Verband der Mineralfarben-industrie e. V.

Working Translation / Original: German

Position Paper and Information on the Classification of Titanium Dioxide

EU Commission still pursues senseless classification of titanium dioxide

The European Commission published on 4th October 2019 its decision to classify titanium dioxide in powder form as a potentially carcinogenic substance (carc. cat. 2) in Annex VI of the CLP Regulation – even though the majority of member state experts pronounced against this proposal. Germany rejected a harmonized classification of titanium dioxide, too. Instead, the Federal Ministry of Labour and Social Affairs (BMAS) demanded the elaboration of an overall concept for the safe handling of inert dusts. In occupational health and safety, this could be achieved by harmonising the dust limits in Europe. This chance is now gone.

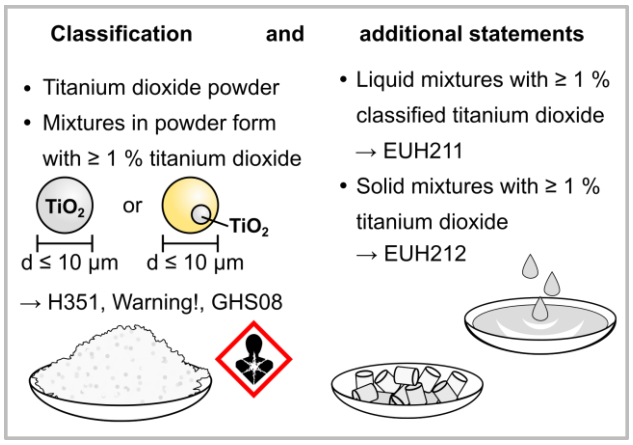
The adopted adaption to technical progress (14th ATP) which was published in the official EU journal on 18th February 2020 includes the classification of

a) titanium dioxide powders which contain 1 % or more particles with an aerodynamic diameter ≤ 10 µm

and

b) powder mixtures containing at least 1 % titanium dioxide in form of particles named under a) or incorporated in other particles with the same dimensions

as carcinogenic category 2. Moreover, solid and also liquid mixtures containing titanium dioxide particles shall bear the additional hazard statements for “dangerous dust” and “dangerous droplets”, respectively.



This classification will not lead to an improvement in health and environmental protection, because there is no hazard of relevance: high dust concentrations are only expected in the working environment, which are already covered by strict occupational exposure limits in Germany. As the expert panel of CARACAL noted, the risk to consumers is negligible as the high exposure level required to observe an effect is unrealistic under normal conditions. Contact with skin or oral intake poses no danger, as the RAC determined in their assessment. The adopted classification is therefore misleading and will have grave and disproportional effects for almost all applications – due to the current legal situation also in areas where no inhalation can occur.

VdMi rejects the classification of titanium dioxide as carcinogen it is neither justified nor appropriate. In our view, this classification entry classifies a single substance on the basis of substance unspecific, general particle effects. This does not meet the criteria of the CLP Regulation. Additionally, the classification of titanium dioxide due to particle effects can be used as a precedent for many other substances.

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

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

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. Thus, to current knowledge, it cannot be replaced adequately.

Titanium dioxide is the most common used pigment in the world. 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 submitted 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 on 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.

Meanwhile, the substance evaluation of titanium dioxide under REACH (“CoRAP”) has started; the evaluating agency is French ANSES[1].

The harmonized Classification – State of the Procedure

The process of classification was changed to a so-called Delegated Act in Regulation (EU) 2019/1243 published on 25th July 2019. Thus, in future the REACH Committee will no longer decide but the European Commission will announce their decision after giving member state experts and the public the opportunity to comment. Thereafter, the European Parliament and Court can both reject the decision within a two-month timespan in case of insufficient consideration of the given comments. A sub-group within CARACAL was formed on the meeting at 1st and 2nd July as responsible group of experts.

The 14th ATP was added to the schedule of the CARACAL meeting on 18th September 2019 and discussed among the experts. The majority of the member state experts pronounced against the classification. Further stakeholders e. g. from trade partners or industry were heard, most of them requesting a thorough analysis of all socio-economic consequences like it is intended for Delegated Acts with significant impact. However, the Commission rejected all criticism as irrelevant and expressed its will to finalize the classification timely.

This was now done on 4th October 2019. The draft of the 14th ATP including the classification of titanium dioxide was adopted and sent to the European Parliament and Court. After the already expanded review period of four months, the classification was published in the official journal on 18th February 2020 and came into force 20 days later. There is an 18 months transition period after which the classification needs to be applied throughout the whole supply chain.

[1] ANSES = Agence nationale de sécurité sanitaire de l’alimentation, de l’environnement et du travail. (French Agency for Food, Environemental and Occuational Health & Safety)

Why does VdMi reject the proposed classification?

For the following reasons VdMi considers the classification of titanium dioxide as carcinogenic (category 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

All arguments can be found in detail in the VdMi input to the public consultation.[2] Obviously, a carcinogenic substance should be classified, but a substance should not be declared as carcinogenic without adequate and convincing evidence.

Which economic impact does the 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.

Therefore, waste containing more than 1 % of carcinogenic substances (Cat. 2) may be classified as "hazardous waste" which requires separate disposal. According to a recent study, this would affect around 50 % of all plastic waste in Germany.[3] Even though first drafts of a revised EU Guidance on waste treatment were elaborated, the publication of this revised documents as well as the national implementations are still pending. Furthermore, such guidance documents do not provide legal certainty for the affected companies.

For example, in cosmetics (sunscreen) and toys, to which sector specific regulations do apply, the application of titanium dioxide will 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 will be hindered.

To the German manufacturers e. g. of pigments, pigment preparations, masterbatches and ceramic colours the classification of specific 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.). In case of usage of non-classified titanium dioxide powder, a careful differentiation is required. The complexity of the classification entry will 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 will lead to a strong consumer uncertainty, which is unjustified from a toxicological point of view.

Contact:

Verband der Mineralfarbenindustrie e. V.
Dr. Heike Liewald

liewald@vdmi.vci.de

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

[2] Available for download (in German) on the VdMi homepage.
[3] Summary of study results available for download (in German).