

**Request for an opinion on the safety of titanium dioxide in toys
with regard to a possible derogation from its prohibition**

1. Background

The Toy Safety Directive 2009/48/EC¹ prohibits the use of substances in toys if those substances are classified as carcinogenic, mutagenic or toxic for reproduction (CMR).^{2, 3} Under certain conditions, however, the use of such substances may be permitted.

To permit the use of a CMR substance of category 2, the substance has to be evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure. An additional condition is that the substance is not prohibited for use in consumer articles under REACH.^{4, 5}

Titanium dioxide (CAS number 13463-67-7) in powder form containing 1% or more of particles with aerodynamic diameter $\leq 10 \mu\text{m}$ has been classified as carcinogenic category 2 by inhalation.⁶ Liquid mixtures containing 1% or more of titanium dioxide particles with aerodynamic diameter $\leq 10 \mu\text{m}$ have to be labelled with the warning that hazardous respirable droplets may be formed when sprayed which should not be inhaled. Solid mixtures containing

¹ Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys. OJ L 170, 30.06.2009, p. 1.
<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1589882074178&uri=CELEX:02009L0048-20191118>

² Annex II, Part III, point 3 of the Toy Safety Directive.

³ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1.
<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1589288952589&uri=CELEX:32008R1272>

⁴ Annex II, Part III, point 5 (c) of the Toy Safety Directive.

⁵ REACH: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. OJ L 396, 30.12.2006, p. 1.
<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1589281141090&uri=CELEX:32006R1907>

⁶ Commission Delegated Regulation (EU) 2020/217 of 4 October 2019 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting that Regulation. OJ L 44, 18.2.2020, p. 1.
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2020.044.01.0001.01.ENG&toc=OJ:L:2020:044:TOC

1 % or more of titanium dioxide have to be labelled with the warning that hazardous respirable dust may be formed when used which should not be inhaled.⁷

The toy industry⁸ reported that the vast majority of titanium dioxide placed on the market is in powder form and contains 1% or more particles with an aerodynamic diameter of $\leq 10 \mu\text{m}$. The toy industry further signalled a wide use of titanium dioxide in toys and toy materials, including coatings, chalks and powder paints, clays and putties, and polymeric materials. The highest content of titanium dioxide has been indicated as ranging between 1% and 30%. – The toy industry also provided a compilation on toxicology, exposure and risk assessment of titanium dioxide with regard to toys.

The writing instruments industry⁹ reported the use of titanium dioxide in colour pencils and wax crayons (which can both be toys), in particular when white. It also reported the results of abrasive tests with colour pencils and wax crayons, including the number and mass of the dust particles observed after abrasion. Similarly, it reported abrasive tests on dried finger paint and with oven dried modelling clay. Finally it transmitted also an occupational exposure study with titanium dioxide.

2. Terms of reference

SCHEER is asked:

1. to review the available data on the use of titanium dioxide leading to inhalation exposure in particular in toys and toy materials
2. to evaluate whether the uses of titanium dioxide in toys and toy materials can be considered to be safe in light of the exposure identified, and in light of the classification of titanium dioxide as carcinogenic category 2 as outlined in the background above. Safe toys and toy materials should be indicated.

In replying to the above questions and in order to ensure coherence with other scientific bodies, SCHEER is invited to consult in particular the Scientific Committee on Consumer Safety (SCCS).

Timeline:

Preliminary opinion – mid-2021

Final opinion – Autumn 2021

Annex 1-x: Toy Industries of Europe (TIE).

- 1-1: Background document ... [on the] uses of titanium dioxide. 5 May 2020;
- 1-2: Support ... for a derogation ... for uses of Titanium Dioxide ... in toy materials. November 2020.

⁷ Annex I, No (2) of the afore-mentioned Commission Delegated Regulation (EU) 2020/217.

⁸ Toy Industries of Europe (TIE). See annexes 1-x to this mandate.

⁹ European Writing Manufacturer's Association (EWIMA). See annexes 2-x, 3-x, 4-x and 5-x to this mandate.

Annexes 2-x, 3-x, 4-x, 5-x, 6 and 7-x: European Writing Manufacturer's Association (EWIMA).

- 2-1: Background document. 30 June 2020;
- 2-2: Colour pencils – Results of TiO₂ dust measurement of TÜV Rheinland;
- 2-3: Colour pencils – Original report from TÜV Rheinland;
- 2-4: Colour pencils – Results of TiO₂ dust measurement of TÜV Rheinland;
- 2-5: Colour pencils – Original report from TÜV Rheinland;
- 2-6: Colour pencils – Results of TiO₂ dust measurement of TÜV Rheinland;
- 2-7: Colour pencils – Original report from TÜV Rheinland;
- 2-8: Colour pencils – Results of TiO₂ dust measurement of TÜV Rheinland;
- 2-9: Colour pencils – Original report from TÜV Rheinland;
- 3-1: Wax crayons 4% TiO₂ – Results of TiO₂ dust measurement of TÜV Rheinland;
- 3-2: Wax crayons 4% TiO₂ – Original report from TÜV Rheinland;
- 3-3: Wax crayons 20% TiO₂ – Results of TiO₂ dust measurement of TÜV Rheinland;
- 3-4: Wax crayons 20% TiO₂ – Original report from TÜV Rheinland;
- 3-5: Wax crayons, TiO₂ content – Extract of report from TÜV Rheinland: only white wax crayons have 20% TiO₂, other colours much less.
- 3-6: Wax crayons – Results of TiO₂ dust measurement of TÜV Rheinland;
- 3-7: Wax crayons – Original report from TÜV Rheinland;
- 4-1: Finger paint – Results of TiO₂ dust measurement of TÜV Rheinland;
- 4-2: Finger paint – Original report from TÜV Rheinland;
- 5-1: Modelling clay – Results of TiO₂ dust measurement of TÜV Rheinland;
- 5-2: Modelling clay – Original report from TÜV Rheinland;
- 6: Summary of TiO₂ release studies;
- 7-1: Summary of occupational exposure study on TiO₂;
- 7-2: Occupational exposure study on TiO₂.