



Inspiring Generations of Play

July 3, 2022

The European Commission TBT Enquiry Point  
DG for Internal Market, Industry, Entrepreneurship and SME's  
Unit GROW B2  
Avenue des Nerviens 105  
1049 Brussels  
Belgium

**VIA Email:** via U.S. TBT Enquiry Point

**RE: European Commission - Public consultation on the Preliminary Opinion on the Safety of Titanium Dioxide (TiO<sub>2</sub>) in toys.**

Dear Sir/Madam:

These comments are provided on behalf of The Toy Association, in support of the European Commission and its Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) review on the safety of TiO<sub>2</sub> in toys. We have divided out our comments against each corresponding chapter of the Preliminary Opinion, along with each page and line item and have submitted our comments through the SCHEER web portal here: [https://health.ec.europa.eu/consultations/public-consultation-preliminary-opinion-safety-titanium-dioxide-toys\\_en](https://health.ec.europa.eu/consultations/public-consultation-preliminary-opinion-safety-titanium-dioxide-toys_en).

Consistent with the European Commission’s obligations under the World Trade Organization’s *Agreement on Technical Barriers to Trade*, we encourage the Commission to notify the WTO of its Preliminary Opinion on the Safety of TiO<sub>2</sub> for consultation. This will help to ensure awareness amongst impacted parties prior to implementation.

The Toy Association is the North American-based trade association, whose membership includes more than 900 businesses – from inventors and designers of toys to toy manufacturers and importers, retailers, and safety testing labs – all involved in bringing safe, fun toys and games to children. The toy sector is a global industry generating more than US\$90 billion annually, and our members account for more than half this amount. The Toy Association is committed to working with legislators and regulators around the world to reduce barriers to trade and to achieve the international alignment and harmonization of risk-based standards that will provide a high level of confidence that toys from any source can be trusted as safe for use by children.

Chapter	Page	Line	The Toy Association (TA) Comments
<b>3. SCIENTIFIC OPINION</b>	13	44	The toy industry (Toy Industries of Europe) originally provided data on lipgloss/lipstick for information. It was not anticipated (based on the inhalation exposure) that this product type would be considered for evaluation. As SCCS now has a mandate to further evaluate the safety of TiO <sub>2</sub> in cosmetics, it is proposed that this exposure scenario is removed from the Opinion. This is especially critical as the identified mechanism of action underpinning the classification of TiO <sub>2</sub> as a Category 2 carcinogen is inflammation created by lung overload, a scenario to be found only in occupational, not consumer, settings; therefore, this route of exposure is irrelevant to toys.
<b>3. SCIENTIFIC OPINION</b>	16	1	Can SCHEER comment on the apparent inconsistency between the conclusion that casting kits, chalk and powder paint are not safe when an ultrafine fraction is present, and the SCCS Opinion for cosmetics where face powders (that also contain and ultrafine fraction) are safe for use by consumers to 25% TiO <sub>2</sub> ?

<p><b>6.4.2.2 Exposure scenarios – inhalation</b></p>	<p>30</p>	<p>7</p>	<p>We believe the concern about particle release from chalk and crayons is unfounded. An historical U.S. CPSC staff report concludes that, despite measurable amounts of asbestos in sampled crayons, release is negligible in use. This may have an impact because TiO<sub>2</sub> is a potential replacement for talc in crayons to avoid the possibility of asbestos contamination. CPSC staff report can be found here: <a href="https://www.cpsc.gov/s3fs-public/pdfs/crayons.pdf">https://www.cpsc.gov/s3fs-public/pdfs/crayons.pdf</a></p>
<p><b>6.4.2.4 Conclusions on potential release of TiO<sub>2</sub> into the air</b></p>	<p>34</p>	<p>10</p>	<p>The calculated air concentrations for the different scenarios are not differentiated by particle size. The exposure assumptions (and the subsequent MOS calculations), particularly for ultrafine particles assumes that the TiO<sub>2</sub> aerosol produced by the toy is equivalent to the test material used in the Bermudez 2004 study. Bermudez <i>et al</i> exposed the rat subjects to an aerosol of ultrafine TiO<sub>2</sub> with an average particle size of 21nm. This is clearly overly conservative and not justified when considering the likely particle size distribution of pigmentary TiO<sub>2</sub> used in toys. Although the mean particle size in the study was 1.44um with a GSD of 2.60 (due to agglomeration), the authors assumed that dis-agglomeration would occur in vivo. While this may be the case when the test material was nano sized to start with, in the case of toys the particle size distribution is significantly different, and this should be considered when estimating the exposure to ultrafine particles. Since the calculated MOS is only one order of magnitude less than 25, such an adjustment is justified.</p>
<p><b>6.4.2.5 Exposure scenarios –oral</b></p>	<p>35</p>	<p>16</p>	<p>Finger paints must contain an embittering agent to prevent unintentional ingestion according to the harmonized and referenced standard EN71-7. Therefore, the exposure assumptions made in the draft Opinion should be revised accordingly. See also comments above regarding the SCCS cosmetic opinion and the remote likelihood of lung overload from such products.</p>
<p><b>6.4.2.5 Exposure scenarios –oral</b></p>	<p>37</p>	<p>26</p>	<p>Oral route of exposure is irrelevant based upon the rationale for classification of TiO<sub>2</sub> for toy exposures, and is of questionable relevance even in occupational settings, where exposure is many orders of magnitude greater. Additionally, an Ad-Hoc group (led by the German BfR) to the European standardization Committee dealing with toy chemical safety standards (CEN/TC52/WG5) has recently worked on EN 71-7 related to toxicological risk assessment. Latest draft “concept on exposure estimation” provides a proposal for estimating systemic event exposure to substances due to the repeated use of finger paints. This document (CEN/TC52/WG5 N 1783 - November 2021) can be obtained directly from the secretariat of CEN/TC52. This document indicates “The mandatory use of embittering agents according to standard EN 71-7 on finger paints prevents repeated oral ingestion of finger paints; <u>therefore, oral intake is not considered in systemic exposure due to repeated use of finger paints</u>”.</p> <p>It also indicates: “In the introduction of the standard EN 71-7:2014 it is stated that oral exposure to finger paints needs to be considered as well. Therefore, according to requirement 4.6 in EN 71- 7:2014, use of embittering agents is mandatory. A young child might explore the taste of finger paints upon first contact, which could eventually lead to systemic exposure following absorption in the oral mucosa or gastrointestinal tract. <u>However, a child is not expected to try eating finger paint a second time due to the negative experience. Hence, repeated ingestion of finger paints is very unlikely.</u> “</p> <p>On frequency of exposure, this document indicates: “RIVM assumes a use frequency of 100 events per year in its Toys Fact Sheet [RIVM 2002]. This value was supported by the Nordic Exposure Group for Health [Norden 2011] and used by the Danish</p>

			EPA in its risk assessment of preservatives in toys [DK EPA 2014]. Scott and Moore estimated a use frequency of two times per week [Scott and Moore 2000].” Therefore, the exposure assumptions made in the draft Opinion should be revised accordingly.
<b>6.4.2.5 Exposure scenarios –oral</b>	37	28 & 29	It shall be noted that white finger paint is uncommon, and most finger paints are primary colors that contain less than 1% TiO <sub>2</sub> and rarely up to 4%. Therefore, the exposure assumptions made in the draft Opinion should be revised accordingly.
<b>6.4.2.5 Exposure scenarios –oral</b>	38	5 & 6	The estimated frequency of exposure (2 x 8mg/day) is in contradiction with the way the Toy Safety Directive migration limits have been established (once a day for scraped-off materials). Therefore, the exposure assumptions made in the draft Opinion should be revised accordingly.
<b>6.5.2. Oral exposure</b>	41	29	Absorption data in the gastrointestinal tract (GIT) is based on pure particles. This is of limited relevance when evaluating exposure from toy materials such as white pencils as it ignores the matrix effect. Colored pencils are a mixture of clay fillers and approximately 15% paraffin wax which acts as a binder. TiO <sub>2</sub> in the pencil will be contained within this homogeneous matrix. In 2000, the US Consumer Products Safety Commission investigated asbestos fibers in wax crayons and concluded that since the wax melts above body temperature the matrix would be intact, and no release of fibers would occur. While the proportion of wax is lower in pencils, the remaining matrix consists of compressed insoluble mineral clays suggesting a low probability of free TiO <sub>2</sub> in the GIT.
<b>6.7.3 Exposure assessment</b>	57	2	Aggregated exposure was considered for the three oral exposure scenarios. The above represents a daily direct ingestion of 400 mg of finger paint, 2x 8mg for white colored pencil and 2 mg of lipstick. It is difficult to understand why aggregated exposure was retained. Taking into consideration the fact that finger paints must contain an embittering agent and the unlikely repeated oral exposure (see above comment for pages 35 and 37) and that lipsticks should not be considered (also considering the SCCS opinion for cosmetics), only the exposure from white coloring pencil (8mg per day – see comment for page 38) should be considered. Therefore, the exposure assumptions made in the draft Opinion should be revised accordingly.
<b>6.7.4.2 PoD for inhalation</b>	57	30	Since toys that contain TiO <sub>2</sub> are predominantly mixtures where agglomeration is highly plausible, we would question why the NOAEC of 0.5mg/m <sup>3</sup> is used as the POD. Evidence shows that for cosmetics containing nanomaterials ‘a user would be exposed to nanomaterial predominantly through nanoparticle-containing agglomerates larger than the 1–100-nm aerosol fraction’ and ‘Predominant deposition of nanomaterial(s) will occur in the tracheobronchial and head airways— not in the alveolar region as would be expected based on the size of primary nanoparticles.’ (Potential for Inhalation Exposure to Engineered Nanoparticles from Nanotechnology-Based Cosmetic Powders, Nazarenko et al; (2012); Environmental Health Perspectives; 120; 6; pp885-892. The NOAEC for fine particles is therefore the most appropriate POD.
<b>6.7.7 Final Conclusions</b>	66	6 & 7 and table 6.24	SCHEER indicates that it cannot be concluded that the described toy materials can be used safely by children. Not being able to conclusively determine that a use is safe is not logically equivalent to the converse conclusion that the use is “not safe”, as convincing evidence of unsafe use does not appear to have been demonstrated.

			<p>On 20 June 2022, Health Canada published a comprehensive report on the State of the Science of Titanium Dioxide (TiO<sub>2</sub>) as a Food Additive (<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/reports-publications/titanium-dioxide-food-additive-science-report.html">https://www.canada.ca/en/health-canada/services/food-nutrition/reports-publications/titanium-dioxide-food-additive-science-report.html</a>), considering recent studies since the EFSA Opinion, and concluded that there was no evidence of adverse effects and did not identify any health concerns for the use of TiO<sub>2</sub>. We recommend SCHEER to take this report into consideration to revise the current SCHEER preliminary opinion.</p> <p>In addition, The European Commission issued a new mandate to SCCS to re-assess the safety of TiO<sub>2</sub> with focus on genotoxicity and exposure via the inhalation and oral route (lip care, lipstick, toothpaste, loose powder, hair spray).  <a href="https://health.ec.europa.eu/system/files/2022-06/sccs2022_q_007.pdf">https://health.ec.europa.eu/system/files/2022-06/sccs2022_q_007.pdf</a>                  We are of the opinion that SCHEER should wait for the SCCS conclusions and take them into consideration prior to issue a final opinion on the use of TiO<sub>2</sub> in toys.</p>
<b>7. RECOMMENDATIONS FOR FUTURE WORK</b>	66	16	TA would agree that more data is required. The exposure assumptions in the SCHEER draft opinion for air concentrations of TiO <sub>2</sub> seem far more than the measured room air concentration in the SCCS Opinion on cosmetics which was 14ug/m <sup>3</sup> (15 min TWA).
<b>Annex VI: Calculation of the Human Equivalent Concentration (HEC)</b>	105	3	The Bermudez (2004) study is not included in the references.
<b>8. REFERENCES</b>	67	39	
	General comments		<p>The European Commission's mandate asked SCHEER to assess the use of TiO<sub>2</sub> in toys in light of the inhalation exposure identified, and in light of the classification of titanium dioxide as carcinogenic category 2 after inhalation.</p> <p>It also required that safe toys and safe materials should be indicated. The Toy Safety Directive indicates that, when substances and mixtures classified as CMR by the CLP Regulation (EC) No 1272/2008 are contained in individual concentrations exceeding the CLP thresholds for their classification (1% for TiO<sub>2</sub> of specific size), a decision in accordance with Article 46(3) can be taken to permit a substance and its use via TSD Appendix A.</p> <p>The SCHEER preliminary opinion should make it clearer in its conclusion that it refers to the use/presence of CLP-classified TiO<sub>2</sub> in concentrations exceeding 1% in toy materials. It should also provide safe limits for CLP-classified TiO<sub>2</sub> in toys where there is a likelihood of exposure.</p>

We would like to offer our continued expertise and support as you consider our comments. Please do not hesitate to contact me or my colleague, Joan Lawrence, if you have questions or would like further information. I can be reached at [akaufman@toyassociation.org](mailto:akaufman@toyassociation.org) and Joan at [jlawrence@toyassociation.org](mailto:jlawrence@toyassociation.org).

Sincerely,



Alan P. Kaufman  
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