DATA SUPPLEMENT

Alkyl Gallates

2-Bromo-2-Nitropropane-1,3-Diol

Cocoyl Hydrolyzed Collagen

Phthalates

Admin – Airbrush Conclusion

Admin – Use Tables

EXPERT PANEL MEETING
MARCH 12-13, 2026

Commitment & Credibility since 1976

Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Priya Ferguson, M.S., Senior Scientific Analyst/Writer, CIR
Date: March 3, 2026
Subject: Wave 2 - Draft Amended Report on the Safety Assessment of the Alkyl Gallates as Used in Cosmetics

Updated concentration of use data have been received (*data_AlkylGallates_Wave2_032026*), correcting the maximum reported concentration of use for Propyl Gallate. According to the revised data, the maximum concentration of use for Propyl Gallate in face and neck creams, lotions, and powders (leave-on, not spray) is 0.1%. Previously submitted (2024) data indicated a maximum concentration of 0.2%.

Concentration of Use by FDA Product Category[1]

Caprylyl Gallate
Dodecyl Gallate
Ethyl Gallate
Ethylhexyl Gallate
Propyl Gallate
Stearyl Gallate

Ingredient	Product Category	Maximum Concentration of Use
Propyl Gallate	Baby lotions, oils, and creams	0.00076%
Propyl Gallate	Eyeliners	0.02%
Propyl Gallate	Other eye makeup preparations	0.02%
Propyl Gallate	Perfumes	0.000023%
Propyl Gallate	Hair conditioners (rinse-off)	0.003%
Propyl Gallate	Blushers and rouges	0.045%
Propyl Gallate	Lipstick	0.0003-0.05%
Propyl Gallate	Nail creams and lotions	0.00026%
Propyl Gallate	Mouthwashes and breath fresheners	0.0037%
Propyl Gallate	Bath soaps and body washes	0.0000024-0-001%
Propyl Gallate	Face and neck creams, lotions and powders (leave-on) Not spray	0.000003-0.1%
Propyl Gallate	Body and hand creams, lotions, and powders (leave-on) Not spray	0.00055%
Propyl Gallate	Moisturizing creams, lotions, and powders Not spray	0.00055%

*The ingredients included in the title of the table but not found in the table were included in the concentration of use survey, but no uses were reported.

Information collected in 2024
Table prepared: December 10, 2024
Updated: February 19, 2026 Face and neck product maximum use concentration decrease to 0.1%; 0.2% moisturizer product deleted

[1] The new FDA cosmetic product categories under MoCRA were used for this survey.

Cosmetic Ingredient Review

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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Monice Fiume, M.B.A,
Senior Director, CIR
Date: March 3, 2026
Subject: Wave 2 - Draft Final Amended Report on the Safety Assessment of 2-Bromo-2-Nitropropane-1,3-Diol as Used in Cosmetics

Enclosed please find comments submitted by PCPC on the Draft Final Amended Report on the Safety Assessment of 2-Bromo-2-Nitropropane-1,3-Diol as Used in Cosmetics (*PCPCcomments_2-Bromo-2-Nitropropane-1,3-Diol_Wave2_032026*). Specific instructions from the Panel are needed to address the key issues.

Personal Care Products Council

Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review

FROM: Jaap Venema, Ph.D.
EVP and Chief Scientist – Personal Care Products Council
Industry Liaison to the CIR Expert Panel

DATE: February 26, 2026

SUBJECT: Draft Final Amended Report: Amended Safety Assessment of 2-Bromo-2-Nitropropane-1,3-Diol as Used in Cosmetics (March 2026 meeting draft)

The Personal Care Products Council respectfully submits the following comments on the draft final amended report, Amended Safety Assessment of 2-Bromo-2-Nitropropane-1,3-Diol as Used in Cosmetics.

Key Issues

Discussion – As noted in the Discussion, the Expert Panel reached their conclusion based on the data from the RLD obtained in 2024. The current report includes RLD data from 2025. The 2024 date needs to be changed if the Expert Panel considers the data sufficient to support safety for the use information in the 2025 RLD (or the 2025 data need to be replaced with the 2024 data on which the "safe in the present practices of use and concentration" conclusion was reached).

Discussion – Unless the information to support "endogenous formation of nitrosamines upon dermal penetration" is summarized in this CIR report, this statement in the fourth paragraph of the Discussion should be deleted.

Additional Considerations

Acute, Oral – What were the doses of 2-Bromo-2-Nitropropane-1,3-Diol administered orally to rats and mice that caused gastrointestinal lesions?

Developmental and Reproductive Toxicity, old report summary – What effects were observed at the LOELs in the last two studies described in this section?

Retrospective and Single or Multicenter Studies, old report summary – Is “contact clinics” the correct name for the European dermatitis clinics?

Retrospective and Single or Multicenter Studies – The first date range (2002-2012) is stated oldest to most recent, while the second date range (2016-2012) is stated as most recent to oldest. Are they both correct? If these date ranges are correct, please state them in the same order.

Summary – In the Summary, in addition to the total number of uses reported to FDA, it would also be helpful to include the number of uses reported in disposable wipes.

Table 2 – Please revise Table 2 to be consistent with the memo from PCPC concerning tattoo products (memo dated February 26, 2026).

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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Monice Fiume, M.B.A.
Senior Director, CIR
Date: March 3, 2026
Subject: Wave 2 - Draft Final Amended Report on the Safety Assessment of Cocoyl Hydrolyzed Collagen Ingredients as Used in Cosmetics

Enclosed please find comments submitted by PCPC on the Draft Final Amended Report on the Safety Assessment of Cocoyl Hydrolyzed Collagen Ingredients as Used in Cosmetics (*PCPCcomments_HydrolyzedCollagens_Wave2_032026*).

Personal Care Products Council

Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review

FROM: Jaap Venema, Ph.D.
EVP and Chief Scientist – Personal Care Products Council
Industry Liaison to the CIR Expert Panel

DATE: February 26, 2026

SUBJECT: Draft Final Amended Report: Amended Safety Assessment of Cocoyl Hydrolyzed Collagen Ingredients as Used in Cosmetics (March 2026 meeting draft)

The Personal Care Products Council respectfully submits the following comments on the draft final amended report, Amended Safety Assessment of Cocoyl Hydrolyzed Collagen Ingredients as Used in Cosmetics.

Abstract; Discussion –The abstract says that the "cosmetics industry should continue to use necessary procedures to limit infectious agents, and/or biologically-derived impurities (e.g., nucleic acids, proteins, endotoxins)". In contrast, the Discussion states: "They stressed that these ingredients must be free of detectible pathogenic viruses, infectious agents or biologically-derived impurities." The language in the Discussion should be revised so that it is the same as presented in the Abstract.

Table 2 – Please revise Table 2 to be consistent with the memo from PCPC concerning tattoo products (memo dated February 26, 2026).

Commitment & Credibility since 1976

Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Jinqiu Zhu, PhD, DABT, ERT, DCST, CIR Toxicologist
Christina Burnett, MS, Senior Scientific Analyst/Writer, CIR
Date: March 3, 2026
Subject: Wave 2 –Amended Safety Assessment of Dibutyl Phthalate, Diethyl Phthalate, and Dimethyl Phthalate as Used in Cosmetics

Attached are comments dated February 26, 2026 from Weaving Voices for Health & Justice (WVHJ; formerly Women's Voices for the Earth, WVE) on the Draft Amended Safety Assessment of Dibutyl Phthalate, Diethyl Phthalate, and Dimethyl Phthalate as Used in Cosmetics submitted (identified as *WVHJcomments_Phthalates_Wave2_032026*).

In their comments, WVHJ raised concerns regarding several aspects of the draft assessment. Specifically, they questioned the accuracy of the RLD data presented in Table 3; recommended revision of the respiratory exposure language; requested updating the maximum reported use concentration of Diethyl Phthalate to 1.0% and recalculation of the MOE; recommended recalculating the MOE using dermal absorption parameters generated from physiologically based toxicokinetic (PBTK) modeling, including 56.2% uptake into skin for personal care product (PCP) exposure and approximately 24.9% absorption into systemic circulation; and suggested expanding the neurodevelopmental and epidemiological sections to incorporate more recent literature and biomonitoring studies. Response to those comments follow the WVHJ submission (*response-WVHJcomments_Phthalates_Wave2_032026*).

The Panel is asked to review the comments submitted by WVHJ and the CIR response to those comments, and provide guidance on any revisions deemed appropriate.

Weaving Voices
FOR HEALTH & JUSTICE

February 26, 2026

Re: Comments on the Amended Safety Assessment of Dibutyl Phthalate, Diethyl Phthalate, and Dimethyl Phthalate as Used in Cosmetics

To the CIR:

The following comments are submitted on behalf of Weaving Voices for Health & Justice. (Weaving Voices is the new name for the organization you are familiar with - previously known as Women's Voices for the Earth).

1) **Table 3 RLD data (on p.91 of the .pdf) product numbers appear to be inaccurate.**
   - The table claims there are 284 total products containing Diethyl Phthalate, while also claiming, for example, that there are 350 leave-on products that contain Diethyl Phthalate. Presumably the total number of products should be equal or greater to the number of products found in any single category.

2) **Language used in the Cosmetics use section regarding potential inhalation of products (p.53 of the .pdf) is not supported by the Panel's respiratory exposure resource document as claimed and should be corrected.**
   - The wording "*most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and tracheobronchial regions and would not be respirable (i.e., they would not enter the lungs) to any appreciable amount*" is no longer stated in the most recent version of the respiratory exposure resource document and should be removed from this assessment.
   - The resource document does state that "*tested deodorant spray aerosols have a median d ae of 10 µm with a coefficient of variation of 0.3, suggesting that approximately **half** of these particles are within the range considered to be respirable*."
   - The California Safe Cosmetics Database includes two recent reports of aerosol deodorant sprays containing Diethyl Phthalate currently on the market.

     Lagerfeld Classic Deodorant Spray
     https://cscpsearch.cdph.ca.gov/search/searchresult/131752
     (Reported 12/13/23 and last updated 4/3/24 by manufacturer Interparfums)

     Montblanc Legend Deodorant Spray
     https://cscpsearch.cdph.ca.gov/search/searchresult/127392

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(Data entered 7/12/2023. And most recently updated 3/12/24 by manufacturer Interparfums)

- The assessment should clarify that 50% of the particles from these products are likely to be respirable (i.e. they **would** enter the lungs). The respiratory health ramifications of this information should be discussed by the Expert Panel.

3) **Maximum concentration use of Diethyl Phthalate should be updated to 1.0%.**
   - The California Safe Cosmetics Database provides reports of concentrations for 52 of the 903 products in the database reported to contain Diethyl Phthalate.
   - The highest reported concentration was 1.0% in 3 bath products. 20 products reported concentrations higher than 0.1% (the current maximum concentration listed in the assessment for rinse-off products)
   - The MOE (on p.79 of the .pdf) should also be recalculated with these updated maximum concentrations.
   - (See attached Excel sheet download of data from the California Safe Cosmetics Database) Reminder: This data is all self-reported by manufacturers in compliance with California state law.

4) **The safety assessment still uses an outdated DEP absorption study from 1994 (Ref. 125). A newer study published in 2022 designed specifically for "application to health risk assessment" found DEP absorption into human skin at 56.2%, with 24.9% of the dermal dose becoming systematically available.**
   - This newer data from **Physiologically-based toxicokinetic modeling of human dermal exposure to diethyl phthalate: Application to health risk assessment** https://www.sciencedirect.com/science/article/abs/pii/S0045653522024249 should be added to the draft assessment and should be incorporated into the MOE calculation on p. 79 of the .pdf.

5) **The draft summary of Phthalate Exposure and Neurodevelopment (on p. 80 of the .pdf) is incomplete and based on conclusions from older data.**

   - A crucial 2021 paper: **Neurotoxicity of Ortho-Phthalates: Recommendations for Critical Policy Reforms to Protect Brain Development in Children** (https://pmc.ncbi.nlm.nih.gov/articles/PMC7958063/) should be included in the assessment and discussed by the Expert Panel. This more recent systematic analysis of neurodevelopment research urgently calls for reducing phthalate exposure and regulating phthalates to protect children's developing brains. In contrast to the 2013 review (Reference 127) currently cited in the assessment, this 2021 review clearly states "*the weight of evidence strongly supports a relationship between certain phthalates and altered neurobehavioral development*" and provides significant support for this claim particularly for Dibutyl Phthalate. The CIR Expert Panel should take seriously their opportunity and responsibility to protect the developing brains of children.

6) **The Epidemiological Studies section (beginning on p. 80 of the .pdf) should be expanded.** The studies included make clear that higher urinary concentrations of DEP and/or DBP are often correlated with higher risk of disease. But many recent epidemiological studies are still missing. Particularly of concern is the current omission of any of the highly relevant studies showing the extent to which use of personal care products significantly impact levels of phthalate exposure measured in the body – in some cases doubling or even tripling urinary concentrations.
    - Examples include:

    https://pmc.ncbi.nlm.nih.gov/articles/PMC6037613/ **Personal care product use as a predictor of urinary concentrations of certain phthalates, parabens, and phenols in the HERMOSA study**

    "*Girls who reported using makeup every day vs. rarely/never had higher urinary concentrations of monoethyl phthalate (MEP) (102.2 ng/mL vs 52.4 ng/mL)… Girls who reported recent use of specific makeup products, including foundation, blush, and mascara, had higher urinary concentrations of MEP, mono-n-butyl phthalate (MBP)*."

    https://pubmed.ncbi.nlm.nih.gov/16263507/ **Personal care product use predicts urinary concentrations of some phthalate monoesters**

    Men who used cologne or aftershave within 48 hr before urine collection had higher median levels of monoethyl phthalate (MEP) (265 and 266 ng/mL, respectively) than those who did not use cologne or aftershave (108 and 133 ng/mL, respectively). For each additional type of product used, MEP increased 33% (95% confidence interval, 14-53%).

    https://pubmed.ncbi.nlm.nih.gov/24041567 **Predictors of urinary bisphenol A and phthalate metabolite concentrations in Mexican children**

    "We demonstrated that personal care product use is associated with exposure to multiple phthalates in children. Due to rapid development, children may be susceptible to impacts from exposure to endocrine disrupting chemicals; thus, reduced or delayed use of certain personal care products among children may be warranted."

    https://pubmed.ncbi.nlm.nih.gov/35358548/ **Exposure to phthalates from personal care products: Urinary levels and predictors of exposure**

    "The most striking association between any phthalate and PCPs was observed between MEP and perfumes or fragrance-containing products such as shampoos, body lotions and hair products."

    https://pubmed.ncbi.nlm.nih.gov/21429583/ **Personal care product use and urinary levels of phthalate metabolites in Mexican women**

    "Our results suggest that the use of some personal care products contributes to phthalate body burden that deserves attention due to its potential health impact.

Thank you for your consideration of these comments.

Sincerely,

Alexandra Scranton

Director of Science and Research

Weaving Voices for Health & Justice

Response to WVHJ Comments

1. RLD Data (Table 3)

WVHJ noted that the total number of products reported to contain Diethyl Phthalate (284) appears lower than the number of leave-on products (350). This apparent discrepancy reflects the structure of the FDA Registration and Listing Database (RLD), rather than an error in calculation.

This issue has been discussed in the Admin memorandum on Use Table Update submitted to the coming CIR Expert Panel March meeting. As discussed in such document, *"the total number of uses listed in the RLD does not match the sum of uses listed by duration of use or that of use by exposure type. The reason for this is because ingredients may be used in cosmetic formulations that are reported under more than one product category."*

RLD data are derived from product formulation listings, and a single product may be listed under multiple product categories. Category-specific counts are often generated using different query filters and do not remove duplicate listings across categories. As a result, the number of products reported within an individual category may exceed the reported total number of products.

For clarity, a footnote has been proposed for the Use Table, stating that *"The sum of the counts given for duration of use and by exposure type, and the sum of the frequency reported by product category, may not equal the sum of total uses because each ingredient may be used in cosmetic formulations that are reported under more than one product category"* (see page 7 at https://www.cir-safety.org/sites/default/files/Admin_UseTableUpdate_032026.pdf)

2. Respiratory Exposure Language

WVHJ commented that the inhalation language is inconsistent with the Expert Panel's most recent Respiratory Exposure Resource Document. The Panel last reviewed this resource document at the March 2025 meeting. During that meeting, the Panel deliberated on modifying the inhalation boilerplate (BP) language, particularly in cases where inhalation toxicity data are absent, to better highlight potential inhalation risks associated with the use of specific cosmetic spray products. The resource document was revised following their discussion and guidance. The updated BP language is provided below; however, this revision has not yet been finalized because consensus will be sought at an upcoming Expert Panel meeting. The Panel may determine whether revisions to the respiratory exposure language in the report are warranted to ensure consistency with the updated resource document.

> *"In the absence of inhalation toxicity data, the Panel considers that these ingredients can be used safely in aerosolized products, provided that measures are in place to minimize the presence of respirable particles. While complete elimination of respirable fractions may not be feasible in all formulations, packaging and product design should prioritize reducing exposures to levels that do not pose a significant health concern.*
>
> *In practice, as stated in the Panel's respiratory exposure resource document (https://www.cir-safety.org/cir-findings), **[if only pump spray uses are known:** the particle size of cosmetic pump sprays (> 60 µm) is large compared to the median aerodynamic diameter of ~ 4 µm for a respirable particulate mass. Typically, < 1% of the airborne droplets/particles released from pump sprays are in the range considered to be respirable. Therefore, the Panel reasoned that most droplets/particles incidentally inhaled from pump sprays would be deposited in the nasopharyngeal and tracheobronchial regions and would not be respirable to any appreciable amount, meaning they do not significantly enter the deep lung. **[if there are known propellant-based spray uses**: Some evidence suggests that propellant-based sprays, such as aerosol deodorant sprays and dry shampoos may emit larger fractions of particulates with aerodynamic equivalent diameters considered respirable (< 10 µm). The proportion of respirable droplets/particles released depends on the product characteristics and formulation. The deposition of aerosols and particles in specific regions*

*of the respiratory tract, along with their biological properties and potential toxic effects in both the upper airways and deep lung, must be carefully evaluated. [**if there are known powder uses**: Conservative estimates of inhalation exposures to respirable particles during the use of loose powder cosmetic products are at least 400-fold less than protective regulatory and guidance limits for inert airborne respirable particles in the workplace.] "*

3. Maximum Reported Concentration (1.0%) and MOE Recalculation

WVHJ requested that the maximum reported use concentration of Diethyl Phthalate be updated to 1.0%, citing three bath products listed in the California Safe Cosmetics Database. In that database, these products are categorized as "Bubble and Foam Bath Products– Bar or other hard solid", which correspond to solid bath tablets or fizzers intended to be added to bath water prior to use. However, such uses are not captured under the "Diluted for (Bath) Use" category in the FDA RLD. In addition, a concentration of approximately 0.83% has been reported for nail cream products, and these uses are also not reflected in the RLD.

CIR's exposure assessment and MOE calculations are based on the maximum use concentrations reported in the Council's concentration of use survey. According to the 2025 Council survey, Diethyl Phthalate has a reported maximum use concentration range of 0.1- 0.15%, with 0.15% reported in leave-on face and neck products. In CIR's MOE calculation, the leave-on product concentration of 0.15% was used as a conservative estimate, with a retention factor of 1.0 applied.

Additional concentrations reported in the California Safe Cosmetics Database include values up to approximately 0.8% in certain soap products and approximately 0.4% in shampoos. These values are derived from manufacturer self-reported submissions. Rinse-off products are substantially diluted during normal consumer use and therefore do not represent direct dermal exposure at the labeled concentration; for example, a retention factor of approximately 0.01 may be applied for rinse-off bar soap.

Manufacturers seeking to ensure that their specific use patterns are reflected in CIR safety assessments may submit updated concentration of use information through the Council survey process. The exposure assessment in this report reflects the most current survey data available for risk evaluation purposes.

4. Dermal Absorption in 2022 PBTK Modeling Study

WVHJ recommended recalculating the MOE using dermal uptake and systemic availability estimates from a 2022 PBTK modeling study,[1] which reported 56.2% uptake into skin following personal care product exposure and approximately 24.9% systemic availability. While this study provides useful modeling insights, several considerations limit its applicability for quantitative exposure estimation in risk assessment.

The model relies on several key assumptions, including 100% dermal bio-accessibility for air-to-skin exposure, formulation-dependent release assumptions, and back-calculation of systemic dose from urinary monoethyl phthalate (MEP) levels. Each of these assumptions introduces uncertainty into the estimated absorption fractions.

Model-derived estimates are inherently dependent on input parameters and calibration datasets. For Diethyl Phthalate, release and dermal availability vary substantially across product types and formulations, particularly because Diethyl Phthalate is commonly used as a solvent within fragrance systems and may be diluted, encapsulated, or retained within complex cosmetic matrices. Factors such as product composition, volatility, rinse-off dilution, retention factors, and skin contact time can substantially influence dermal bioavailability, yet product-specific release data are generally unavailable. As a result, model predictions rely on generalized assumptions that may not reflect typical consumer exposure conditions.

Importantly, the absorption values (e.g., 56.2% uptake into skin and 24.9% systemic availability) derived from the 2022 PBTK model are much higher than those measured in available human dermal absorption studies (~ 5.5%)[2] and were based on calibration using a small human exposure study (n = 5). CIR safety assessments generally rely on empirically measured human dermal absorption data when available and apply conservative exposure assumptions to ensure public health protection. The Panel may consider whether inclusion of the Hu et al. (2022) model outputs is appropriate as a supplementary line of evidence, e.g., qualitative discussion of dermal uptake and systemic availability.

5. Expansion of Epidemiological and Biomonitoring Studies

WVHJ recommended inclusion of a 2021 review[3] addressing associations between phthalate exposure and neurodevelopmental outcomes and requested expansion of epidemiological and biomonitoring studies. The draft amended assessment summarizes the broader epidemiological literature evaluating potential associations between prenatal phthalate exposure and neurodevelopmental outcomes. The studies cited in the 2021 review include cohort investigations using biomarker measurements, environmental exposure estimates, and other observational approaches. Many of the other studies cited by WVHJ are biomonitoring-based cohort studies that measure urinary phthalate metabolites.[4-8] Such biomarkers reflect aggregate exposure from multiple sources, including

diet, environmental media, and consumer products, and cannot attribute exposure specifically to cosmetic use of individual ingredients.

While the 2021 review may be cited for completeness, it does not provide new ingredient-specific evidence that would materially alter the weight-of-evidence evaluation for Dibutyl Phthalate, Diethyl Phthalate, or Dimethyl Phthalate under cosmetic use conditions.

The biomonitoring literature on phthalates is extensive, comprising hundreds of studies globally. It is neither feasible nor scientifically necessary to cite every individual study in a cosmetic ingredient safety assessment. Instead, the Panel relies on systematic literature searches and evaluates representative, methodologically robust studies to characterize exposure context and inform weight-of-evidence conclusions.

References

1. Hu, M., et al. Physiologically-based toxicokinetic modeling of human dermal exposure to diethyl phthalate: Application to health risk assessment. Chemosphere, 2022. 307(Pt 2): p. 135931.
2. Mint A, Hotchkiss SA, Caldwell J. Percutaneous absorption of diethyl phthalate through rat and human skin in vitro. Toxicol In Vitro. 1994;8(2):251–256.
3. Engel, S.M., et al. Neurotoxicity of Ortho-Phthalates: Recommendations for Critical Policy Reforms to Protect Brain Development in Children. Am J Public Health, 2021. **111**(4): p. 687-695.
4. Berger, K.P., et al. Personal care product use as a predictor of urinary concentrations of certain phthalates, parabens, and phenols in the HERMOSA study. J Expo Sci Environ Epidemiol, 2019. **29**(1): p. 21-32.
5. Duty, S.M., et al. Personal care product use predicts urinary concentrations of some phthalate monoesters. Environ Health Perspect. 2005. 113(11): p. 1530-5.
6. Lewis, R.C., et al. Predictors of urinary bisphenol A and phthalate metabolite concentrations in Mexican children. Chemosphere, 2013. **93**(10): p. 2390-8.
7. Pagoni, A., O.S. Arvaniti, and O.I. Kalantzi. Exposure to phthalates from personal care products: Urinary levels and predictors of exposure. Environ Res, 2022. **212**(Pt A): p. 113194.
8. Romero-Franco, M., et al. Personal care product use and urinary levels of phthalate metabolites in Mexican women. Environ Int, 2011. **37**(5): p. 867-71.

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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Monice Fiume, M.B.A.
Senior Director, CIR
Date: March 3, 2026
Subject: Wave 2 – Airbrush Conclusion

Enclosed please find comments submitted by Weaving Voices for Health & Justice (previously known as Women's Voices for the Earth) for consideration during review of the Airbrush Conclusion Admin document (*WVHJcomments_AirbrushConclusion_Wave2_032026*).

Weaving Voices
FOR HEALTH & JUSTICE

February 26, 2026

Re: Comments on the Insufficient data conclusion for ingredients with known airbrush use

To the CIR:

The following comments are submitted on behalf of Weaving Voices for Health & Justice (previously known as Women's Voices for the Earth).

I appreciate the efforts and discussion of the CIR Expert Panel regarding the potential respiratory harm associated with airbrush cosmetics over the years since I first brought concerns about these products to the CIR back in 2020. I am especially pleased to see that the FDA RLD is now collecting information on airbrush application of cosmetics, no doubt as a result of the voiced concerns and specific requests from the CIR.

However, it is disappointing, given that over five years have passed, that the CIR Expert Panel still does not have even basic information on consumer habits and practices for these products, information that is crucial to assessing risk and thus protecting the health of users. This is not impossible or even difficult data to gather, and should have been a priority for both the industry and the PCPC, whose reputations are on the line for not acting to protect the health of their customers, when the CIR Expert Panel has expressed clear concern for respiratory health from cosmetic airbrush technology.

Despite my disappointment in the continued lack of data, for the time being, **I agree with the suggestion to clearly state in the Conclusion that data are insufficient to determine safety in products applied via airbrush application.**

I hope the CIR Expert Panel will not be satisfied with this Conclusion wording, but will continue to use their authority to reaffirm and emphasize the crucial need for greater information about airbrush cosmetics products going forward. I believe it is the responsibility of the CIR Expert Panel to keep asking vociferously for the information they need to protect the safety of cosmetic users.

With respect to the Known Airbrush Use – Cosmetic Use section and Discussion boilerplate, I would like to suggest an important edit to improve accuracy. The proposed language states:

> *"…However, no consumer habits and practices data or particle size data are publicly available to evaluate the exposure associated with this use type, thereby preempting the ability to evaluate risk or safety."*

It is not accurate to say that "no particle size data are publicly available" and should instead state there is "limited particle size data available."

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In December 2020, in my comments on the Amended Safety Assessment of Dimethicone, Methicone, and Substituted-Methicone Polymers, I referenced a publicly available study that specifically measured particle size distribution of particles emitted from a cosmetic airbrush. The study submitted was:

Pearce K, Goldsmith WT, Greenwald R, Yang C, Mainelis G, Wright C. **Characterization of an aerosol generation system to assess inhalation risks of aerosolized nano-enabled consumer products.** Inhal Toxicol. 2019 Aug-Aug;31(9-10):357-367. doi: 10.1080/08958378.2019.1685613. https://pubmed.ncbi.nlm.nih.gov/31779509/

The CIR Expert panel discussed the paper and acknowledged that it did indeed measure particle size from a cosmetic airbrush and that the particle sizes emitted were small and of concern (see below excerpts from the transcript of that meeting).

DECEMBER 2020 PANEL MEETING – THIRD REVIEW: DRAFT FINAL AMENDED REPORT
Amended Safety Assessment of Dimethicone, Methicone, and Substituted-Methicone Polymers as Used in Cosmetics

Belsito Team – December 7, 2020

"DR. LIEBLER: So anyway, the [Pearce 2019] study appears to use techniques that are appropriate to gauging particle size distributions. And these distributions do include a much smaller particle size than we normally associate with sprays and certainly with pump sprays.
So, I think that this has to be -- we really do have to take this into consideration. I don't know how widely used these airbrushes are in application of cosmetic products. But it was easy to me to look on the web and find multiple products in both airbrushes for sale and products that go with them.
So I don't know if we're capturing this in our assessment of products use concentrations. And I just don't know if the industry surveys are capturing this type of application. Because if they're not, it's something, it's a gap in our knowledge that's potentially very important.

…
DR. SNYDER: So the point of departure here would be from the 2003 paper where we said that the incidental inhalation was not an issue because of the particle size. We now have data of a different aerosolization method, which we don't know the particle size. Is that the summation of what we're saying?
DR. LIEBLER: No, we actually do know the particle size and it's small.
DR. SNYDER: Okay.
DR. LIEBLER: Yeah, it's submicron. So that's the issue there literally in our face."

I fully agree that more cosmetic airbrush particle size distribution data is still needed for the assessment of risk and protection of health. Again, collecting this type of data is not rocket science. I firmly believe the manufacturers of airbrush cosmetics do this research all the time to assess the ideal particle size needed to optimize results for their products. Again, the CIR Expert Panel should continue to vociferously ask for this information which is crucial to protecting health. There is significant epidemiological data that cosmetologists, for example, experience disproportionate risk of respiratory disease, but it is still unknown how much airbrush cosmetic application contributes to this excess disease burden. The CIR Expert Panel has both the potential and the responsibility to reduce this disease burden, allowing beauty professionals to do their jobs more safely, and their customers to lower their respiratory risks as well.

Lastly, I offer this recent information which may be helpful to the CIR Expert Panel's discussions around airbrush cosmetic safety. While it does not reflect traditional "habits and practices" information, a better understanding of the airbrush cosmetic market can be gleaned from existing market research that is publicly available. Here is one of the latest reports on airbrush cosmetics market trends, indicating (and explaining) the considerable expected growth in the airbrush makeup market in the next 10 years:

Airbrush Makeup Market Size, Share, Growth, And Industry Analysis, By Type (Corded, Cordless), By Application (Professional, Residential), Regional Insights And Forecast From 2026 To 2035

> *"The increasing popularity of high-definition cameras and televisions has created a demand for makeup that can provide flawless coverage without appearing heavy or cakey on camera… Many makeup schools and training programs now offer courses in airbrush application, which can provide aspiring makeup artists with the skills and knowledge they need to succeed in this growing field. The popularity is expected to continue to rise as high-definition technology becomes even more widespread, creating new opportunities for makeup artists and businesses in the market."*
>
> *"The market is witnessing significant growth globally. While the market is expanding across various regions, one region that stands out is North America. It is considered the leading region in the market, with a substantial share of the market."*
>
> *"The global airbrush makeup market size is forecasted to be worth USD 0.73 Billion in 2026, expected to achieve USD 1.12 Billion by 2035 with a CAGR of 4.84% during the forecast from 2026 to 2035."*

Source: https://www.businessresearchinsights.com/market-reports/airbrush-makeup-market-106176

I encourage the CIR to collect this and other existing market research on Airbrush cosmetics for their consideration until the needed habits and practices data is produced.

Thank you for your consideration of these comments.

Sincerely,

Alexandra Scranton
Director of Science and Research
Weaving Voices for Health & Justice

Cosmetic Ingredient Review

Commitment & Credibility since 1976

Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Monice Fiume, M.B.A,
Senior Director, CIR
Date: March 3, 2026
Subject: Wave 2 - Use Tables

Enclosed please find PCPC comments to be considered during the review of the Use Table Admin document (*PCPCcomments_UseTables_Wave2_032026*). Specifically, these comments, which have been submitted by Thomas Myers, PCPC President and CEO, and Dr. Jaap Venema, PCPC EVP and Chief Scientist and industry liaison to the Panel, and are in regard to the inclusion of tattoo product categories in CIR reports.

Personal Care Products Council

Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director – Cosmetic Ingredient Review

FROM: Thomas Myers
President and CEO – Personal Care Products Council
Chair of the CIR Steering Committee

Jaap Venema, Ph.D.
EVP and Chief Scientist – Personal Care Products Council
Industry Liaison to the CIR Expert Panel

DATE: February 26, 2026

SUBJECT: Inclusion of Tattoo Product Categories in Cosmetic Use Information in CIR reports

The Personal Care Products Council (PCPC) respectfully submits the following comments on cometic use information included in Cosmetic Ingredient Review (CIR) reports.

As part of the changes resulting from the Modernization Act of Cosmetics Products (MoCRA) of 2022, FDA added tattoo preparations (permanent tattoo inks, temporary tattoo inks, and other tattoo products) to the product categories for which companies need to list their products with FDA.

In supporting CIR, PCPC receives data from its member companies, such as maximum concentration of use of ingredients in member products. This information is provided to CIR for consideration in the ingredient review process. PCPC, however, does *not* represent its member companies on tattoo preparations, and therefore will not be able to assist in CIR's review of this category.

Consequently, we strongly recommend that FDA frequency of use information for tattoo preparations not be included in the use tables of CIR reports, and that CIR's scope *exclude* the review of ingredients as to their use in tattoo preparations.