Cosmetic Ingredient Review

Commitment & Credibility since 1976

November 9, 2018

Alexandra Scranton
Women's Voices for the Earth
P.O. BOX 8743
Missoula, MT 59807

Dear Ms. Scranton:

Thank you for your letter dated September 12, 2018. The Cosmetic Ingredient Review (CIR) is also very interested in the potential health impacts of parabens. After careful consideration of your comments, the CIR Expert Panel proceeded as follows:

- You provided the assertion, and a published article to support the notion, that there is new research indicating significant hazards to sperm motility from the levels of parabens commonly found in vaginally applied cosmetic products. The Expert Panel reviewed your submission and discussed the safety of parabens as used in vaginally-applied cosmetic products. However, of the multiple endpoints asserted in the provided article, each was either constructed around an improperly chosen/designed assay to make such assertions unequivocally, and/or resulted in no significant effects.

  You provided another published reference, along with an assertion these ingredients may increase the chances of developing a vaginal yeast infection. However, the cell culture studies performed therein were dosed with extremely high concentrations compared to cosmetic use (i.e. 15 - 25% preservative in these studies vs a maximum use concentration of parabens in cosmetics of 0.5%). The Expert Panel requested that these studies be included in the CIR report. However, the Expert Panel's discussion thereof classified these studies as illustrations of potential, general hazards, which fail to demonstrate risks relevant to cosmetic safety in the context of concentration of use.

- You provided the assertions (and supporting documents): 1) that the CIR's prior claim that parabens do not accumulate in the body is outdated, and not supported by more recent research which finds parabens considerably more persistent and accumulative than previously believed, and 2) the vast majority of the literature that has measured paraben exposure with respect to the use of cosmetic products has concluded that the use of cosmetics or personal care products is the most significant source of paraben exposure. The Expert Panel reviewed your submission and discussed concerns about the bioaccumulation potential of parabens. The Expert Panel noted that, as lipid-soluble chemicals, parabens may distribute to tissues despite metabolism. Recent studies with sensitive analytical methods have demonstrated the presence of parabens in various human tissues. However, the data are equivocal regarding cumulative storage in such tissues; and importantly, the available evidence suggests no significant association of parabens exposure with diseases or other adverse health conditions. The Panel noted that paraben exposures are attributed to cosmetic products, foods, medicines and other sources, and refined aggregate exposure models suggest that cosmetic product use is a major source of topical exposure to parabens. However, the vast quantity of biomonitoring data indicate that systemic exposure to these ingredients resulting from cosmetic use is very low.

- You provided an assertion that the ECHA data indicate that for Propylparaben, 37.8% of particles are smaller than 10 microns in diameter and that the CIR's established level of concern for inhalation and that this information contradicts the summary claim found in the report that 95 - 99% of particles have diameters greater than 10 microns and are thus unlikely to be inhaled deeply. The Expert Panel reviewed your submission and discussed concerns about particle size and incidental inhalation. However, "the summary claim found in the report that 95 - 99% of particles have diameters greater than 10 microns" is made with regard to final cosmetic formulations, not individual ingredients. The consumer is not exposed to incidental inhalation of the pure ingredient, Propylparaben, under conditions of cosmetic use. Instead, potential consumer incidental inhalation exposure may be via a final cosmetic formulation comprising a pump spray at no more than 0.13% Propylparaben or powder at no more than 0.3% Propylparaben.

  Particle size distributions are final cosmetic product specific. Numerous factors determine the initial size distribution of droplets or particles released from a spray product, including the product formulation (e.g., volatile or nonvolatile solvent), propellant, can size, and differential pressure through the nozzle for propellant sprays, and formulation and nozzle characteristics for pump sprays. The other constituents in formulation (i.e. the other $\geq$ 99.7%), processing, handling, and cosmetic use conditions also play a significant role in the initial size distribution of particles released from use of a powder. After release to the air, whether from a spray or a powder use, the particle size distribution can change rapidly through aggregation, agglomeration, sedimentation, evaporation of volatile components, or hygroscopic absorption of water. The median aerodynamic equivalent diameter (d_{ae}) of airborne droplets/particles of pump hair sprays, for example, range from 60 µm to 80 µm. Typically, < 1% of the airborne droplets/particles released from pump sprays are in the range considered to be respirable (i.e., d_{ae} < 10 µm). Thus, the inhalation exposure of respirable droplets/particles from cosmetic products is likely to be very small, even negligible, compared with dermal contact and other exposure

routes associated with the use of these products. Further, simulation studies revealed that all of the droplets/particles released from pump sprays settle quickly after spraying, including the respirable and inhalable fractions, which substantially reduces the overall potential for inhalation exposure. Moreover, even in the purely theoretical absence of aggregation, agglomeration, sedimentation, formulation, cosmetic use conditions, etc., the maximum percentage of paraben airborne particles of any size that could result from use of a cosmetic product, could not exceed the maximum amount added to the formulation (i.e. 0.6%).

- You provided an assertion that the calculation used to derive a margin of safety (MOS) for parabens needs to be updated to reflect more conservative product usage amounts and more conservative absorption rates that are consistent with data included in other sections of the assessment. After the Expert Panel reviewed your submission and discussed concerns about the underlying components and calculation of an MOS for these ingredients, they instructed extensive revisions to better identify, and explain the rationale for, the values utilized in conducting the risk assessment therein. The Expert Panel also requested that the MOS should be re-calculated, weighing the different use concentrations and exposures in various cosmetic products categories.

The Draft Final Amended Safety Assessment of Parabens as Used in Cosmetics is likely to be finalized at the April 2019 CIR Expert Panel Meeting. Should you have any further relevant data that you believe may inform the Expert Panel's decision making process, please provide such as a submission well in advance of that meeting to ensure thorough consideration.

Sincerely,

Bart Heldreth

Bart Heldreth, Ph.D.
Executive Director, Cosmetic Ingredient Review

1620 L Street, NW, Suite 1200, Washington, DC 20036
(Main) 202-331-0651 (Fax) 202-331-0088
(Email) cirinfo@cir-safety.org (Website) www.cir-safety.org