

Working Translation / Original: German

## **Position Paper and Current Situation – Titanium Dioxide and CLP Regulation**

### **RAC's opinion to classify titanium dioxide as Carc. 2 is not comprehensible**

The European Chemicals Agency ECHA has recently published the conclusion of its Committee for Risk Assessment (RAC): The scientific panel suggests a harmonised classification of titanium dioxide as Carcinogen, Category 2 through the inhalation route. Thus, RAC dissents the proposal of the French government agency ANSES (Agency for sanitary safety in food, environment and work), who initiated the procedure for a harmonised classification and labelling in November 2015. ANSES demanded a classification as carcinogen by inhalation, Category 1B ( $\cong$  H350i).

VdMi rejects any classification of titanium dioxide as carcinogen (Category 1B or 2), as he considers it to be neither justified nor appropriated. The classification proposal is based on studies whose findings are controversial discussed and which have no relation to the regular handling of titanium dioxide. The classification would not lead to an improvement in the protection of health and environment, but would have serious and disproportional impacts on almost every sector using titanium dioxide. Due to the current legal situation the harmonised classification under CLP would also affect sectors, where no exposure by inhalation does occur.

The RAC's opinion could be assessed in detail as soon as it is published by ECHA.

Due to the unique colouristic properties and the low toxicity, for many applications there is no equivalent substitute available to our knowledge. As the carcinogenic effect in the animal study is apparently not specific to the substance but is characteristic of dusts, it could be expected that the classification may be transferred to other poorly soluble inert dusts. The implications hereof would be severe to almost every value chain.

### **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 – at an optimal particle size distribution in the range of 0.2 - 0.35  $\mu\text{m}$  – 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.

### **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.

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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?**

After being formally adopted by the RAC the opinion will be sent to the European Commission. The REACH committee (consisting of Member States representatives) will make the final decision. If the 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).

### **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](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 to which sector specific regulations do apply. For example in cosmetics (sunscreen), toys and food contact materials 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.

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

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*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.*