
VdMi statement on the proposal for a harmonized classification of Titanium dioxide

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General comments

The proposed classification and labelling for titanium dioxide by the French MSCA is inappropriate for the following reasons and would have serious and disproportionately negative impacts on the European and German market, regarding the products manufactured by our member companies.

Titanium dioxide is produced in Germany with a total production capacity of more than 480000 tons per year. Within our industry, titanium dioxide is by far the most prominent raw material.

It is worth pointing out that titanium dioxide is a raw material which is used even by SMEs, e.g. manufacturer of pigment preparations or masterbatches, in quantities up to several hundred tons per year each.

It is used as starting material for the synthesis of important inorganic coloured pigments (e.g. with rutile type structure). Here, titanium dioxide is fully converted during the production process. As a structure-giving component, titanium dioxide is the indispensable basis for the manufacture of these colour pigments.

- Titanium dioxide is used as the most important white pigment, for example by our member companies in
 - o both organic and inorganic pigments (including effect pigments/pearlescent pigments) as constituent and for finishing and coating
 - o ceramic colours
 - o Pigment preparations (powder, liquid, paste)
 - o Masterbatches for subsequent colouring of polymers
 - o Artists' and school colours
- Because of its excellent brightening and hiding capacity vis-à-vis coloured media, titanium dioxide is also used as a filler, e.g. for industrial uses or in cosmetics or pharmaceuticals.
- Another use is as UV filter, e.g. in sunscreen products.

Depending on the uses, contents of titanium dioxide in pigment preparations range between 1% and nearly 100%, in ceramic colours between 5% and 60%, in artist's colours between 10% and nearly 100% and in masterbatches between 0.1% up to 80%. The TiO₂-concentration in final products strongly depends on the application, e.g. for TiO₂- masterbatches up to 3% in the final product.

Pigments and pigment preparations containing titanium dioxide are firstly used in industrial (e.g. high quality coatings, paintings, printings inks, plastics, paper) and professional (dispersion paints and varnishes) applications and, secondly, in the field of private consumer applications (e.g. cosmetics, pharmaceuticals, wall paint artist's colours).

Downstream applications

Titanium dioxide is used as white pigment, filler and UV-stabilizer. Therefore, it can be found in products with materials based on:

Plastics (e.g. food packaging and storage, toys, mobile phones, window frames), fabrics, textiles and apparel (e.g. clothing, mattress, curtains or carpets, textile toys), paper (e.g. tissues, feminine hygiene products, nappies, books, magazines, wallpaper), stone, plaster, cement, glass or ceramic (e.g. dishes, pots/pans, food storage containers, construction and isolation material), metal (e.g. cutlery, pots, toys, jewellery), wood (e.g. lacquers and protective coatings on floors, furniture, toys), leather (e.g. gloves, shoes, purses, furniture) and rubber (e.g. tyres, shoes, toys)

Justification to reject the French proposal

For the following reasons we consider the submitted proposal for a classification of titanium dioxide as carcinogenic category 1 B neither as justified nor as appropriated:

Safe use for many decades – no indications of problems from epidemiological studies and application practice

Titanium dioxide has been used safely for many decades.

The classification for titanium dioxide was assessed by the industry, as part of the REACH Registration dossier submission in 2010. This involved an extensive review of all available scientific data and, since then, has been updated with new findings and subsequent studies.

No increased incidence of lung cancer has been observed in humans.

This conclusion is supported by the findings of epidemiological studies of 20,000 workers in 15 titanium dioxide manufacturing plants over several decades, in which no connection was found between exposure at the workplace and a cancer risk. This is also noted in the CLH report: "*Human data do not suggest an association between occupational exposure to titanium dioxide and risk of cancer [...]*" (CLH Report, page 8).

Weight of evidence of "lung overload" studies in rats

The classification proposal in the CLH report is based essentially on studies in rats, exposed to extremely high concentrations of titanium dioxide dusts, which led to so-called "lung overload"-effects.

All relevant guidance documents by ECHA, OECD and ECETOC-Report unanimously observe that the results from “lung overload” studies in rats should not be transferred to humans for several reasons. Therefore, a classification is neither justified nor appropriate from the toxicological perspective. For justification purposes, we refer to CLP regulation Annex I, 3.9.2.8.1.(e):

“substance-induced species-specific mechanisms of toxicity, i.e. demonstrated with reasonable certainty to be not relevant for human health, shall not justify classification.”

The respective guidance document to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures, Ver 4.1 June 2015 - explicitly states that overload studies are still part of the scientific discussion. As long as the French MSCA provides no justification why - in this case - the current guidance opinion does not apply, the evidential weight of the cited “lung overload” studies is weak.

C&L inventory information

Currently 2387 notifiers do not foresee any classification or labelling for titanium dioxide. There are only nine notifiers classifying titanium dioxide as a carcinogenic substance, with the proposed classification H350i – without providing any further objective evidence. Since the French MSCA emphasizes their scientific approach in the CLH document, it must be noted that their conclusion, “titanium dioxide is a carcinogenic substance” according to the notifications to the C & L inventory, is by no means scientific.

Intrinsic substance property required

For identifying carcinogens, CLP requires intrinsic data as outlined in its annex:

“3.6.2.2.1 Classification as a carcinogen is made on the basis of evidence from reliable and acceptable studies and is intended to be used for substances which have an intrinsic property to cause cancer [...]”

This is in line with the purpose, scope and application of globally harmonized system of classification and labelling of Chemicals (GHS):

“1.1.3.1.1. The goal of the GHS is to identify the intrinsic hazards found in chemical substances and mixtures and to convey hazard information about these hazards. [...]”

With regard to this provisions and the French MSCAs statement in its dossier:

„All possible crystal modifications, morphologies and surface chemistries in all possible combinations of TiO₂ are expected to be biopersistent and of poor solubility, and therefore covered by this CLH dossier. Indeed TiO₂ in all these combination is considered to behave in the same way as other poorly soluble low toxicity particles.” (CLH report, p. 8).

The French MSCA stated by its own conclusion, that the potential inhalation health risk of titanium dioxide is linked to a substance independent property of dust. This is obviously not intrinsic. Therefore, a harmonised classification would be not the right measure to address their findings.

Additionally we refer to the detailed toxicological assessment of the Verband der Chemischen Industrie e.V. (German Chemical Industry Association) and TDMA (Titanium Dioxide Manufacturer Association) and the TDIC (Titanium Dioxide Industry Consortium).

No suitable alternatives available

Titanium dioxide has been used safely for many decades, as a pigment of an extraordinary light and weather fastness, a high refractive index and – at an optimal particle size distribution in the range of 0.2 - 0.35 μm – a very high light scattering capability. From the coloristic perspective it has, therefore, the highest opacity among all white pigments and an excellent brightening capacity vis-à-vis coloured media.

No suitable alternatives are available with respect to these outstanding properties of titanium dioxide and the resulting performance regarding health, safety and environment.

Hence, any change to its classification will have a huge impact on our industry and on the entire downstream industries as well. The harmonised and thus legally binding classification of a substance according to the CLP Regulation – especially for carcinogenic, mutagenic and reproductive toxic substances and sensitising substances by inhalation - has far-reaching impacts on almost all uses of this substance, whether or not the use of the substance poses risks.

At this point we would like to emphasise that in the vast majority of downstream uses, titanium dioxide is bound in a matrix (e.g. in a polymer matrix) and thus not freely available¹.

Some examples of direct legal consequences in downstream regulations are :

- Consumer products (e.g. artist's colours, wall paint, paints or coatings, personal care products, food contact) would, inter alia, fall under the ban of the sale to the general public according to the REACH Regulation (EC) No. 1907/2006 Annex XVII.
- REACH restriction/Authorisation (SVHC Candidate list)
- EU Cosmetics Products Regulation (Regulation [EC] No 1223/2009)
- European waste law
- IED Directive and TA Luft (technical instruction for clean air)
- German ordinance on the ban of chemicals (Chemikalien-Verbotsverordnung)

Existing legislation provides sufficient safety

Exposure by inhalation to titanium dioxide can be expected primarily at the workplace. Consequently, relevant dust limit values are in place in several Member States. In Germany, there are additionally a number of provisions for tighter protection measures to minimise dust exposure (e.g. German technical rule TRGS 900). At the European level, dust exposure could be regulated in directives on occupational health and safety. A harmonized classification of titanium dioxide is not necessary for this purpose.

¹ *Nanoparticle release from nanocomposites due to mechanical treatment at two stages of the life-cycle*, Daniel Göhler, André Nogowski, Petra Fiala and Michael Stintz **2013 J. Phys.: Conf. Ser.** 429 012045

Already now, existing legislation provides adequate safety

A classification would not contribute to improving the protection of health and environment, while it would have serious and disproportionately negative effects, in almost all applications of titanium dioxide.

Socio economic impact

Our member companies expect serious negative effects on their business – ranging from a significant reduction up to 50 %, to a total loss of business in Europe. Apart from the legal implications outlined above, this will also be driven by customer buying behaviour. Titanium dioxide will be stigmatized and, thus, - even if it legally could be used - it will be entirely banned in consumer applications/products.

Some examples of negative effects:

- Loss of business, due to less market acceptance, especially in end consumer applications (e.g. cosmetics, personal care products, food, food contact, , artist's colours, paints or coatings, pharmaceuticals).
- Loss of functionality, e.g. UV-protection in construction materials, hiding power in paints.
- A reduction of the variety in products, e.g. light coloured articles/materials (e.g. plastics) might no longer be available.
- In case titanium dioxide would be added to the REACH Candidate list a significant disadvantage for EU businesses vis-à-vis their non EU competitors will be generated.

Summary/Conclusion

Titanium dioxide is broadly used as a white colorant because of its excellent coloristic performance which cannot be achieved by known alternatives.

With this situation in mind, we emphasize that the decision on a classification that would essentially ban the use of the substance must involve a particularly thorough and critical evaluation of all existing animal and human epidemiological data.

Obviously a carcinogenic substance should be classified, but a substance should not be declared as carcinogenic without adequate and convincing evidence.

Classification of titanium dioxide as Carc Cat 1Bi as proposed in the CLH dossier would group titanium dioxide with CMR substances in general although the postulated mode of action would only apply for inhalable forms. This currently results in various legal bans even for non-inhalable forms of the substance as the affected regulations do not have provisions for such an unprecedented case.

Furthermore, a classification would not contribute to improve the protection of health and environment, while it would have serious and disproportionately legal consequences in almost all market segments.

The submitted proposal for classification and labelling of titanium dioxide is inappropriate from the toxicological perspective. As a consequence no classification as hazardous should be made.

Who we are:

Verband der Mineralfarbenindustrie e. V. (VdMi) is a German industry association, representing the German producers of inorganic and organic pigments, of products for the ceramic industry (e. g. ceramic decorating colours, glass colours), of synthetic amorphous silica uses as reinforced fillers, of carbon black and food colourants and downstream users of colourants. These are producers of pigment preparations, masterbatches and producers of artist's colours. One sector group also represents the manufacturer of photo catalysts as well as users, like the construction and coatings industry. VdMi represents in total 75 companies, about 75 % of the companies are SMEs. The combined annual turnover of these sectors is about 3.5 billion Euro.

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