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Verband der Mineralfarben-industrie e. V.

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Position Paper and Current Situation – Titanium Dioxide and CLP Regulation

A classification of titanium dioxide as Carc. 2 is unjustified and disproportionate

The European Chemicals Agency ECHA's Committee for Risk Assessment (RAC) suggests a harmonised classification of titanium dioxide as Carcinogen, Category 2 through the inhalation route. A classification as Carcinogen, Category 1B, as demanded by the French government agency ANSES (Agency for sanitary safety in food, environment and work) at the beginning of the procedure, is not supported by the experimental and human evidence. Both ANSES and RAC unanimously state that there is no concern for dermal or oral exposure. For the inhalation route RAC takes the view that in spite of extensive epidemiological studies a carcinogenic potential in humans could not be entirely excluded.

RAC mentions that the carcinogenicity profile is not exclusively characteristic for titanium dioxide but applies also to other inert powdered substances – so-called PSLT (poorly soluble low toxicity) particles. The RAC's opinion is mainly based on a single earlier rat study which is not compliant to actual guidelines. Thus, selected studies on other PSLT substances are used to support the 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. Likewise, a general broadening of such a classification to other PSLT substances on this deficient data basis is unacceptable.

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 protects 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.

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 underpinned 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?

The European Commission has consulted CARACAL (Competent Authorities for REACH and CLP) about the further implementation of the classification. In this context, several Member States have expressed their concerns and asked to discuss the remaining issues.

The issue will be discussed once more at the next CARACAL meeting in March. A decision of the REACH committee (consisting of Member States representatives) on the classification is expected after the conclusion of the CARACAL discussions.

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

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,

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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.

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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