



EuPC statement on TiO₂ potential classification. For CARACAL meeting of 15 and 16 November 2017

Brussels, 10 November 2017

EuPC is the leading EU-level Trade Association, based in Brussels, representing European Plastics Converters. EuPC now totals about 51 European Plastics Converting national and European industry associations, it represents close to 50,000 companies, producing over 45 million tonnes of plastic products every year. The European plastics industry makes a significant contribution to the welfare in Europe by enabling innovation, creating quality of life to citizens and facilitating resource efficiency and climate protection. More than 1.6 million people are working in about 50,000 companies (mainly small and medium sized companies in the converting sector) to create a turnover in excess of 280 billion € per year.

EuMBC (European Masterbatchers and Compounders) is an association representing more than 70% of the masterbatches and compounds manufactured in Europe. EuMBC is a sector group of EuPC (European Plastics Converters).

Message :

Classification of TiO₂ is not appropriate and contradicts the principle of proportionality :

- **It would lead to disproportionate economic consequences including potential unjustified deselection**
- **It would be based on questionable evidence**
- **The measure is not the most effective to reach the objective of ensuring a high level of human health protection in this specific case**

On 12 October 2017, the European Chemicals Agency (ECHA) released an opinion of the Risk Assessment Committee (RAC) dated 14 September 2017. The opinion concludes that the available scientific evidence meets the criteria in the CLP Regulation to classify titanium dioxide (CAS 13463-67-7) as a substance suspected of causing cancer through the inhalation route – **hazard code carcinogen category 2, hazard statement: H351 (inhalation), Label GhS08 Dgr** . The full version of the opinion can be found [here](#).

Whilst criteria for classification are hazard based, the choice of a regulatory tool should also respect the principle of proportionality laid down in article 5 of the Treaty on European Union. “Under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties”.

In the case at hand, the ECHA Risk Assessment Committee identifies a mode of action, which the opinion recognizes there is no scientific consensus: lung overload¹. As downstream user of the substance, we believe that the issue should be further clarified before decisions are taken. The basis of RAC opinion is a study by

¹ « The CLP Guidance refers to overload conditions in general terms, stating that the “relevance of lung overload in animals to humans is currently not clear and is subject to continued scientific debate” (section 3.9.2.5.3., page 470 of the CLP Guidance”, RAC opinion in TIO₂ classification, p. 16.

Heinrichs et al. (1995) using a non-standard protocol, a study on another poorly soluble low toxicity particle (Gebel et al. 2012) and some findings in coal miners (Kuempel et al. 2009 and 2014). No clear evidence shows that results on rats may be extrapolated to other species or humans.

In essence, effects are not clear and at most this evidence points at the fact that exposure to dust should be controlled in order to avoid potential lung overload. TiO₂ is not marketed to consumer in powder form. The issue is therefore related to workers safety only. Other regulatory provisions such as occupational exposure limits may adequately achieve the aim of protecting workers from TiO₂ airborne dust. Measures are already in place throughout the plastics industry in order to control or minimize exposure to dust.

The classification of TiO₂ as carcinogen 2 by inhalation on the other hand may have major disruptive effects on the market: TiO₂ is necessary to ensure the functionality of about 77% of the European plastics articles production. This represents a value of € 170 billion of converted products or € 270 billion for the whole plastics supply chain. It must be understood that TiO₂ is not just used to make white products: it is also used as base colour to increase the visibility of a main colour, to enable to obtain proper colour or shading (Hex colour code : see annex) or it is also used in labels to allow contrast and legibility. This means that many transparent packaging materials for instance stop to serve their function if they cannot be accompanied by the appropriate and legible sleeve or label. Moreover, the absence of TiO₂ would decrease the shelf life of articles.

The classification of TiO₂ as carcinogen 2 by inhalation would not lead to a labelling of articles as carcinogenic, nor to an inclusion in the REACH candidate list entailing disclosure of presence in articles on the basis of article 33 of REACH. It however creates a communication problem: consumers don't want a carcinogen in what they are buying (although the TiO₂ is not anymore in the dusty form that could potentially cause a risk). At the minimum this classification increases the burden of communication for members companies, creates alarm at consumer level on perceived safety of products and may eventually lead to unjustified product deselection.

As was highlighted in our comment of June 2016 in the public consultation, there are currently no satisfactory alternatives to TiO₂.

Two more direct consequences may be envisaged:

TiO₂ powder and potentially mixtures containing TiO₂ could be classified (although in our view the entry should take into account the physical state of TiO₂ : once it is encapsulated in a plastic matrix, it is not a dust anymore and the mode of action specific hazard "lung overload" would not exist). This raises alarm of workers without providing a concrete solution to address the potential issue.

Last but not least, for certain categories of waste (mirror entries), the classification is in principle based on hazardous substances content. Some categories of plastics waste might become classified whilst again the actual hazard would not be there in the form in which TiO₂ is present in waste.

In summary, we call the Commission and Member States not to classify TiO₂ as the evidence for classification is questionable, the economic effect potentially disproportionate and the measure is not the most effective to reach the objective of ensuring a high level of human health protection in this specific case.

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Annex 1 : the unique TiO₂ properties enable to obtain the right colour shade and tone for a plastics article

The preparation of colour masterbatches, polymeric mixtures with pigment concentrates enabling article colouration by plastics converters, can be considered somewhat of an art. When a product is designed, designers often have a specific colour in mind for a product. This can be supplied to a masterbatching company in the form of a simple Hex Colour Code² or more exotic samples³. The colour is shown to 'the colour matcher' employed by the masterbatching company, who through trial & error and if lucky the experience of a senior colleague has learned how to combine plastics compatible⁴ pigments to achieve the requested colour.

Titanium Dioxide is an invaluable tool for this colour matcher, as it is the only pure white pigment. In the event the tone of the colour is correctly matched through the use of a mixture of pigments, but shade is not white enough the colour matcher simply adds an amount of TiO₂ to achieve a match. Any other white pigment is not pure white; addition would therefore change the tone, resulting in either significantly more work to correct the tone to take into account the brightening non-pure white additive or non-matching colours.

² A computer code consisting of a 6 character hexadecimal number representing a colour. More information: <http://www.color-hex.com/>

³ E.g. one EuMBC member company once had a client come in with a shard of glass from a broken church window

⁴ Certain pigments have a negative effect on the mechanical properties of plastic material and depending on the application may or may not be used in the article.