Verband der Mineralfarben-industrie e. V.

Consequences of the Classification of Titanium Dioxide Powders

FAQs on titanium dioxide, the classification as a carcinogen (cat. 2), and impacts in the fields of product management and occupational health and safety (OHS)

Purpose of this brochure

Titanium dioxide (TiO_2) is the most frequently produced and used pigment worldwide. The annual production volume is ca. 7.2 million tonnes (status 2016). Given the immense importance of TiO_2 for the pigment and filler industry and its wide range of applications, many products represented by the VdMi are directly or indirectly affected by the classification. For this reason, the VdMi has been actively accompanying the classification process from its beginning in 2016 and regularly provides information about the consequences for the industry and consumers.

In the light of recent developments, we have summed up the most frequently asked questions regarding the classification of TiO_2 powders in this brochure in an easily legible form. Even though it is not yet possible to assess the full consequences in all areas, we would like to give an overview of the most important topics. The 14th ATP including the classification of titanium dioxide powders was published on 18th February 2020 and will come into force on 9th March 2020. A transitional period of 18 months is given so that the classification will apply from 1st October 2021.

Question 1

What substance is titanium dioxide?

Titanium dioxide is an inorganic, crystalline, white solid. It is chemically and biologically inert, i. e. slow-reacting or very stable. TiO_2 does not decompose when heated, is non-flammable and almost insoluble in water, acids and organic solvents.

These properties ensure that TiO_2 used in products retains its useful properties for a very long time. It does not detach from the product or degrade in any other way.

Question 2

What are the concerns and are they justified?

Due to its negligible solubility in water and in relevant bio-liquids and its extreme inertness combined with the absence of substance-specific (intrinsic) toxicity, TiO_2 has been used for many years as a model substance for the testing of granular, bio-persistent dusts which are also called PSLT (poorly soluble substances of low toxicity). Thus, there are many studies on TiO_2 since it is investigated as a representative of a whole class of substances. Consequently, the observed effects are not specific for this one substance but are based on general modes of action (general particle effects).

In such investigations, the inhalation of fine dusts is often of special interest. This is because effects of such PSLTs can be observed in the lungs – in contrast to oral intake e. g. with food or dermal intake e. g. via a cream. When working with these dusts, precautions are always necessary!

This is precisely why very strict dust limit values are in place in Germany (see question 11). Workplaces are monitored in order to protect workers from general particle effects, with measures to be taken to comply with dust limit values (air filters, extraction systems etc.) – while consumers have no contact with such dusts.

However, high dust loads are deliberately brought about in animal testing so that the occurring effects can be observed in a targeted manner. In this context, one also speaks of a lung overload or overload effects. But experts agree that such exposures can be excluded even at workplaces. Furthermore, there are different cleaning mechanisms in the various animal species. For example, rats are unable to cough to protect their lungs from high dust exposure. For this reason, the study results cannot be transferred to humans.

Question 3

Where is titanium dioxide used? Are there alternatives?

Titanium dioxide is extremely light-resistant, has a high refractive index and an excellent light scattering capacity. From a coloristic point of view, it therefore has the best opacity of all white pigments as well as an excellent brightening capacity against coloured media. For these reasons, TiO_2 is the most frequently used pigment worldwide. It is used in large quantities in technical applications such as paints and coatings, plastics, fibres, and paper. Further fields of application are cosmetics, pharmaceuticals, enamel, and ceramics. Special forms of titanium dioxide are used in UV filters or as photocatalysts. According to current knowledge, there are no adequate substitutes.

With zinc sulphide, lithopones (zinc sulphide / barium sulphate), zinc oxide or calcium carbonate, other compounds are used as white pigments. But it should be noted that these pigments are insoluble powders, too. As far as is currently known, TiO_2 cannot be fully substituted in many applications especially paints and coatings because of its outstanding technical properties

Question 4

How did the classification come about?

In 2016, France presented the proposal to classify titanium dioxide as a carcinogen (cat. 1) by inhalation. The Committee for Risk Assessment (RAC), which was competent for assessing the hazard potential, did not agree with the French proposal. However, it was accepted that inert dusts can be problematic in inhalation. This is due to the general particle effects and regardless of the chemical composition of these dusts. From this, a classification of TiO_2 as a suspected carcinogen (cat. 2) was derived.

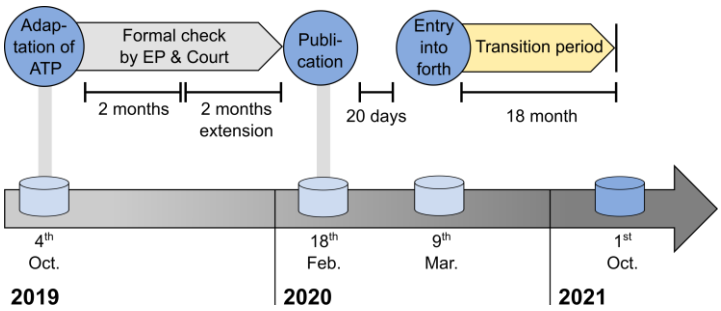
Ignoring serious objections from the Member States, industry and NGOs, the EU Commission decided on 4th October 2019 to classify titanium dioxide in powder form as a *"substance suspected of causing cancer by inhalation"*. The Commission refered to the RAC assessment to justify this decision.

According to the CLP Regulation, the classification by the EU Commission is the wrong instrument since it is only intended to describe substance-specific (intrinsic) effects. Instead, a solution should have been sought by harmonising the general dust limit values in the EU, as was demanded by many industry associations and some Member States such as Germany.

Question 5

When will the classification become binding?

The classification of titanium dioxide powders was published on 18th February 2020 as part of the 14th ATP. It entered into force 20 days later.[1] After the 18-month transition period, the classification has to be implemented along the entire supply chain by 1st October 2021.



Question 6

How does the classification affect my products? What are the resulting labelling requirements? What has to bear additional statements?

Legally classified (CLP Regulation, Annex VI) are titanium dioxide in powder form with an aerodynamic particle diameter of ≤ 10 µm and mixtures in powder form containing ≥ 1% of titanium dioxide in the form of such particles or incorporated in other particles with the same external dimensions. Powders affected by this classification will have to be labelled with a GHS symbol (GHS08), a signal word (warning!) and a hazard statement (H351: Suspected of causing cancer by inhalation).

Furthermore, mandatory warning statements (CLP Regulation, Annex II) are planned for liquid and solid mixtures containing ≥ 1% of titanium dioxide, even if they will not fall under the classification. For liquid mixtures, it must be warned against the formation of hazardous droplets when sprayed (EUH211) if the contained TiO_2 particles have an aerodynamic diameter ≤ 10 µm. Solid mixtures require a warning against hazardous dusts (EUH212), regardless of the particle size. In both cases, the packaging must also point out that a safety data sheet is available on request (EUH210), unless other components lead to a classification of the mixture.

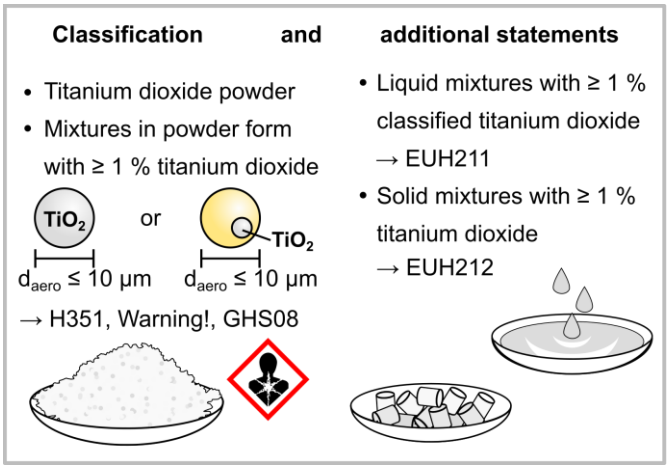


Figure 1: Differentiation between the classification of TiO_2 containing powders and additional warning statements for liquid and solid mixtures with TiO_2.

[1] Delegated Regulation (EU) 2020/217, published in the Official Journal of the European Union L44 and L51, available on EUR-Lex.

Question 7

Which powders fulfil the classification criteria? How does that affect my products?

The Titanium Dioxide Manufacturer Association TDMA performed thorough measurement studies to identify appropriate methods to determine the aerodynamic diameter and to assess the affect of the classification.

The measurement results indicate that the majority of titanium dioxide powders do not fulfil the classification criteria. According to the measurement data, producers are not obliged to classify these products. The classification decision has to be made by each individual producers for his respective products.

Liquid mixtures must bear the additional warning statement EUH211 if classified titanium dioxide is used. It this is not the case each mixture producer should decide on his available information whether the use of EUH211 can be dispensed.

Solid mixtures which also includes mixtures in powder form must bear the additional warning statement EUH212 regardless the classification of the used titanium dioxide if more than 1 % is included.

Question 8

Does titanium dioxide become a hazardous substance? What obligations result from the German hazardous substances regulation (GefStoffV)?

The German hazardous substances regulation considers a substance as hazardous if it is classified according to the CLP criteria or if an OEL applies. Therefore, with the classification only the affected TiO_2 powders become hazardous substances. However, as titanium dioxide dusts already fall under the general dust limit (see Question 11), respirable titanium dioxide dust had to be treated like as hazardous even before the classification. This does not include those solid and liquid mixtures, which only require labelling with a warning according to Annex II. These mixtures are not considered hazardous.

According to Article 6 GefStoffV, the employer must determine in a risk assessment whether a hazardous substance is being worked with or whether a hazardous substance can form or be released. The risk assessment must be recorded in writing and include an examination of possibilities for substitution. This must be observed also when working with non-classified, solid mixtures (e. g. masterbatches) whose wear or use could generate dust (= powder) that might fall under the classification.

Additionally, Article 14(2) provides for at least annual training of all staff who work with hazardous substances. Such training must be documented in writing.

Question 9

Does titanium dioxide become a dangerous good?

The classification as hazardous substance does not make an affected TiO_2 powder simultaneously a hazardous good.

Question 10

How does the classification impact the communication along the supply chain (MSDS)? Do I need to notify my product to the poison notification centres?

In future, only titanium dioxide powders meeting the classification criteria will also be treated as hazardous substances. Mixtures in powder form falling under the classification will become hazardous mixtures.

This results in the obligation to prepare a safety data sheet (SDS) or – where an SDS already exists – to include the classification in section 2 (possible hazards) which could necessitate further changes (e.g. in the sections on toxicology and disposal). Moreover, classified powder mixtures need to be notified to poison notification centres.

TiO_2-containing mixtures, which are only labelled with an additional warning according to Annex II and not classified due to other components, do not need to be classified as hazardous. The preparation of an SDS is not mandatory but has to be kept at hand upon request. Additionally, these mixtures are not subject to the notification requirement to poison notification centres. However, safety data sheets of such solid or liquid mixtures must list in section 3 (composition) TiO_2 in powder form with information on the concentration or the concentration range if the titanium dioxide is classified. If the titanium dioxide does not fulfil the classification criteria, this specification is not mandatory provided TiO_2 is not the main ingredient.

Question 11

What do I need to observe in occupational health and safety? Was I at risk in the past?

In German OHS regulations, titanium dioxide is categorised in “carcinogenicity category 4”, analogously to other granular, bio-persistent dusts. Category 4 sums up various insoluble, non-toxic substances. In the handling of such dusts, problems can arise due to their inert properties (see question 2). Insofar as the occupational health limit (general dust limit value according to TRGS 900: 10 mg/m³ E-dust, 1.25 mg/m³ A-dust) is complied with when working with TiO_2 powders, there is no change – as this value was already adhered to at the workplace. Thus, the strict dust limit values in Germany already protected workers against particle effects.

Most recently, the competent Subcommittee III of the Committee on Hazardous Substances (AGS) looked into the limit value for titanium dioxide in August 2018. As no new data were submitted in the course of the TiO_2 classification and the RAC reference to the problem of general particle effects, the Subcommittee saw no need for action.

Question 12

How do I handle TiO_2-containing wastes?

The handling of waste is regulated on a national level in the EU. Therefore, differences occur depending on the relevant Member State.

The German waste legislation categorizes wastes according to their origin, reflected in so-called key numbers. Several key numbers have mirror entries for non-hazardous and hazardous wastes. Wastes falling under such a mirror entry and that are subject to classification must be

treated as hazardous waste. A revision of the EU Guidance Document on waste classification shall clarify that the whole classification entry shall be taken into account. Thus, only waste in powder form with a share of titanium dioxide particles with an aerodynamic diameter ≤ 10 µm of ≥ 1 % may be treated as hazardous waste. How this complex criterion can be implemented in practice is still open. In addition, a guideline is not legally binding. Thus, the interpretation of the national enforcement authorities is also important.

The treatment of hazardous wastes involves more stringent conditions and additional permits. Thus, a restriction to – in first proximity – waste in powder form makes sense.

Typical end products (plastic product, construction material, coated article etc) would no longer become hazardous waste due to their titanium dioxide content. For waste in powder form (filter cakes, clippings, scraps etc.) it should be calculated as a first step whether the titanium dioxide share exceeds the threshold of 1 %. Only if this is the case, it might eventually be treated as hazardous waste. Companies should include higher disposal costs in calculations, as well as be early to clarify with their disposal partners whether the necessary permits and capacities for accepting their wastes are available.

Question 13:

What consequences must be expected in the downstream legislation?

Many downstream legislations refer to the classification according to the CLP Regulation. In the classification processes, it was already repeatedly emphasized how high the impact on waste legislation (see question 12) and the use in toys will be. At the same time, the use of titanium dioxide, for example, in medical devices, cosmetic products, or consumer goods (e. g. made of plastic) remains unchanged for the time being as product-specific regulations apply.

The European Toys Regulation states in Annex II in the section of specific safety requirements regarding chemical properties that cmr substances must not be used in toys or toy components above the respective classification thresholds. In case of titanium dioxide this means 1 %. As the specific exposition (inhalation) as well as the defined form (powder) are not considered, titanium dioxide must not exceed this value. Paint and coating layers are specifically defined as a component.

Due to the restriction of the classification to inhalable powders, there are justified arguments for an exemption. A respective request is currently being examined by the competent committee (SCHEER).

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Any further Questions?

Basis for all interpretations are the corresponding legal texts.

You receive information on the classification of your used titanium dioxide from your supplier. Information on the exact measurement results of the TDMA study were published in several papers and additionally presented in TDMA webinars for downstream users and interested parties.

In Germany, the BG RCI (employers' liability insurance for raw materials and the chemical industry) is an excellent contact regarding occupational health and safety. In November 2019, the BG RCI published a position with some important information.

An even more detailed assessment of the effects of classification is given in the VdMi member information. The association is, of course, available to answer your questions on titanium dioxide. Further details are provided by the VdMi supported information campaign *Forum Titanium Dioxide* or other impacted industry federations.

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The Verband der Mineralfarbenindustrie e. V. 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 colorants, artists' and school paints, masterbatches and products for applied photocatalysis.

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