 2 carcinogen through respiratory inhalation¹ under CLP Regulation, the British Plastics Federation (BPF) has put together some questions and answers for members.

The ECHA Risk Assessment Committee agreed on the classification of TiO₂ as carcinogen category 2 by inhalation, despite the fact that there is a vast body of scientific evidence that does not support a classification of TiO₂ for humans, which is supported by over 50 years of epidemiological data on more than 24,000 workers and demonstrates there is no link between cancer in humans and exposure to titanium dioxide²:

Is there a risk of exposure from plastics products?

No.

The RAC opinion is specifically for the inhalation of TiO₂ in powder form – once bound within the polymer matrix, the article presents no risk to the consumer for exposure to titanium dioxide powder.

Are TiO₂-containing plastic products safe?

Yes.

All plastic products adhere to strict European and National regulations, including for food contact and consumer use. Furthermore, TiO₂-containing plastic products present no consumer health risk as the TiO₂ is encapsulated by the polymer, meaning the consumer has no contact with TiO₂ powder and the plastic products are therefore safe to use.

Is there a worker/environmental health risk?

TiO₂ dust exposure will only occur in the upstream process sectors of the plastics industry, namely the additives/masterbatch/compound areas. Therefore, for downstream users (i.e. moulders, packaging, recyclers) there is limited risk based on the proposed hazard classification; this risk may also be readily managed safely.
Manufacturers should be familiar already with Workplace Exposure Limits (WEL) under the Health & Safety Executive’s EH40/2005 Workplace exposure limits document. This contains exposure limits for various dusts, including TiO₂. As well as this, typical risk management measures used in industry to control/avoid exposure to dust (e.g. buying the additive already encapsulated in plastics, liquid masterbatches or compounds; closed systems for mixing to handling precautions; separate mixing rooms; local exhaust ventilation with filtration before release to the atmosphere; wearing of masks in specific loading and cleaning steps) should be observed as per regulations - this will ensure worker safety for those handling the material.

Furthermore, as TiO₂ has been suggested to be adopted as a category 2 carcinogen, the Carcinogen and Mutagen Directive (2004/37/EC) is not applicable.

European process following the decision

It is also important to note that at this moment in time the opinion of the RAC is a proposal, meaning no immediate changes to the supply chain (i.e. in terms of labelling) are required. The RAC together with ECHA shall now prepare a formal written proposal to be issued to the European Commission later this year. If accepted by the European Commission, a period will then follow whereby potential regulatory measures shall be evaluated. During this time, industry representatives will continue to communicate with members of the authorities to highlight the safe history of use in application that has existed for many years without need for additional classification. There could potentially be derogations from the labelling obligations for certain industries, if the Commission deems it necessary and that safe use is adequately demonstrated. The BPF are working together with other sectors of industry to propose automatic exemption from labelling obligations to non-dusting formats.

Potential classification and labelling for masterbatches & compounds

The classification and labelling of a plastic masterbatch and compounds as per CLP Regulation will depend on the concentration of TiO₂ contained within the products.

TiO₂ concentration in final articles will be dependent on the particular application, with levels between 1% and 30% (lower quantities are also observed).

Depending on the uses, contents of TiO₂ in pigment preparations range between 0.1% - 80% in masterbatches.
A classification of a substance as carcinogen 2 by inhalation provides a labelling obligation under the CLP Legislation if the sum of a mixture’s ingredients that carry this classification are equal to or greater than 1% in concentration. Companies may have an opportunity to derogate from this labelling obligation if there is sufficient evidence that the product as placed on the market does not pose a hazard to human health (see Annex I: 1.3.4. of the CLP Regulation).

What science is the ruling based on?

It is important to note that highly respected members of the independent scientific community have analysed the laboratory data used in the RAC proposal for TiO$_2$. It has been observed that the data showing risk of lung tumour relates to studies in rats at extreme levels of lung overload. The historic studies referred to adopted levels of exposure far in excess of an industrial working environment and were also found to be unique in impact when assessing rats. Other species did not indicate the same risk of lung tumour and the relevance to humans, therefore, has been questioned. Tests for cancer via ingestion or through skin contact all proved negative i.e. no risk was identified.

Background Information

“TiO$_2$ is used mainly as a white pigment, brightener or opacifier in most plastics applications. It also provides excellent UV stability important for outdoor applications.

In the plastics converting industry, most of the applications contain TiO$_2$ substance. The European plastics converting industry turnover is estimated at €280 billion (Eurostat 2014). The impact upstream is not taken into account here but as an order of magnitude the whole plastics supply chain consolidated turnover in Europe is estimated at €350 billion (including polymer producers).

It is estimated that almost all the 50,000 companies in the plastics converting sector in Europe, mainly SMEs, may be potentially impacted in case the availability of titanium dioxide would become uncertain.

In the plastics industry, exposure is effectively controlled today; there are currently no alternatives with the same properties and those alternatives may not be better from environment or health point of view.” – EuPC Executive Summary

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