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 definitely assess the full consequences in all areas, we would like to give a first 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 is 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, 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 invariably 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?

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, foodstuffs, 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.

Question 4

Are there alter-natives to titanium dioxide?

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 because of its outstanding technical properties.

Question 5

How did the classification come about?

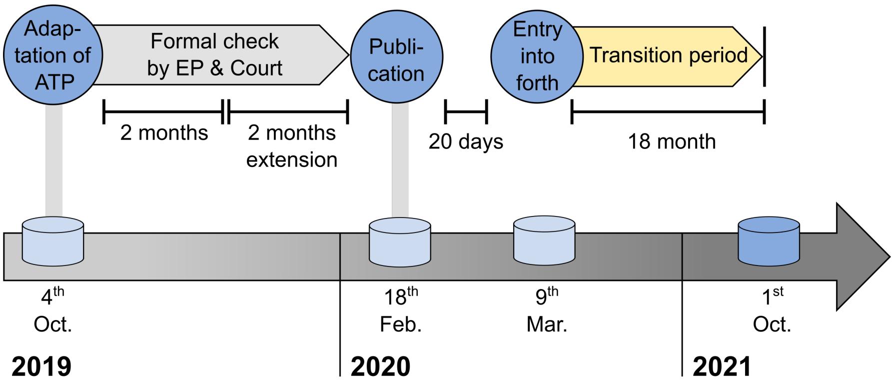
In 2016, France presented the proposal to classify titanium dioxide as a carcinogen (cat. 1) by inhalation. The Committee for Risk Assessment (RAC), which was competent for assessing the hazard potential, did not agree with the French proposal. However, it was accepted that inert dusts can be problematic 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 massive protests 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 resorted 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 6

When will the classification become binding?

On 4th October 2019, the Commission announced the classification of titanium dioxide powders within the 14th ATP to the CLP Regulation. After a review period for the European Parliament and the Council, which was extended to 4th February 2020, the ATP was published in the Official Journal on 18th February 2020 and will enter into force 20 days later. This will be followed by an 18-month transition period, so that the classification can be implemented along the entire supply chain. First labelling can be expected soon after entry into force. Classification will be binding throughout the whole supply chain from 1st October 2021.



Question 7

How does the classification affect my products? What are the resulting labelling requirements?

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 warnings (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 are ≤ 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.

In practice, this classification will result in the labelling of many products. Beside titanium dioxide powders, many pigment mixtures in powder form will have to be classified and labelled accordingly with the GHS symbol and the indication of a potential carcinogenic effect. Moreover, many products like solid or liquid pigment mixtures, masterbatches, paints, and construction products such as mortar or plaster will need to be labelled with an additional warning.

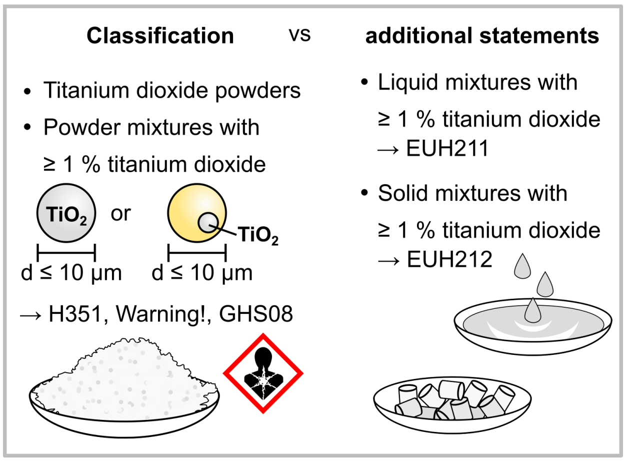


Figure 1: Differentiation between the classification of TiO_2 containing powders and the additional statements for liquid and solid mixtures with TiO_2 as well as the resulting labelling obligations.

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 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. There 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.

This can also lead to more enquiries from customers to suppliers. Work involving the relevant substance can start only after the risk assessment has been carried out and the protective measures, which are possibly derived, have been taken. Therefore, it is recommended to become active already before the classification applies.

Question 9

What do I need to observe in transport? Does titanium dioxide become a dangerous good?

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

The entries listed in class 9 under “M1 Substances which, on inhalation as fine dust, may endanger health” refer to asbestos and asbestos-containing compounds. However, this is a description and no criterion.

Question 10

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

In future, classified powders will also be treated as hazardous substances or hazardous mixtures, respectively. For example, 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, such powders need to be notified to poison notification centres. Product examples with the described consequences would be titanium dioxide power and TiO_2-containing powder pigment mixtures.

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. This means that they are not subject to the notification requirement to poison notification centres. However, in future the 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. So far, this information was not mandatory unless TiO_2 was the main component. Relevant product examples are masterbatches or wall paints.

Question 11

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

In the German OHS, 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 TRGS900: 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 German Federal Institute for Occupational Safety and Health (BAuA) 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 BAuA 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. Since no particle sizes are (can be) determined in waste and as there is no differentiation between solids and powders, this will in practice lead to a situation where all wastes under such mirror entries with ≥ 1% TiO_2 will be treated as hazardous waste. The treatment of hazardous wastes involves more stringent conditions and additional permits. This means that not only the disposal of such wastes becomes more expensive, but also – in many cases – no further use in the meaning of recycling will be possible either.

Therefore, it is worthwhile to do some mathematics beforehand, in order to determine the TiO_2 content in the end product (plastic product, construction material, coated article etc). If the TiO_2 content is less than 1 %, nothing changes for customers regarding disposal. Similar considerations should be made for in-house wastes in companies (filter cakes, scraps etc). Additionally, the corresponding key numbers should be determined. 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 and the use in toys will be – while the use of titanium dioxide, for example, in medical devices, cosmetic products, consumer goods (e.g. made of plastic) or foodstuffs remains unchanged for the time being. These application fields have their own, product-specific regulations where, in some cases, positive lists are kept which explicitly allow TiO_2.

The impacts on waste legislation are already explained in question 12. According to a study of 2019 that was mandated, inter alia, by the VdMi, these impacts currently affect e.g. around 50 % of all plastic wastes in Germany.[1] Moreover, construction or refurbishing wastes (painted wallpaper, plaster etc.), for example, can be impacted to a high degree.

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. As the specific exposition (inhalation) as well as the defined form (powder) are not considered, titanium dioxide must not be used in principle for toys any longer. Paint and coating layers are specifically defined as a component. While finger paints or the classic painting box will only be available in drastically reduced versions, as titanium dioxide cannot be substituted in these application, plastic toys or coated toys like (wooden) construction blocks must not contain titanium dioxide any more. Due to the restriction of the classification to powders, there are justified arguments for an exemption. According to our current knowledge, the toys industry examines this possibility at the moment.

[1] TiO_2 in plastics – Summary version of the results from an analysis of plastics processing, waste volumes of plastics and the recovery of plastic wastes in Germany 2017, available for download at this link (in German language).

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Any further Questions?

In Germany, the employers' liability insurance for raw materials and the chemical industry BG RCI 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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