BG RCI
Berufsgenossenschaft
Rohstoffe und chemische Industrie

Classification of titanium dioxide

Information on classification and labelling as well as occupational health and safety protection for activities that involve titanium dioxide

Background: Titanium dioxide has found universal application as a white pigment for decades: it is used in paints and coatings, in products such as toothpaste and sunscreen, in adhesives and plastics, in the paper industry, and even as a food additive.

Current situation: After lengthy discussions at EU level, the European Commission adopted an amendment to the CLP Regulation on 4 October 2019 ("14th ATP") in which titanium dioxide in powder form containing 1% or more of particles with aerodynamic diameter ≤ 10 µm is classified as a carcinogen (suspected, Category 2) and additional EUH statements are introduced. This amendment was published as Delegated Regulation (EU) 2020/217 in the Official Journal of the EU on 18 February 2020, thereby entering into force on 9 March 2020. A transition period is in place until 1 October 2021.
The approaching classification of titanium dioxide has already led to numerous inquiries. This information is meant to present the debate in more objective terms. To do so, it outlines the new classification, conveys the scientific background and answers questions regarding occupational health and safety protection.

Classification of titanium dioxide in the "14th ATP" – amendment of the CLP Regulation

Titanium dioxide in powder form containing 1% or more of particles with aerodynamic diameter ≤ 10 µm will be classified as follows:
Carcinogenicity category 2, H351 (inhalation), or Carc. 2, H351 (inhalation) for short

Pictogram:

Signal word: WARNING
Hazard statement H351 (inhalation): **May cause cancer if inhaled.**

The classification applies to pure titanium dioxide powder and to all mixtures in powder form containing 1% or more of titanium dioxide in the form of, or incorporated in, particles with an aerodynamic diameter of ≤ 10 µm.

That means that the classification does not apply to liquid coatings and paint, to toothpaste, etc. The classification also does not apply to products such as wallpaper, to objects painted or dyed in white (with paint containing titanium dioxide), to paper and the like.

> There are further notes in the entry on titanium dioxide in the CLP Regulation for titanium dioxide fibres with special dimensions and for titanium dioxide particles with modified surface chemistry. For these specific titanium dioxide particles, suppliers must check the classification of these products as a "confirmed carcinogen", category 1A or 1B, using the criteria of the CLP Regulation and may then classify these products in a higher category. For these particles, additional routes of exposure (oral or dermal) must also be checked.

Additional labelling for liquid and solid mixtures with 1% or more of titanium dioxide

The label on the packaging of liquid mixtures containing 1% or more of titanium dioxide particles with a diameter equal to or below 10 µm shall bear the following statement:

> EUH211: Warning! Hazardous respirable droplets may be formed when sprayed. Do not inhale spray or mist.

For all solid mixtures containing 1% or more of titanium dioxide:

> EUH212: Warning! Hazardous respirable dust may be formed when used. Do not inhale dust.

The additional labelling with EUH211 or EUH212 applies to many typical applications of titanium dioxide such as paints and coatings. It only applies to mixtures, not to products. Products are defined as objects that are given a specific shape, surface or design during production, thereby determining their function to a greater extent than the chemical composition does. Examples of products are paper, (dyed) polyester fibres or packaging.

When does this go into effect?

The European Commission adopted the 14th ATP as a "delegated Regulation" on 4 October 2019. The EU Council and Parliament did not object, so the (extended) deadline expired on 4 February 2020. The Regulation was published in the Official Journal of the European Union on 18 February 2020 followed by a corrigendum to the Regulation on 25 February 2020.

On the 20th day of publishing the Regulation – i.e. on 9 March 2020 – it enters into force. The classifications determined in this Regulation may be used as of that day. The entries will, however, only become mandatory after an 18-month transition time. Until 30 September 2021, packing drums therefore do not need to be classified and labelled according to the new regulations. As a rule, new findings in the endangerment assessment should be taken into account immediately for occupational health and safety. In this case, however, no additional protective measures are required – please refer to the section on occupational health and safety.

> The delegated act procedure – also for the CLP Regulation – was only made possible by EU regulation in the summer of 2019. Before, a qualified majority of the Member States had to agree to such a regulation – and thus to the classification of titanium dioxide. Germany, the UK and other countries had prevented this from happening for more than a year. Then in September, the Member States took part in a hearing under the now "new" procedure – but without casting a vote. The EU Commission then adopted the Regulation without change and forwarded it to the EU Council and EU Parliament. Although Parliament extended the deadline, there was no majority against this Regulation in the relevant parliamentary committee. Thus, the Regulation can now be published immediately.

What is the scientific background?

Contrary to valid scientific requirements (guidelines of OECD, ECHA and ECETOC), the toxicological studies supporting the classification of titanium dioxide as a carcinogenic substance are based on ”lung overload“ effects on rats. These studies are not transferable to humans due to the sensitivity of rats to overload effects on one side, and on the other side to a fragile relevance of such massive exposure of the respiratory tract and organs of laboratory animals. So this should not be used as a basis for the classification as a category 2 carcinogen.

The effect of titanium dioxide in these animal studies is based on particle-induced inflammatory processes in the lungs caused by the onset of lung overload (when the physiological lung cleansing processes are overloaded) after exposure to high concentrations of dust from inhalation. This is not substance-specific for titanium dioxide but is characteristic of poorly soluble dusts (granular biopersistent dusts), regardless of the substance on which they are based.

The Federal Ministry of Labour and Social Affairs, just like the statutory accident insurance, does not consider such a classification to be appropriate. To protect against dust and general particle effects is mostly a matter for occupational health and safety. Germany, therefore, has corresponding dust limit values to protect against inflammatory processes in the lungs caused by particles from dust exposure through inhalation. The general dust limit value (ASGW) is intended to prevent lung function impairment as a result of the general effects that dust can produce in the respiratory organs and applies to all poorly soluble or insoluble dusts. The value has also been derived in light of the studies now used by the EU. **We are not speaking of new findings here!** Initiatives at European level to have uniform rules regarding dust exposure have not yet been taken up.

What must be done for occupational health and safety?

If the general dust limit value is complied with, then all measures have been taken to protect employees effectively from dangers arising from titanium dioxide and other similar toxicologically harmless, water-insoluble and biopersistent particles. There is no danger of developing lung cancer through titanium dioxide inhalation when complying with the occupational exposure limit (AGW).

Such compliance of this ASGW (general dust limit value according to TRGS 900) is required by law. If the ASGW is not complied with, protective measures must be taken: substitution, technical measures, organisational measures, and finally personal measures such as respiratory protection.

The requirement of these protective measures and the safety to health, provided that this value is complied with, **does not depend** on the new classification of titanium dioxide!
This means that if everything is in order in terms of occupational health and safety today, this will also be the case after the 14th ATP comes into force with the new classification for titanium dioxide. If action is already required today, this will also be the case later on.

With the new classification being a category 2 classification (suspected substance), no measures according to Sec. 10 of the Ordinance on Hazardous Substances (Gefahrstoffverordnung) are necessary.

If the ASGW has been complied with so far, merely the internal labelling, the list of hazardous substances and the operating instructions have to be adapted if classified titanium dioxide is used in the activities. If titanium dioxide particles can be released from non-classified input materials and the ASGW is complied with, the operating instructions should also be modified.

In addition to making a reference to the actual exposure level, the risk assessment should also note that in this case there is no further risk in relation to the new classification. Reference can also be made to this document. Moreover, employees should receive training explaining the new classification and the background on the basis of the operating instructions, which are to be updated if necessary.

Conclusion

The weeks and months to come will see a tremendous amount of inquiries, a media response and uncertainties revolving around the new classification of titanium dioxide.

The new classification of titanium dioxide will not improve occupational health and safety in Germany. One can only hope that numerous unclarified questions in other areas of the law (such as in waste law, the use of titanium dioxide in foodstuffs or cosmetics, and the like) will be reasonably clarified and decided.

BG RCI cannot advise on these questions related to other areas of the law or the matter of whether and how products containing titanium dioxide can be marketed in the future.

For all questions regarding occupational safety and dust prevention at the workplace, the labour inspectors are pleased to give you the competent support your company needs.

This information is provided by the German Social Accident Insurance for the raw materials and chemical industry, Prevention, competence centre for hazardous substances, biological substances, analytical chemistry, Section: hazardous material database (GisChem)

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