



January 16, 2025

Via Electronic Submission

Dr. Meredith Williams, Director
Department of Toxic Substances Control
California Environmental Protection Agency
1001 "I" Street
P.O. Box 806 Sacramento, CA 95814

Re: Comments on the Background Document on Propylparaben and Butylparaben in Skin-Applied Leave-On Products

Dear Director Williams,

The Personal Care Products Council (PCPC) appreciates the opportunity to submit the following comments to the Department of Toxic Substances Control (DTSC) on the Background Document on Propylparaben and Butylparaben in Skin-Applied Leave-On Products. Founded in 1894, the Personal Care Products Council (PCPC) is the leading national trade association representing the cosmetics and personal care products industry (www.personalcarecouncil.org). PCPC is dedicated to promoting product safety, quality, and innovation, serving as a unifying voice that champions science-based standards and responsible practices to support health, well-being, and economic growth. PCPC's global members are some of the beloved and trusted brands in beauty and personal care today, providing millions of consumers with the diverse products they rely on every day – from sunscreens, toothpaste and shampoo to moisturizer, makeup, and fragrance. We are joined in these comments by the Consumer Healthcare Products Association (CHPA). Founded in 1881, CHPA is the national trade association representing the leading manufacturers and marketers of consumer healthcare products, including over-the-counter (OTC) medicines, dietary supplements, and consumer medical devices (www.chpa.org). CHPA is committed to empowering self-care by ensuring that Americans have access to products they can count on to be reliable, affordable, and convenient, while also delivering new and better ways to get and stay healthy.

We therefore have a strong interest in the scope and applicability of this report as it applies to these products and ingredients and any subsequent actions. PCPC and CHPA maintain that the use of propyl- and butyl- parabens in cosmetic and cosmetic/drug products at current concentrations has been determined to be safe for human health and the environment.

General Comments

Parabens are ingredients that are active against a broad spectrum of microorganisms. They are used as preservatives in not only cosmetic products, but also food and pharmaceutical products. Parabens are highly effective in preventing the growth of bacteria, mold, and yeast and have superior coverage against fungi and gram-positive bacteria. They are chemically inert, have no odor, and are extremely stable making them a preferred preservative to ensure the formulation and consumer are protected. They are safe and effective as biocides from preservation and cutaneous allergenicity standpoints (Fransway et al., 2019). Parabens used in cosmetics are derived from para-hydroxybenzoic acid (PHBA) which occurs naturally in foods we eat like blueberries and barley. The human body quickly metabolizes parabens used in cosmetics into water-soluble PHBA and they are eliminated in the urine.

PCPC is encouraged that DTSC has expressed an interest in properly executing any regulatory actions related to these parabens (Virtual Workshop on Propylparaben and Butylparaben in Skin-Applied Leave-On Products; Dec. 17, 2024).

Scope

PCPC and CHPA recommend the removal of over-the-counter (OTC) drug products such as sunscreens and medicated topical creams and lotions as defined by the U.S. Food and Drug Administration (FDA) from the scope of this proposed regulation. These products should be treated as drug products and not categorized, as DTSC has, as part of “Beauty, Personal Care, and Hygiene Products”. Sunscreen drug products, in particular, are currently undergoing evaluation via the FDA’s 2021 Proposed Administrative Order to confirm their GRASE (Generally Recognized as Safe and Effective) status. Therefore, they should be deemed out of scope.

Proposed Alternatives to Parabens

During the Workshop, DTSC staff proposed preservation alternatives to parabens in skin-applied leave-on products including benzyl alcohol, salicylic acid, citric acid, engineering changes, etc. Some of the alternatives are not broad-spectrum actives and would need additional preservative ingredients to ensure product integrity. Some of the alternatives would need to be added at high concentrations in products to be effective against microorganisms, which raises further concerns. Engineering changes would potentially be costly and only be effective during manufacturing processes and would not address potential contamination introduced during the product usage phase. It is also important to continue discussions that differentiate between potential hazards and actual risks, emphasizing the role of risk assessment in evaluating ingredient safety. Propyl- and butyl- parabens are largely non-irritating and non-sensitizing, broad-spectrum actives used at low concentrations, and, as DTSC has indicated, have been used in products since the 1920’s. In 2019, the American Contact Dermatitis Society (ACDS) named parabens the ‘non-Allergen’ of the year due to the low frequency of allergic contact dermatitis reactions (Fransway et al., 2019a).

DTSC Questions

In the background document, DTSC posed questions to stakeholders and potentially affected groups. PCPC and CHPA recommend that DTSC staff review and include in any further DTSC documents and decision-making processes several peer-reviewed and expert scientific opinions related to these parabens.

One noticeable omission from the reference list, which would inform many of the questions related to toxicological concerns, is the review article [Paraben Toxicology](#) (Fransway et al., 2019). This review of decades of data includes research on skin penetration, chronic effects, hormonal effects/fertility, carcinogenicity, perinatal exposure, and environmental issues of parabens used in cosmetics, food and pharmaceutical industries.

Additionally, and more specifically, the Expert Panel for Cosmetic Ingredient Safety (CIR Panel) has reviewed ([Final Amended Report on the Safety Assessment of Methylparaben, Ethylparaben, Propylparaben, Isopropylparaben, Butylparaben, Isobutylparaben, and Benzylparaben as used in Cosmetic Products](#), 2008) and rereviewed ([Cherian et al.](#), 2020) parabens as used in cosmetic products and found parabens to be generally safe for use in cosmetic products, as studies consistently show no significant irritation, sensitization, or toxicity at typical use concentrations.

For US habits and practices data for some of the leave-on product categories under consideration we recommend consulting three peer-reviewed papers published in *Food and Chemical Toxicology* ([Loretz et al., 2005](#) (lipstick, body lotion and face cream), [Loretz et al., 2006](#) (liquid foundation), [Loretz et al., 2008](#) (eye shadow)).

Two Scientific Committee on Consumer Safety (SCCS) opinions on [Propylparaben](#) (2021) and [Butylparaben](#) (2023) were recently published, determining that both of these parabens are safe for use in cosmetic products up to a maximum concentration of 0.14% or up to a combined maximum concentration of 0.14%, as the sum of the individual concentrations of butylparaben, propylparaben and their salts.

While the SCCS opinions do not address environmental aspects of [propyl-](#) and [butyl-](#) paraben, the European Chemical Agency (ECHA) dossiers do contain environmental data that is readily accessible.

Conclusion

We appreciate the opportunity to provide DTSC with comments on the draft documents. We hope to see our comments addressed and look forward to additional opportunities to participate in this rulemaking process.

Sincerely,

A handwritten signature in black ink, appearing to read "Emily Manoso". The signature is fluid and cursive, with the first name being more prominent.

Emily Manoso
Executive Vice President, Legal and Regulatory Affairs & General Counsel
Personal Care Products Council

Kathleen Stanton

Kathleen Stanton
Senior Director, Science and Regulatory Affairs
Personal Care Products Council

C.R. Ondracek

Caitlin R. Ondracek, Ph.D.
Senior Director, Medical Science & Regulatory Affairs
Consumer Healthcare Products Association