# Guide on the classification and labelling of titanium dioxide

September 2021

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This document has been elaborated and developed from the following publication of the German Helpdesk:

S. Darschnik, C. Haas, N. Heuer, R. John. **Hilfestellung zur Anwendung der harmonisierten Titandioxideinstufung.**

1. Auflage. Dortmund: Bundesanstalt für Arbeitsschutz und Arbeitsmedizin 2020. Seiten 5, PDF-Datei, DOI: 10.21934/REACH:kompakt20200724

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The classification of certain forms of titanium dioxide ($TiO_2$) as suspected carcinogens by inhalation was published on 18.02.2020. The hazard class Carc. 2 was assigned with the hazard statement H351 (inhalation) 'suspected of causing cancer (inhalation)' in Commission Delegated Regulation (EU) 2020/217 (14th Adaptation to Technical and Scientific Progress, 'ATP') amending Regulation (EC) No 1272/2008 (CLP Regulation). In addition, provisions have been made for the classification of mixtures as well as the labelling of certain mixtures containing $TiO_2$ with EU-specific EUH statements. These requirements will apply after an eighteen-month transitional period from 01.10.2021. However, suppliers can already apply them, on a voluntary basis, before this date.

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

According to the 14th ATP, Annex VI to CLP is amended by including, amongst others, $TiO_{2d}$ (substance) as a new entry containing various notes. Annex II is also amended and includes specific labelling requirements for certain mixtures containing $TiO_2$. This is set out below:

**Annex VI**

| *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 ≤ 10 µm]* | *236-675-5* | *13463-67-7* | Carc. 2 | H351 (Inhalation) |  Wng | H351 (inhalation) | | | 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

*'Part 2 of 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. 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

Classification as Carc. 2, H351 (inhalation) is linked to some powder forms of the substance. It is therefore triggered only on the basis of the specific fraction of particles which is effectively responsible for the health effect. In this context, 'powder' refers to the specific physical state of the substance.

Therefore, the classification of titanium dioxide powder is warranted only if at least 1 % (w/w)[1] of the powder consists of particles with aerodynamic diameter ≤ 10 µm.

The supplier must consider whether, based on Note V (related to fibres or particles with modified surface chemistry), a stricter classification (Carc. 1A or 1B) and/or additional routes of exposure (oral or dermal) need to be applied.

In this case, all other specific criteria for the classification and labelling of titanium dioxide are overridden.

[1] Please note that the percentage is calculated on the basis of weight

## 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, in this case on the presence of 'Titanium dioxide [in powder form containing 1% or more of particles with aerodynamic diameter ≤ 10 µm]'. Like the substance titanium dioxide itself, the classification of mixtures in accordance with Note 10 is linked to the powder form of the mixture and should be based on the fraction of particles of titanium dioxide effectively responsible for the health effect. The condition imposed by Note 10 is similar to the substance classification and thus replaces the generic concentration limit in Section 3.6.3 of Chapter 3.6 of Part 3 of Annex I to the CLP Regulation.

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

- either the content of titanium dioxide particles with an aerodynamic diameter ≤ 10 µm is equal to or greater than 1% (w/w); or
- the content of titanium dioxide, which is incorporated in particles with an aerodynamic diameter ≤ 10 µm, is at least 1% (w/w).

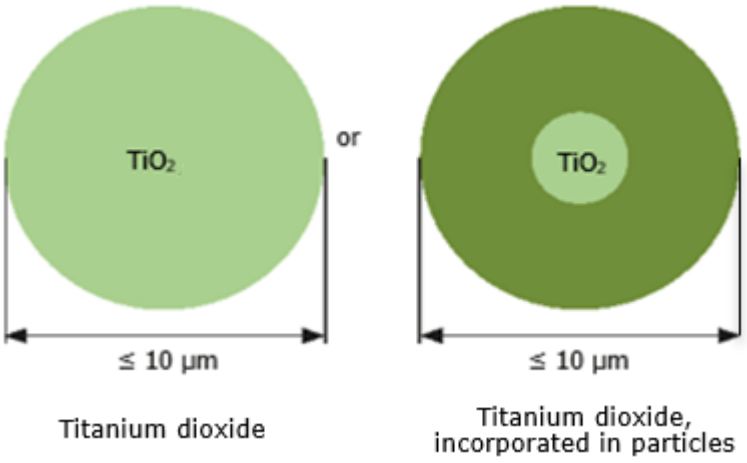


**Figure 1. Note 10, mixtures in powder form**

Note 10 clarifies that the relevant particles do not need to be completely composed of titanium dioxide, but may also be, for example, surface-modified particles or particles embedded in a polymer (see Figure 1, right side).

However, in all cases, the total amount of titanium dioxide in the mixture, distributed among the relevant particles, must be at least 1 % (w/w).

### 3.1 Strategy for assessing the need to classify mixtures containing $TiO_2$

Whether a mixture containing CMR substances meets the criteria for classification should normally be calculated on the basis of the ingredient substances used in the formulation of the mixture. Where it is not possible to identify sufficient information on the ingredient substances, the data may need to be obtained analytically, either on the ingredient substances or on the mixture.

As a general rule, it should first be verified by calculation whether the mixture in powder form contains ≥ 1 % (w/w) of titanium dioxide (embedded in particles). If this is not the case, there are no classification obligations warranted by the $TiO_2$ content.

If ≥ 1 % (w/w) of titanium dioxide is present in the mixture, the distribution of particles according to size shall be considered. An assessment of particle sizes should be carried out in a tiered procedure.
Only if the amount of particles ≤ 10 µm represents at least 1 % of the total mass, it will be necessary to decide in a further step whether further information on the $TiO_2$ content (% w/w) of the relevant fraction of particles needs to be obtained.

In practice, this would mean the following steps in the assessment:

Step (1) Check if the mixture contains 1% or more $TiO_2$;

Step (2) If yes, determine the fraction of the powdered mixture that consists of particles ≤ 10 µm

Step (3) Determine the concentration (%) of $TiO_2$ in the particles ≤ 10 µm;

Step (4) Calculate whether the content of $TiO_2$ in the particles ≤ 10 µm constitutes ≥ 1% (w/w) of the total powdered mixture

**Example 1:**

You have formulated a powder form mixture containing 20 % (w/w) of $TiO_2$ in the mixture. You have determined that 6 % of the particles in the mixture (w/w) are within the size range ≤ 10 µm.

To determine the $TiO_2$-content in the ≤ 10 µm particles, you calculate
(6 x 20)/100 = 1.2 % (w/w)

Thus, the concentration of $TiO_2$ in the mixture that is incorporated in the particles ≤ 10 µm is 1.2 %, and you will need to classify the mixture as Carc 2.

**Example 2:**

The formulation is the same as in Example 1, but you determine that the $TiO_2$ content in the ≤ 10 µm particles is < 16.6% (=100/6). Since 16.6 % (w/w) x 6% is < 1 % (w/w), there is no need to classify the mixture as Carc. 2

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 distribution of particles according to size. Should an analysis of the ingredient substances or the mixture be necessary, the methods chosen shall be appropriate to the individual case.

## 4. Labelling with EUH211 or EUH212

The labelling of a mixture in accordance with Part 2 of Annex II to the CLP Regulation is mandatory, in accordance with Article 25 (6). Specific labelling rules apply to solid and liquid mixtures containing titanium dioxide, if they contain titanium dioxide that is hazardous or may become hazardous during the formulation of a mixture.

### 4.1 Labelling of solid mixtures

A solid mixture may occur in various forms, such as a mixture in powder form or as polymer pellets incorporating titanium dioxide, or as pressed blocks.

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

Non-classified mixtures: Other solid mixtures must be labelled with the supplemental labelling element EUH212 if they contain at least 1 % (w/w) of titanium dioxide, in accordance with Section 2.12 of Part 2 of Annex II to the CLP Regulation 'Mixtures containing titanium dioxide'.

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

Neither the powder form nor the particle size shall be taken into account for the application of EUH212. It is clear here that the legislator's intention is to draw attention to the possibility that hazardous dust is formed during use, even when the mixture itself does not contain 'classified' titanium dioxide when placed on the market (i.e when the titanium dioxide 'ingredient substance' is not in a mixture in powder form containing at least 1 % (w/w) of $TiO_2$ in the form of or incorporated in particles with aerodynamic diameter ≤ 10 µm.).

### 4.2 Labelling of liquid mixtures

Liquid mixtures containing titanium dioxide do not require classification as Carc. 2, H351 (inhalation). However, they shall be labelled with the supplemental labelling element EUH211 if they contain at least 1 % (w/w) of titanium dioxide particles with an aerodynamic diameter of 10 µm or less.

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

Whether a liquid mixture meets the requirements for supplemental labelling should usually also be calculated on the basis of the ingredient substances used to formulate the mixture. In order to do so, it seems pragmatic to assume that the particles do not change when the ingredient substances are mixed to form a liquid.

Suppliers of 'ingredient substances' can however document if such changes are likely to occur, for example when formulating paint dispersions

### 4.3 Labelling with EUH210

The label on the packaging of liquid and solid mixtures which are not intended for the general public and have not been classified as hazardous and are labelled with EUH211 or EUH212 shall also bear the statement EUH210 'Safety Data Sheet available on request'.

## 5. Questions and Answers/Examples

### 5.1 How must mixtures in powder form, containing titanium dioxide, such as joining mortar, be classified and labelled?

A distinction should be made between the following cases:

1. The mixture contains at least 1 % of titanium dioxide which is in the form of or incorporated in particles with an aerodynamic diameter ≤ 10 µm.

   The mixture must be classified and must be labelled with the pictogram GHS08 and the Wng (Warning) signal word code, with the H351(inhalation) hazard statement code, as well as, with the supplemental labelling element EUH212.

2. The mixture contains at least 1 % of titanium dioxide, but less than 1 % of all particles have a diameter ≤ 10 µm.

   The mixture does not need to be classified for its $TiO_2$ content. However, the EUH212 statement shall be assigned.

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

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

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

According to Note 10 of Annex VI, these mixtures do not need to be classified as Carc. 2, H351 (inhalation), but are labelled with EUH211 in accordance with section 2.12 of Part 2 of Annex II (see above). Assigning EUH211 is subject to the following condition:

> The suspension is formulated with titanium dioxide and contains at least 1 % of $TiO_2$ particles with aerodynamic diameter ≤ 10 µm, and this means that the proportion of titanium dioxide particles with aerodynamic diameter ≤ 10 µm used represents at least 1 % of the total mass of the suspension.

### 5.3 Must chalks or pencils containing titanium dioxide be classified and labelled?

These products are solid mixtures but not in powder form. Therefore, according to Note 10, these mixtures do not need to be classified as Carc. 2, H351 (inhalation). However, they must be labelled with the statement EUH212 in accordance with section 2.12 of Annex II if they contain at least 1 % of titanium dioxide regardless of the size of the particles.

### 5.4 Must articles containing titanium dioxide be classified and labelled?

Articles coloured white with titanium dioxide, such as a plastic box, or finished with a mixture containing titanium dioxide, such as coated paper, do not need to be classified and labelled. The classification and labelling rules only apply to substances and mixtures.

### 5.5 Must articles containing titanium dioxide be classified and labelled if they are able to release dust containing titanium dioxide during use, for example by 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 have to be observed during use, this is regulated either by means of the product safety legislation or by means of measures to protect employees in accordance with Directive 98/24/EC.

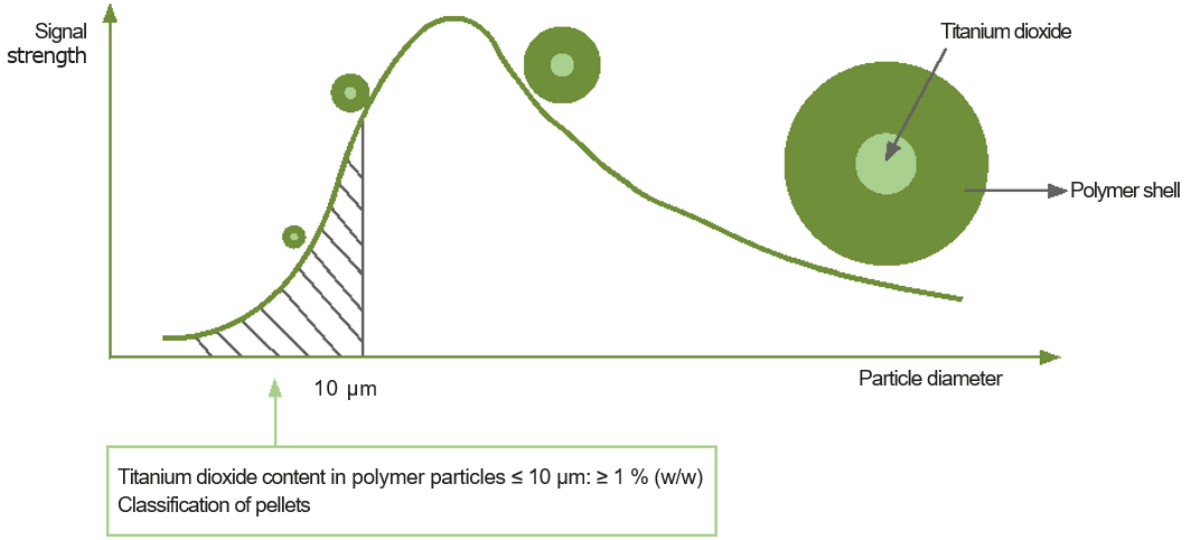


**Figure 2. Distribution of polymer pellets with titanium dioxide core**

## 5.6 Must polymer pellets that contain titanium dioxide be classified?

Polymer pellets must be classified as Carc. 2, H351 (inhalation), if they are in powder form, containing particles with a diameter of 10 µm or smaller and containing at least 1% (w/w) of titanium dioxide in the form of or incorporated in such particles. This is illustrated again in Figure 2, which shows a distribution of such polymer pellets with a titanium dioxide core. The hatched area under the curve is the proportion of particles ≤ 10 µm.

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