

November 16, 2020

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Subject: Comments re: DARTIC Prioritization of Benzophenone-3

The Personal Care Products Council (Council)<sup>1</sup> and the Consumer Healthcare Products Association (CHPA)<sup>2</sup> 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 specifically address benzophenone-3 (BP-3; oxybenzone).

BP-3 is approved by the U.S. Food and Drug Administration (FDA) and other government authorities worldwide as an active ingredient in over-the-counter (OTC) sunscreens. It has been utilized in sunscreen formulations for decades and has undergone review by expert bodies both in and outside the United States as part of the approval process. Sunscreens are widely recognized as having important public health benefits. BP-3, along with all of the other approved UV filters in the U.S., is currently undergoing review by the FDA, as discussed further below. As FDA is recognized as an authoritative body by Proposition 65, we believe that OEHHA should await the outcome of FDA's review rather than bringing BP-3 to the DARTIC for review. Therefore, BP-3 should be concluded to be low priority for review by the DARTIC.

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<sup>1</sup> 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](http://www.personalcarecouncil.org)

<sup>2</sup> The 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](http://www.chpa.org)

### Sunscreens Have Important Public Health Benefits

The public health benefits of sunscreens are well-recognized. The Centers for Disease Control and Prevention, the American Academy of Dermatology, the Skin Cancer Foundation, and health care professionals worldwide all emphasize the importance of sunscreen use as part of a safe sun regimen. Of particular concern, skin cancer is on the rise in the United States, with nearly 5 million people treated for skin cancer every year. Sunscreens are recognized for their effectiveness in protecting the skin against solar UV exposure, their ability to prevent sunburn, in reducing the risk of skin cancer, and in mitigating premature skin aging.<sup>3</sup>

BP-3 is the only midrange (UVA/UVB) active ingredient available in the U.S. with absorbance peaks in both the UVB and UVA range. It fills in the absorbance gap in the middle of the UVA-UVB spectrum between other active ingredients, and augments photostability, making it possible for products to provide broad spectrum UVA protection and high SPF (sunburn protection). These are benefits for which there are no available substitutes.

### FDA is Reviewing All UV Filters as Part of Monograph Reform

UV filters are regulated as OTC drugs under the monograph system in the United States. Monograph reform was included in the CARES Act that passed in March of this year. The current status of BP-3 as a sunscreen is 'Generally Recognized as Safe and Effective' (GRASE). However, FDA is required to issue a proposed Administrative Order by September 2021, addressing the safety and efficacy of all sunscreen active ingredients.

As FDA is recognized as an authoritative body under Proposition 65, and BP-3 is under active review at this time, we strongly urge OEHHA to wait for the FDA review to be completed before any further consideration for possible listing under Proposition 65.

### BP-3 Has Been Reviewed and is Approved Worldwide

BP-3 is approved for use at levels up to 6% as a sunscreen in the U.S. Likewise, the European Union, Canada, and Taiwan have approved use at concentrations up to 6%. Other jurisdictions have approved use at levels up to 10%, including Australia, China, Mexico and Brazil. Japan and Korea limit use to 5%. The broad acceptance of BP-3 as a UV filter around the world attests to its safety profile and supports a 'low priority' designation.

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

Conclusion

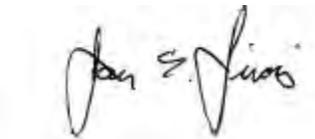
BP-3 is an important sunscreen active ingredient whose safety profile has been confirmed by authorities worldwide. It is currently under review by the U.S. FDA, which is an authoritative body under Proposition 65. A conclusion of 'low priority' is appropriate for BP-3.

Thank you again for the opportunity to submit these comments.

Sincerely,

A handwritten signature in cursive script that reads "Linda Loretz".

Linda Loretz, Ph.D., DABT  
Senior Director, Safety & Regulatory Toxicology  
Personal Care Products Council

A handwritten signature in cursive script that reads "Jay E. Sirois".

Jay E. Sirois, Ph.D.  
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