

How to apply the harmonised classification of titanium dioxide?




Helpdesk compact: CLP

The classification of certain forms of titanium dioxide was published on 18.02.2020 as suspected of causing cancer by inhalation. The hazard category Carc. 2 with the hazard statement H351 (Inhalation) was assigned in the Regulation (EU) 2020/217 (14th ATP) amending Regulation (EC) No 1272/2008 (CLP Regulation). In addition, provisions have been made for the classification of mixtures as well as regulations for the labelling of certain mixtures containing titanium dioxide with European EUH-phrases. The regulations will apply after an eighteen-month transitional period from 01.10.2021. However, they can already be applied now.

1 The provisions of the Delegated Regulation (EU) 2020/217 (referred to as the 14th ATP)

In accordance with the 14th ATP (adaptation to technical and scientific progress), Annex VI with a TiO₂ entry, which contains various notes, and Annex II on specific requirements for the labelling of certain mixtures containing dangerous substances are amended. This is listed below:

Annex VI

Index No.	Chemical Name	EC No.	CAS No.	Classification		Labelling			Specific concentration limits, M-factors and ATE's	Notes
				Hazard class and category code(s)	Hazard statement code(s)	Pictogram, signal word code(s)	Hazard statement code(s)	Supplemental hazard statement code(s)		
022-006-00-2	titanium dioxide; [in powder form containing 1 % or more of particles with aerodynamic diameter ≤ 10 µm]	236-675-5	13463-67-7	Carc. 2	H351 (Inhalation)		H351			V, W, 10

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 = 10 µm.

Note V:

If the substance is to be placed on the market as fibres (with diameter < 3 µm, length > 5 µm and aspect ratio = 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.

This note aims to describe the particular toxicity of the substance; it does not constitute a criterion for classification according to this Regulation.'

Annex II

Annex II to Regulation (EC) No 1272/2008 is amended as follows:

- (1) The introductory paragraph is amended as follows: 'The statements set out in sections 2.1 to 2.10 and 2.12 shall be assigned to mixtures in accordance with Article 25(6).
- (2) Section 2.12 is added: 2.12.: 2.12. Mixtures containing titanium dioxide

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

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

The label on the packaging of solid mixtures containing 1 % or more of titanium dioxide shall bear the following statement:

EUH212: 'Warning! Hazardous respirable dust may be formed when used. Do not breathe dust.'

In addition, the label on the packaging of liquid and solid mixtures not intended for the general public and not classified as hazardous which are labelled with EUH211 or EUH212, shall bear statement EUH210.

2 Classification and labelling of the substance titanium dioxide

The classification as Carc. 2, H351 (Inhalation) is linked to the powder form of the substance. It is therefore only based on the particle fraction that is effectively responsible for the health effect. A powder is understood by the German helpdesk as a loose bulk of particles for which no size information is initially relevant.

However, only the presence of a certain particle fraction in sufficient quantity leads to the classification of titanium dioxide powder. According to the Annex VI entry for the classification of titanium dioxide, at least 1 % (w/w) of the powder must consist of particles with an aerodynamic diameter $\leq 10 \mu\text{m}$.

If the titanium dioxide contains particles in fibre form, the actor placing the substance on the market must check whether a more stringent classification based on Note V needs to be applied. In this case, all other specific criteria for titanium dioxide are invalidated.

3 Classification and labelling of mixtures, which contain titanium dioxide

The classification of a mixture is based on the hazardous substances which the mixture contains, here on „titanium dioxide; [in powder form containing 1 % or more of particles with aerodynamic diameter $\leq 10 \mu\text{m}$]“. Like the substance titanium dioxide itself, the classification of mixtures in accordance with Note 10 is also necessarily linked to the powder form and should be based on the particle fraction effectively responsible for the health effect. The condition imposed by Note 10 is identical to the substance classification and thus replaces the generic concentration limit in Annex I, Part 3, Chapter 3.6, Section 3.6.3 of the CLP Regulation.

The application of Note 10, however, only results in classification of mixtures that are in powder form if:

- either the content of titanium dioxide particles with an aerodynamic diameter of $\leq 10 \mu\text{m}$ is at least 1 % (w/w)
- or the content of titanium dioxide incorporated in particles with an aerodynamic diameter $\leq 10 \mu\text{m}$ is at least 1 % (w/w)

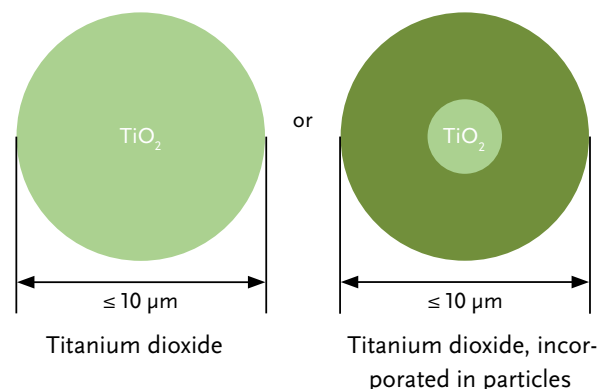


Fig. 1 Note 10, mixtures in powder form

Note 10 clarifies that the relevant particles need not to consist entirely of titanium dioxide, but may also be, for example, alloys or particles incorporated into a polymer (see Figure 1).

However, the total titanium dioxide content in the mixture, distributed over the relevant particles, must be at least 1 % (w/w).

3.1 Strategy for estimating the classification obligation

Whether a mixture meets the requirements for classification should normally be calculated on the basis of the ingredient substances used to formulate the mixture. If sufficient information on the ingredients cannot be obtained, the parameters may have to be determined analytically, either on the ingredient substances or the mixture.

As a rule, it should first be checked by calculation whether the mixture contains ≥ 1 % (w/w) titanium dioxide (incorporated in particles). If this is not the case, the information on particle size is no longer required for the classification decision.

If ≥ 1 % (w/w) titanium dioxide (incorporated in particles) is contained in the mixture, the particle size distribution must be considered. To evaluate the particle sizes, an estimation should be made in a tiered procedure. For a rough estimation, the entire particle fraction in question can be used first. Only if this leads to a classification (i.e. the quantity of particles ≤ 10 μm makes up at least 1 % of the total mass), it must be decided in a further step whether further information about the particle fractions needs to be determined.

Suppliers are usually the most reliable source of information on the substances and mixtures used. In particular, for registered substances, manufacturers and importers should have sufficient information on particle size distribution. If an analysis of the ingredients or the mixture is necessary, the methods chosen must be suitable for the individual case.

4 Labelling with EUH211 or EUH212 according to Annex II

According to Article 25(6) the labelling of a mixture in accordance with Part 2 of Annex II of the CLP Regulation is mandatory if the mixture contains a substance classified as hazardous. For solid and liquid mixtures containing titanium dioxide there are special labelling provisions in Annex II, which are intended to be effective in particular if the mixtures are not themselves classified.

4.1 Labelling of solid mixtures

A solid mixture can appear in different forms, such as powdery mixtures or pellets of polymers in which titanium dioxide is bound, or as pressed blocks.

Mixtures in powder form which, because of their content of titanium dioxide particles in free or incorporated form, must be classified as Carc. 2, H351 (inhalation), also meet the requirements of Section 2.12 of Annex II and must be labelled with the supplemental label element EUH212.

In addition, all other solid mixtures, due to the regulation in Annex II Part 2 Section 2.12 of the CLP Regulation „Mixtures containing titanium dioxide“, must be labelled with the supplementary labelling element EUH212 if they contain at least 1 % (w/w) titanium dioxide particles.

EUH212: ‘Warning! Hazardous respirable dust may be formed when used. Do not breathe dust.’

Neither the powder form nor the particle size is decisive for the application of EUH212. At this point, the intention of the legislator is clear to point out the possible danger of dangerous dusts that can be generated during application even if the mixture itself does not contain classified titanium dioxide. However, this clearly shows a dilemma that is faced when interpreting the legal text. After all, it is a general requirement of the application of Annex II that a hazardous substance is contained in the mixture.

Against this background, the German Helpdesk recommends to label all solid mixtures in question with a content of at least 1 % titanium dioxide with EUH212 even if it is unclear to what extent they contain a substance that is subject to classification.

In this context, we would like to draw your attention to pending proceedings before the European Court of Justice, in which, among other things, the legality of the amendment of Annex II of the CLP Regulation is being negotiated. Depending on the judgements, the present guidance may need to be adapted.¹

4.2 Labelling of liquid mixtures

Liquid mixtures containing titanium dioxide are excluded from classification as Carc. 2, H351 (inhalation). However, they must be labelled with the supplementary labelling element EUH211 if they contain at least 1 % (w/w) titanium dioxide particles with an aerodynamic diameter of not more than 10 μm .

¹ Case T-279/20: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62020TN0279>
Case T-283/20: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62020TN0283&qid=1499273450841>
Case T-288/20: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62020TN0288>

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

Whether a liquid mixture fulfils the requirements for supplementary labelling should also be calculated on the basis of the starting materials used to formulate the mixture. For this procedure, it is pragmatic to assume that the particles used will not change in the liquid.

When deciding whether supplementary labelling is necessary, the approach should be analogous to that described in Chapter 3.1 „Strategy for estimating the classification obligation“.

4.3 Labelling with EUH210

The label on the packaging of liquid and solid mixtures not intended for the general public and not classified as hazardous and labelled EUH211 or EUH212 shall also bear the statement EUH210 „Safety data sheet available on request“.

5 Questions and Answers/Examples

5.1 How must powdered mixtures containing titanium dioxide, e.g. joint mortar, be classified and labelled?

The following cases must be distinguished:

1. The mixture contains at least 1 % titanium dioxide particles with an aerodynamic diameter of $\leq 10 \mu\text{m}$.

The mixture must be classified and in addition, the supplementary labelling element EUH212 has to be assigned.

2. The mixture contains at least 1 % titanium dioxide particles, but not 1 % of all particles have a diameter $\leq 10 \mu\text{m}$.

The mixture does not need to be classified. Insofar the EUH212 would only be assigned if the mixture contains another substance subject to classification. However, the Helpdesk recommends the indication of the EUH212.

3. The mixture contains less than 1 % titanium dioxide particles regardless of the diameter of the particles.

In this case, the mixture does not need to be classified due to titanium dioxide, nor is EUH212 needed.

5.2 How must suspensions containing titanium dioxide, i.e. liquids in which particles are finely dispersed, for example wall paint, be classified and labelled?

According to Note 10 in Annex VI these mixtures do not need to be classified as Carc. 2, H351 (inhalation), but need to be labelled with EUH211 according to Annex II, Part 2, section 2.12 (see above). The requirement for EUH211 is met if:

1. the suspension is formulated with powdered „titanium dioxide; [in powder form containing 1 % or more of particles with aerodynamic diameter $\leq 10 \mu\text{m}$], and
2. the proportion of titanium dioxide particles with an aerodynamic diameter $\leq 10 \mu\text{m}$ used is at least 1 % of the total mass of the suspension.

5.3 Do crayons or coloured pencils containing titanium dioxide have to be classified and labelled?

These products are solid, but not powdery mixtures. Therefore, these mixtures do not have to be classified as Carc. 2, H351 (Inhalation) according to Note 10. However, they must be labelled with EUH212 according to Annex II, section 2.12 if they contain at least 1 % titanium dioxide particles regardless of their size and a substance classified as hazardous in any concentration.

5.4 Do articles containing titanium dioxide have to be classified and labelled?

Articles that are coloured white with titanium dioxide, for example a plastic box, or impregnated with a mixture containing titanium dioxide, for example coated paper, do not have to be classified and labelled. The classification and labelling rules only apply to substances and mixtures.

5.5 Do articles containing titanium dioxide have to be classified and labelled if they may release dust containing titanium dioxide during use, for example through abrasion?

As the CLP Regulation only applies to substances and mixtures, there is no need to classify or label such articles. If special measures for safe handling during use have to be established, this is done in Germany either through the regulations of the "Produktsicherheitsgesetz" or through measures for the protection of employees and other persons when working with hazardous substances in accordance with sections 3-6 of the "Gefahrstoffverordnung".

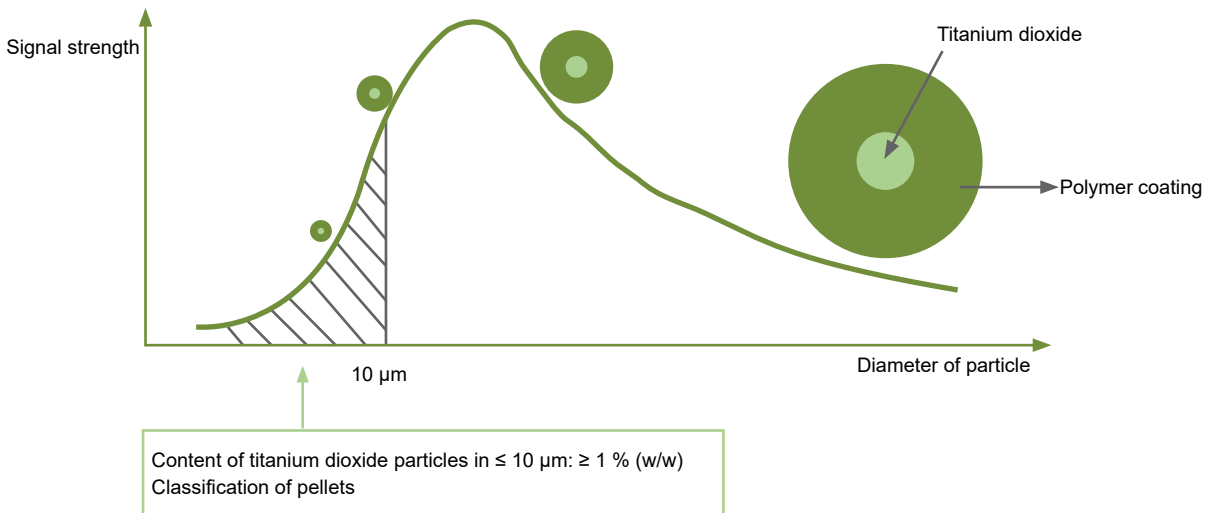


Fig. 2 Distribution of polymer particles with titanium dioxide core

5.6 Must polymer pellets that contain titanium dioxide be classified?

Bulk polymer pellets must be classified as Carc. 2, H351 (inhalation) if fractions with a diameter of 10 µm or smaller contain at least 1 % (w/w) titanium dioxide. This is further illustrated in Figure 2, which shows a distribution of polymer pellets with a titanium dioxide core. The hatched area under the curve is the proportion of particles ≤ 10 µm, which must contain at least 1 % (w/w) titanium dioxide for a classification.

This information is an interpretation of the regulation (EC) No. 1272/2008 by the Federal Institute for Occupational Safety and Health. It has been prepared with the greatest possible care and is based on sound knowledge of chemicals legislation. The information represents the national view, which might need changes after harmonization at European level. Any legal recommendations, information and references are non-binding, legal advice is expressly not given.

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