

## **TÜV Rheinland LGA Products – Information**

**March 2020**

### **14th Adaptation of CLP Regulation (EC) No. 1272/2008 Classification of powdered Titanium Dioxide as carcinogenic**

#### **Current Significance of Titanium Dioxide**

Titanium dioxide is an inorganic, crystalline, white solid material. The extraction is made from the ores ilmenite and rutile, which are very common in nature. Titanium dioxide has been produced industrially for about 100 years and is used for a variety of different products. It is the whitest and brightest pigment known, has a high covering power and is able to reflect UV light. As a white pigment (Titanium White or Pigment White 6), to lighten colours or to achieve a covering through-dyeing, it is often used in paints, lacquers and printing inks, but also used for plastic/rubber, paper, enamel/ceramic and even in cosmetics (CI 77891) and food (E171). It may further serve as a filler (in plastics and high-quality paper) and as a UV protection agent (in sunscreens and textiles) and as self-cleaning/ dirt- and water-repellent nano-coating.

#### **CLH Proposal for a harmonized Classification of Titanium Dioxide**

In November 2015, France submitted a dossier to classify titanium dioxide as "possible carcinogen to human when inhaled" (category 1B). The dossier is based on the assumption that titanium dioxide may cause lung cancer under certain circumstances.

This conclusion is questioned by many toxicologists because the classification is essentially based on studies on rats exposed to extremely high concentrations of titanium dioxide dust for 18h/day. This leads to a so-called "lung overload" effect, a constant overloading of the lungs, which then may also lead to the development of carcinomas. The reason for this is that the ciliated epithelium, which transports particles out of the lungs, which are then coughed up, cannot cope with the quantities inhaled. While one normally leaves the place of exposure under such circumstances, this is not possible in animal experiments. The particles are not soluble in water and ultimately cause irritant cancer via inflammation in the lungs.

This was followed by an intensive discussion phase lasting several years in various European bodies and with extensive participation by the public and various industry associations.

ECHA's Committee for Risk Assessment (RAC) has proposed in its scientific opinion of 14 September 2017 to classify this substance only as "suspected carcinogen by inhalation" (category 2). It should further be noticed that the development of tumors depends on the particle size and solubility of the titanium dioxide (particles must be small enough to reach the deeper tissue of the lung and be able to deposit there). Titanium dioxide dissolved in liquid mixtures is not toxic to the lungs; however, dangerous aerosols and dangerous droplets may form during use. Unjustified classification of non-hazardous forms of the substance should therefore be avoided. However, in the case of mixtures, consumers should be informed of the precautions to be taken when using them by means of specific warnings.

### COMMISSION DELEGATED REGULATION (EU) 2020/217 of 4 October 2019

Finally, the EU Commission has decided to essentially follow the RAC opinion and classify titanium dioxide in powder form as carcinogen category 2.

On 18 February 2020 the 14th adaptation of the CLP Regulation was published in the EU Official Journal. This includes the addition of new substances or updating the classification of other substances in Table 3 of Part 3 of Annex VI to the CLP Regulation (list of substances with harmonised classification). Included is also titanium dioxide, which was not previously classified as hazardous and has now been added as a new entry to the table of the CLP Regulation.

#### New classification of titanium dioxide as a substance

Titanium dioxide is inserted as a new entry under index number 022-006-002:

Index No	Chemical Name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATEs	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
022-006-002	titanium dioxide; [in powder form containing 1 % or more of particles with aerodynamic diameter $\leq 10 \mu\text{m}$ ]	236-675-5	13463-67-7	Carc. 2	H351 (inhalation)	GHS08 Wing	H351 (inhalation)			V, W, 10'

Remarks for classification of substances and describing the particular toxicity of the substance:

- 'Note V:  
If the substance is to be placed on the market as fibres (with diameter  $< 3 \mu\text{m}$ , length  $> 5 \mu\text{m}$  and aspect ratio  $\geq 3:1$ ) or particles of the substance fulfilling the WHO fibre criteria or as particles with modified surface chemistry, their hazardous properties must be evaluated in accordance with Title II of this Regulation, to assess whether a higher category (Carc. 1B or 1A) and/or additional routes of exposure (oral or dermal) should be applied.'
- 'Note W:  
It has been observed that the carcinogenic hazard of this substance arises when respirable dust is inhaled in quantities leading to significant impairment of particle clearance mechanisms in the lung.'

Remarks for classification of mixtures:

- 'Note 10:  
The classification as a carcinogen by inhalation applies only to mixtures in powder form containing 1 % or more of titanium dioxide which is in the form of or incorporated in particles with aerodynamic diameter  $\leq 10 \mu\text{m}$ .'

The Regulation will apply directly in each Member State of the European Union from 1 October 2021 (as corrected by the Official Journal of the European Union L 44 of 18 February 2020); the requirements shall be applied from that date at the latest.

### Specific Labelling

Titanium dioxide powder containing  $\geq 1$  % of small particles with an aerodynamic diameter of  $\leq 10 \mu\text{m}$ , must be labelled as carcinogenic category 2 with H351 "May cause cancer by inhalation".

The decisive factor for the classification is the content of respirable dust particles. The aerodynamic diameter is used here as a measure of the transport and deposition of the dust; an auxiliary quantity in particle measurement technology to describe the behaviour of a gas-borne particle. This is defined as the diameter of a spherical particle with a density of  $1 \text{ g/cm}^3$ , which has the same sinking speed in still air as the particle<sup>1</sup> under consideration.

### Specific warnings for mixtures containing at least 1% titanium dioxide

No substance-specific classification limit is given in Table 3; i.e. for powdery mixtures with titanium dioxide particles of corresponding size, the generic concentration limit of 1 % applies. This is also made clear by "Note W".

A new section 2.1.1 on the labelling of certain mixtures containing titanium dioxide is added to Part 2 of Annex II of the CLP-Regulation (provisions for additional hazard statements to be included on the label of certain mixtures). The following new warnings have been added:

- EUH211: 'Warning! Hazardous respirable droplets may be formed when sprayed. Do not breathe spray or mist.'
- EUH212: 'Warning! Hazardous respirable dust may be formed when used. Do not breathe dust.'

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<sup>1</sup> Not only the geometric size of the particle is considered, but also its density and shape (e.g. isometric, fibrous, agglomerated). A titanium dioxide particle with an aerodynamic diameter of  $10 \mu\text{m}$  therefore has the same sinking speed as a standard sphere of density  $1 \text{ g/cm}^3$  of diameter  $10 \mu\text{m}$ . For the determination of the aerodynamic diameter different measuring techniques are available (among others Aerodynamic Particle Sizer (APS) with time-of-flight measurement, Aerodynamic Aerosol Classifier (AAC) with centrifugation or Aerosol Mass Spectrometry (AMS) with He/Ne lasers).

## Effects on the marketing of mixtures:

### In the future the following mixtures must be classified as carcinogenic (Carc. 2; H351)

- Powdery mixtures containing  $\geq 1$  % titanium dioxide (pure or incorporated) in small particles with aerodynamic diameter  $\leq 10 \mu\text{m}$ .
- Powders affected by this classification are marked with the symbol GHS08 („Health Hazard“), the signal word "warning" and the hazard statement H351: "Suspected of causing cancer by inhalation."



However, if correctly labelled, such mixtures may be placed on the market for the general public (exception: toys).

### The following mixtures must be provided with a warning label (EUH211 or EUH212) in future

- EUH211: Liquid mixtures (paints, etc.) containing  $\geq 1$  % of titanium dioxide particles with aerodynamic diameter not exceeding  $10 \mu\text{m}$
- EUH212: Solid mixtures (chalks etc.) containing  $\geq 1$  % titanium dioxide (regardless of the size of particles)

However, an obligation to label with an EUH phrase does not mean that the mixture is to be classified as hazardous. The EUH phrase is merely an additional hazard warning.

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Aspects not covered by the Regulation:

- a) Question: Is there a definition for 'powder'?

Answer: There is no general definition. For solid substances/mixtures with small particles, the particle size (aerodynamic diameter) should therefore always be considered.

- b) Question: How can one obtain information on the aerodynamic diameter of particles contained in a substance/mixture?

Answer: Analytical evidence could possibly be provided by means of the above-mentioned measuring instruments. In most cases, however, one will have to rely on the information provided by the manufacturer (e.g. in the safety data sheet).

- c) Question: In the case of solid mixtures, do we have to consider that these could form or release small particles during storage/transport or use?

Answer: European chemicals legislation only considers substances and mixtures at the moment they are placed on the market. The risk of forming small particles is covered by EUH212.

- d) Question: How to classify and label aerosols?

Aerosols may contain small titanium dioxide particles which in the original state of the mixture are dissolved in liquid or dispersed in the propellant. These could be present as free solids after evaporation of the solution or during evaporation of the propellant gas.

Answer: Again, depending on the composition of the aerosol, this hazard should be adequately covered by the warning EUH212 or EUH211.

- e) Question: How should titanium dioxide particles, which are virtually inaccessible under an inert surface coating such as  $\text{SiO}_2/\text{Al}_2\text{O}_3$ , be considered?

Answer: It is recommended to consider the particle size alone. It will be difficult to prove that the coating is complete; toxicological reports could provide controversial results.

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### **Effects on toys within the scope of Directive 2009/48/EC:**

The European Directive on the safety of toys 2009/48/EC imposes special requirements on CMR substances in Annex II Part III No. 3+4+5: Substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 pursuant to Regulation (EC) No. 1272/2008 shall not be present in accessible toy materials in concentrations above their classification limit. This means in practice:

- Substances and mixtures classified as Carc. 2, H351 shall not be used in toys.
- Substances and mixtures to which only one EUH phrase has been assigned may be placed on the market with appropriate labelling.
- Materials in products (e.g. paints, plastics/rubber and paper) must not contain more than 1% titanium dioxide (pure or incorporated as a component) in small particles with aerodynamic diameter  $\leq 10\mu\text{m}$ .

However, compliance with the above-mentioned concrete requirements is often not sufficient. Article 18 requires the manufacturer to carry out a risk analysis and an assessment of potential exposure to these risks before placing the product on the market. Point 1 of Part III of Annex II provides that toys, when used as intended or in a foreseeable way, must not present any risk of adverse effects on human health from chemical substances or mixtures contained therein. This means that no particles containing titanium dioxide with an aerodynamic diameter  $\leq 10\mu\text{m}$  may be produced when using the toy.

Such a consideration is particularly relevant for solid (e.g. street crayons) and liquid mixtures (e.g. finger paints) after drying. In the case of products, it is more likely to be assumed that the titanium dioxide particles are firmly embedded in the matrix of the product when it is ready for sale, irrespective of the raw materials used. Nevertheless, it must be estimated separately for each material, which particle sizes could be produced by abrasion on stone, sand, metal or other surfaces in case of foreseeable misuse.

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## Effects on cosmetics

Titanium dioxide is often used as a very effective, covering pigment in sunscreens, in decorative cosmetics, powders, make-up and as a colour base in coloured hairsprays.

CMR substances of category 2 may be used in cosmetic products if the Scientific Committee on Consumer Safety (SCCS) of the EU assesses the substance as safe. There are no current assessments besides the uses listed below according to Annex IV and VI.

If titanium dioxide is classified as Carc. 1B or 1A for the purposes of Notes V and W (see page 2), its use in cosmetic products is prohibited unless all the following conditions are met:

- a) they comply with the food safety requirements laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
- b) an analysis of the alternatives shows that no suitable substitutes are available
- c) the application is for a specific use of the product category with a known exposure
- d) they have been evaluated by the SCCS and their use in cosmetic products has been found safe, in particular as regards exposure to these products and taking into account the overall exposure from other sources and paying particular attention to vulnerable groups

Accordingly, titanium dioxide which is not subject to the above classification is still permitted as:

- Colouring agent according to No 143 Annex IV of Regulation (EC) No 1223/2009, CI 77891
- UV filters up to 25 % according to No 27 of Annex VI of Regulation (EC) No 1223/2009
- UV filter Nano material up to 25 % under No. 27 Annex VI of Regulation (EC) No. 1223/2009 with extensive conditions

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