Verband der Mineralfarben-industrie e. V.

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Position Paper and Current Situation – Titanium Dioxide and CLP Regulation

Pointless classification of titanium dioxide as suspected carcinogen would have serious consequences

The European Commission is currently examining how the recommendation of the Committee for Risk Assessment (RAC) of ECHA for a classification of titanium dioxide as a carcinogen, category 2 by inhalation, can be implemented. The discussion in CARACAL (Competent Authorities for REACH and CLP) showed that the member states have different views on classification – from pushing for rapid implementation to doubting whether a classification under CLP is appropriate. A specially convened sub-group dealt with the open points. However, no answer was found to the question which health benefit would be achieved by a classification.

VdMi rejects any classification of titanium dioxide as carcinogen (Category 1B or 2), as he considers it to be neither justified nor appropriate. With the classification proposal in our view the attempt is made to classify a single substance on the basis of substance-unspecific particle effects. This does not meet the meaning of the CLP regulation.

The classification would not lead to an improvement in the protection of health and environment. The threshold limits for dust at the workplace in Germany and many other EU Member States already protect from high inhalative dust exposure. However, the classification would have serious and disproportional impacts on almost every sector using titanium dioxide – due to the current legal situation also in sectors, where no exposure by inhalation does occur. In case of dermal or oral exposure, there is no concern, as the RAC has also determined in its assessment.

The RAC states that the carcinogenic effect is not specific for titanium dioxide, but can be transferred to other inert, dust-like substances – so-called PSLT particles (Poorly Soluble Low Toxicity Particles). A general broadening of such a classification for titanium dioxide to other PSLT substances is unacceptable in our view. The EU Commission does not seem to be pursuing this approach either. Nevertheless, a classification of titanium dioxide due to particle effects could be used as a precedent for many other substances.

Titanium dioxide has been used for many decades now due to the unique colouristic properties, the low toxicity and the enormously wide applicability. To current knowledge, for many applications there is no equivalent substitute available.

What kind of substance is titanium dioxide?

Titanium dioxide is an inorganic, crystalline, white solid; it is chemically and biologically inert. Rutile and anatase are the industrially produced crystal modifications.

Titanium dioxide is thermally stable, not combustible and nearly insoluble in water, in diluted acids and organic solvents. Titanium dioxide has extreme light fastness, a high refractive index and a very high light scattering capability. From the coloristic perspective it has, therefore, the highest opacity among all white pigments as well as an excellent brightening capacity vis-à-vis coloured media.

Titanium dioxide is the most common used pigment in the world. In many applications it could not be substituted equivalently. Large quantities of titanium dioxide go into technical applications like paints and coatings, polymers, fibres and paper. Titanium dioxide is also used as a colouring agent in cosmetics, foods, pharmaceuticals, enamels and ceramics. Special forms of titanium dioxide serve as UV filter or as photocatalysts, e.g. in pollutant degradation.

Mainzer Landstraße 55
60329 Frankfurt
www.vdmi.de
info@vdmi.vci.de
Telefon: 069 - 2556 - 1351
Telefax: 069 – 2556 - 1250

Current situation under REACH and CLP

The REACH registration of titanium dioxide was made in 2010. In the appertaining dossier - which is revised regularly and adapted to the state of science – industry has made a comprehensive evaluation of all available scientific data, concluding that classification and labelling is not necessary for titanium dioxide.

This appraisal is supported by the results from epidemiological studies which were performed over several decades in ca. 24,000 workers at 18 production sites. No negative impacts on health due to occupational exposure to titanium dioxide were found in these studies.

The substance evaluation of titanium dioxide under REACH ("CoRAP") is scheduled for 2018; the evaluating agency is ANSES.

What are the next steps in the classification procedure?

After the discussion in the CARACAL sub-group, the EU Commission discusses the next steps internally. A draft classification proposal may already be submitted to the REACH Committee for its June meeting. This is to be discussed first and is expected to be voted on in autumn 2018.

If the REACH Committee decided in favour of a classification, this would be included to Annex VI of CLP Regulation by a regulation amending for adaptation to technical progress (ATP). The publication of the ATP is followed by a transitional period of 18 months for implementation in the value chains.

Why does VdMi reject the proposed classification?

For the following reasons VdMi considers the proposed classification of titanium dioxide as carcinogenic (category 1B or 2) to be neither justified nor appropriated:

- Safe use for many decades – epidemiological studies show no indications of problems in application practice
- No intrinsic substance property – though required for CLP classification
- Weight of evidence – "lung overload" studies in rats cannot be transferred to humans
- No suitable alternatives available
- Existing legislation provides sufficient safety at work

The arguments could be found in detail in the VdMi input to the public consultation (http://www.vdmi.de/files/vdmi_input_clh_titanium_dioxide_07_16.pdf). Obviously a carcinogenic substance should be classified, but a substance should not be declared as carcinogenic without adequate and convincing evidence.

Which economic impact would the proposed classification have?

Germany is the world's third biggest producer of titanium dioxide after the USA and China. The white pigment is used in manifold applications. Several European as well as national regulations are linked to the CLP classification. Like this, waste containing more than 1% of carcinogenic substances (Cat. 2) is classified as "hazardous waste" and requires separate disposal.

For example in cosmetics (sunscreen) and toys, to which sector specific regulations do apply, the application of titanium dioxide would be significantly restricted. For each application a potential inhalative exposure has to be evaluated. As there is no equivalent pigment for substitution, the reformulation of the products would be hindered.

To the German manufacturers e. g. of pigments, pigment preparations, masterbatches and ceramic colours the classification of titanium dioxide as carcinogen implies additional efforts due to the legal requirements which have to be expected (such as labelling, documentation obligations, plant engineering etc.). This would lead to competitive disadvantages compared to producers outside of Europe. This is hard to compensate especially for small and midsized companies.

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Not least, the classification would lead to a strong consumer uncertainty, which is unjustified from a toxicological point of view.

Verband der Mineralfarbenindustrie e. V. (VdMi) represents the German manufacturers of inorganic (e.g. titanium dioxide, iron oxides) and organic pigments, fillers (e.g. synthetic amorphous silica), carbon black, ceramic colours, food colourants, artists' and school colours, masterbatches, and products for applied photocatalysis.

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