

November 16, 2020

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Subject: Comments re: DARTIC Prioritization of Titanium Dioxide Nanoparticles

The Personal Care Products Council (Council)¹ and the Consumer Healthcare Products Association (CHPA)² are pleased to submit the following comments in response to the California Office of Environmental Health Hazard Assessment (OEHHA) notice of prioritization of chemicals by the Developmental and Reproductive Toxicity Identification Committee (DARTIC) at their upcoming meeting.

These comments address titanium dioxide nanoparticles (hereafter, TiO₂), defined within the OEHHA prioritization document as “...*ultrafine particles 1 – 100 nanometers (nm) in diameter.*” As TiO₂ serves an important function in numerous consumer products, including as an active ingredient in sunscreens regulated by the Food and Drug Administration (FDA), and has been extensively reviewed and approved by expert bodies both in and outside the United States, we believe TiO₂ should be considered a low priority for review by the DARTIC.

TiO₂ nanoparticles have been utilized in sunscreen formulation for over 20 years, both in the U.S. and worldwide. The public health benefits of sunscreens are well-recognized. They are

¹ Based in Washington, D.C., the Personal Care Products Council is the leading national trade association representing the global cosmetic and personal care products industry. Founded in 1894, PCPC’s more than 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the United States. As the makers of a diverse range of products that millions of consumers rely on every day, from sunscreens, toothpaste, and shampoo to moisturizer, lipstick, and fragrance, member companies are global leaders committed to product safety, quality, and innovation. Visit www.personalcarecouncil.org

²The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing the leading manufacturers and marketers of over-the-counter (OTC) medicines, dietary supplements, and consumer medical devices. Every dollar spent by consumers on OTC medicines saves the U.S. healthcare system more than \$7, contributing a total of \$146 billion in savings each year. CHPA is committed to empowering consumer self-care by preserving and expanding choice and availability of consumer healthcare products. www.chpa.org

effective in protecting the skin against solar UV exposure, preventing sunburn, reducing the risk of skin cancer, and in mitigating premature skin aging.³

The nano form of TiO₂ offers several advantages in sunscreen formulation. It allows for a more even application, thereby enhancing sunscreen function and resulting in reduced volume of use compared to non-nano TiO₂. Nano TiO₂ allows for transparent application. The smaller particles blend into sunscreen formulas more easily, and leave less of a white residue on the skin. Without the nano form, higher SPF values cannot be achieved in products suitable for all skin colors. The ability of dermally applied nano TiO₂ to penetrate the skin has been extensively studied and found to be negligible.⁴

TiO₂ is one of only two UV filters to receive a designation as Category 1: Generally Recognized as Safe and Effective (GRASE) by the FDA in their review published in February 2019.

The FDA continues to review all currently approved UV filters, including TiO₂, and must issue a proposed Administrative Order addressing the safety and efficacy of all sunscreen active ingredients, including TiO₂, by September 2021.

FDA is recognized as an authoritative body under Proposition 65. Given that FDA has already recently reviewed the safety and efficacy of TiO₂ (including use of this UV filter in its nanosized form) a low priority ranking is appropriate.

TiO₂ has been reviewed and approved by authorities around the world. In Europe, the Scientific Committee on Consumer Safety (SCCS) noted that the nano form of TiO₂, when used as a UV-filter up to 25%, was *'considered to not pose any risk of adverse effects in humans after application on healthy, intact or sunburnt skin'*⁵

The European Food Safety Authority (2016)⁶ reviewed the available data on developmental and reproductive effects of TiO₂ (including nanosized TiO₂) and found that results from prenatal development studies "...did not give concern for maternal or developmental toxicity up to the highest dose tested (1,000 mg/kg bw per day)."

The European Chemicals Agency has recently (2019) undertaken a critical review of studies on the reproductive and developmental toxicity of nanomaterials, including TiO₂,⁷ finding that "In

³ 76 Fed. Reg. 117 35620 (June 17, 2011) FDA Final Rule: Labeling and Effectiveness Testing: Sunscreen Drug Products for OTC Human Use.

⁴ Sadrieh, N et al. (2010) Lack of Significant Dermal Penetration of Titanium Dioxide from Sunscreen Formulations Containing Nano- and Submicron-Size TiO₂ Particles. *Tox Sci.* Vol. 115: 156-166.

⁵ Opinion on Titanium Dioxide (nano form) Colipa n° S75, July 2013; available at https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_136.pdf

⁶ Re-evaluation of titanium dioxide (E 171) as a food additive, European Food Safety Authority 2016, *EFSA Journal* 14(9):4545

⁷ https://euon.echa.europa.eu/documents/23168237/24095696/critical_review_of_studies_on_reproductive_and_developmental_toxicity_of_nanomaterials_en.pdf

general, results from studies applying OECD TG [Test Guideline] (oral exposure in rats) indicated no to limited concern for developmental toxicity of TiO₂ [nanoparticles] ...”.

Thus, given the extensive characterization of nano TiO₂ and confirmation of its safety profile by numerous worldwide expert regulatory bodies, the DARTIC should designate TiO₂ as a low priority chemical for prioritization.

Thank you again for the opportunity to submit these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Jay E. Sirois". The signature is written in a cursive style with some loops and flourishes.

Jay E. Sirois, Ph.D.
Senior Director, Regulatory & Scientific Affairs
Consumer Healthcare Products Association

A handwritten signature in black ink, appearing to read "Linda Loretz". The signature is written in a cursive style with a prominent loop at the end.

Linda Loretz, Ph.D., DABT
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