

Data Supplement

2026 Priorities

4-Chloro-2-Aminophenol

Fatty Amphocarboxylates

Hair Dye

Nelumbo nucifera

Octoxynols

Sodium Borate

EXPERT PANEL MEETING

SEPTEMBER 8-9, 2025



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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Bart Heldreth, P.hD., Executive Director, CIR
Date: August 28, 2025
Subject: Wave 2 – 2026 Draft Final Priorities

Please find attached the comments provided by the Personal Care Products Council (Council) on the 2026 Draft Final Priorities. Therein, the Council remarks that Colophonium is the EU trivial name for Rosin. However, both Colophonium and Rosin each have monographs in the INCI Dictionary and there are some distinctions between the definitions in those monographs. Additionally, the Council notes that since the Panel previously assessed the safety of certain rosin esters (i.e., rosinate), it is not necessary to assess the safety of Rosin; no further rationale is provided on how this substantiates the safety of Rosin (or Colophonium).



Memorandum

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

FROM: Kimberly Norman, Ph.D., DABT, ERT
Industry Liaison to the CIR Expert Panel

DATE: August 25, 2025

SUBJECT: 2026 Priorities (September 8-9, 2025 meeting)

The Personal Care Products Council respectfully submits the following comments on the proposed 2026 final priorities.

Key Issue

Although Octocrylene is also used as a light stabilizer, it should not be reviewed by CIR as FDA is conducting a review of its safety as a sunscreen ingredient. A 2025 concentration of use survey indicates that as a light stabilizer, Octocrylene is used at concentrations up to 0.5% compared to concentrations up to 10% when used as a sunscreen ingredient (see attached table). If there are data gaps for Etocrylene, data on Octocrylene may be useful to fill the gaps, but to avoid duplicating efforts, the Expert Panel for Cosmetic Ingredient Safety should not be reviewing the safety of Octocrylene as used in cosmetics.

Additional Considerations

Colophonium is the EU trivial name for Rosin. If this ingredient is reviewed, it should be reviewed under the US INCI name Rosin, not Colophonium. As the Expert Panel has already found a number of Rosinate ingredients, e.g., Glyceryl Rosinate, safe for use in cosmetics, it is not necessary to review the safety of Rosin.

Two re-reviews should be removed from the list. Oxyquinoline, as the re-review is already underway (insufficient data announcement issued during the June 2025 meeting), and Glyceryl monoesters as most of these ingredients were included in the 2020 Monoglyceryl monoester report, with the remaining "orphans" considered at a recent CIR meeting.

Concentration of Use by FDA Product Category¹
 Etocrylene and non-sunscreen uses of Octocrylene*

Ingredient	Product Category	Maximum Concentration of Use
Etocrylene	Basecoats and undercoats (manicuring preparations)	0.5%
Etocrylene	Nail polish and enamel	10%
Etocrylene	Suntan products (not spray)	3%
Etocrylene	Suntan products (spray) Aerosol	3%
Octocrylene	Nail polish and enamel	0.5%
Octocrylene	Other manicuring preparations	0.2%

*In the United States, 10% is the maximum concentration of Octocrylene permitted for use in sunscreen products. The concentrations of Octocrylene included in this table are for non-sunscreen uses.

Information collected in 2025
 Table prepared: May 21, 2025

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

Colophonium

INCI Monograph ID: 9435

Published On: 07/17/1995

CAS Number:

8050-09-7

EC Number:

232-475-7

Definition: Colophonium is a complex combination derived from wood, especially pine wood. It is composed primarily of resin acids and modified resin acids such as dimers and decarboxylated resin acids. It also includes rosin stabilized by catalytic disproportionation.

For further information about EU Trivial Names, see Trivial Names in "Regulatory and Ingredient Use Information" section of *INCI Nomenclature – Conventions and Reference Information*.

Safety/Regulatory Information

Information Sources:

ECG

IECIC

TSCA

UNII 88S87KL877

Chemical Classes:

Botanical Products and Botanical Derivatives

Reported Functions:

Film Formers

Ingredient Sources:

Plant

Technical Names:

Rosin (U.S.)

Chinese Name: 松香 (COLOPHONIUM)

Korean Name: 로진

Rosin

INCI Monograph ID: 2729

Last VCRP Frequency Update: March, 2022

Published On: 12/04/1979

VCRP Reported Name:

VCRP Frequency of Use: 102

Rosin

CAS Number:

8050-09-7

EC Number:

232-475-7

Definition: Rosin is the residue left after distilling off the volatile oil from the oleoresin obtained from *Pinus palustris* and other species of *Pinaceae*.

For further information about EU Trivial Names, see Trivial Names in "Regulatory and Ingredient Use Information" section of *INCI Nomenclature – Conventions and Reference Information*.

Safety/Regulatory Information

Information Sources:

21CFR172.510

21CFR175.105

21CFR175.125

21CFR175.300

21CFR176.170

21CFR176.200

21CFR176.210

21CFR177.1200

21CFR177.1210

21CFR177.2600

21CFR178.3120

21CFR178.3800

21CFR178.3850

21CFR178.3870

21CFR310.531

21CFR73.1

BP
CTFA D
ECG
ECHA-R
IECIC
MI
TSCA
UNII 88S87KL877
USP

Chemical Classes:

Botanical Products and Botanical Derivatives

Reported Functions:

Binders
Epilating Agents
Film Formers
Viscosity Increasing Agents - Nonaqueous

Ingredient Sources:

Plant

Technical Names:

Colophonium (EU)
Colophony
Gum Rosin
Rosin Gum
WW Wood Rosin

Trade Names: [Click here to view full list of Trade Names](#)

Chinese Name: 松香

Japanese Name: ロジン

Korean Name: 로진

Reported Product Categories:

Bubble Baths
Lipsticks

Mascara

Depilatories

Makeup Preparations (Not eye), Misc.

Nail Polish and Enamels



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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Christina L. Burnett, MSES, Senior Scientific Analyst/Writer, CIR
Date: August 28, 2025
Subject: Wave 2 – Amended Safety Assessment of 4-Chloro-2-Aminophenol as Used in Cosmetics

Please find attached the comment provided by the Personal Care Products Council on the Draft Final Amended Report on 4-Chloro-2-Aminophenol. The comment regards wording of the Discussion, and the Panel should consider if editorial changes should be made.



Memorandum

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

FROM: Kimberly Norman, Ph.D., DABT, ERT
Industry Liaison to the CIR Expert Panel

DATE: August 25, 2025

SUBJECT: Draft Final Amended Report: Amended Safety Assessment of 4-Chloro-2-Aminophenol as Used in Cosmetics (draft prepared for the September 8-9, 2025, meeting)

The Personal Care Products Council respectfully submits the following comments on the draft final amended report, Amended Safety Assessment of 4-Chloro-2-Aminophenol as Used in Cosmetics.

Discussion – The list of data needs in the Discussion is unnecessary with a conclusion of unsafe. Because of genotoxicity data and bladder tumors in an oral rat study, the Expert Panel has indicated that there are no additional data that will change the conclusion.



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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Priya Ferguson, M.S., Senior Scientific Analyst/Writer, CIR
Date: August 28, 2025
Subject: Wave 2 - Safety Assessment of Fatty Amphocarboxylates as Used in Cosmetics

Data (*data_FattyAmphocarboxylates_Wave2_092025*) were provided from the Alkylamphoacetates Consortium comparing the method of manufacture and impurities for amphoacetates versus alkylamidopropyl betaines (e.g., CAPB). Notably, the "amidoamine" impurity found in amphoacetates is chemically distinct from the amidoamine present in CAPB. In amphoacetates, the amidoamine refers to amido hydroxyethyl ethylenediamines, while in alkylamidopropyl betaines, it refers to amidopropyl dimethylamines.



Memorandum

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

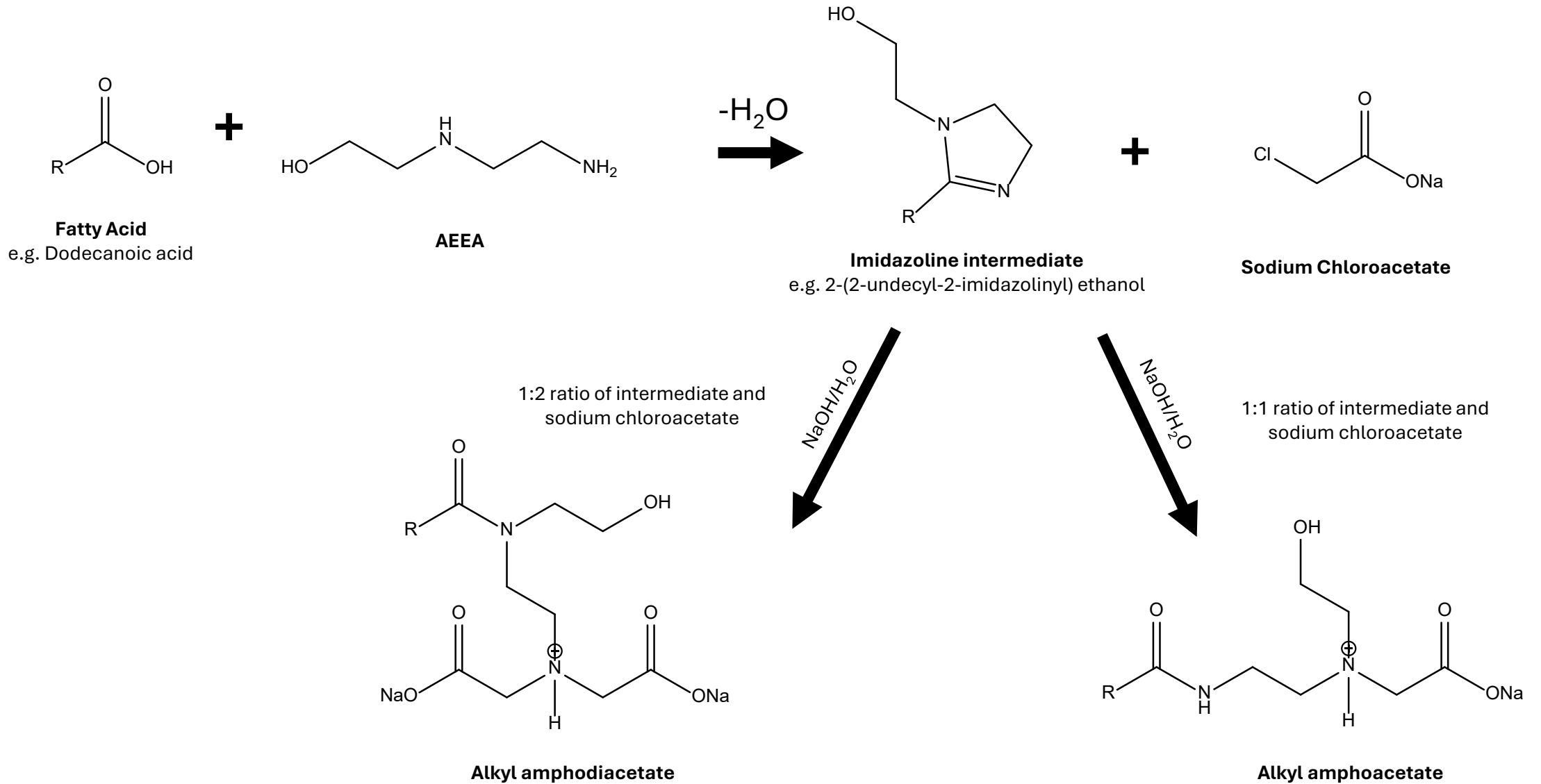
FROM: Carol Eisenmann, Ph.D.
Personal Care Products Council

DATE: August 26, 2025

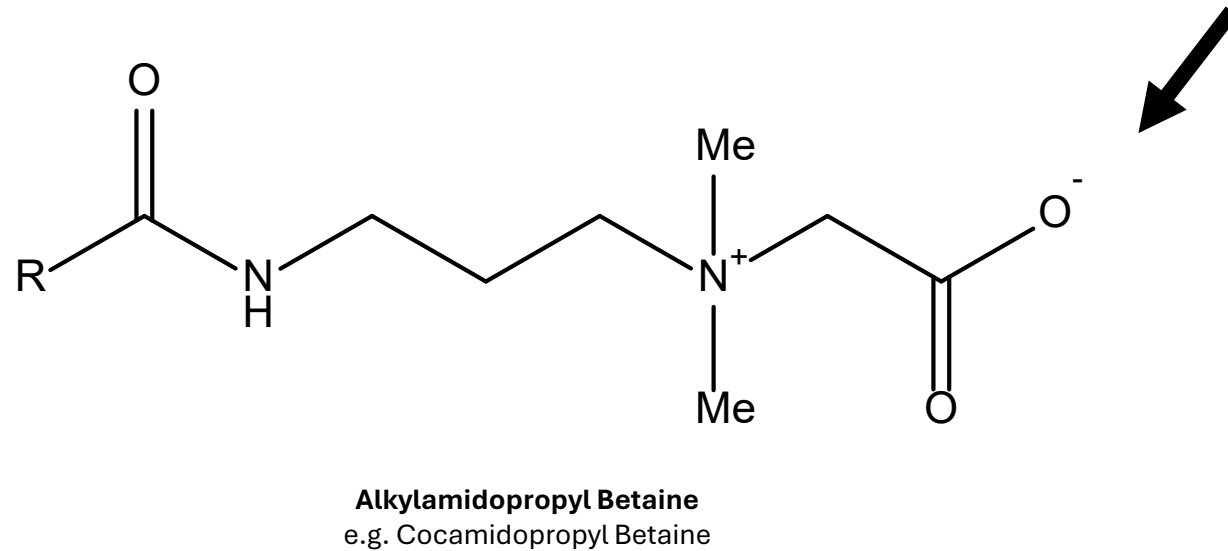
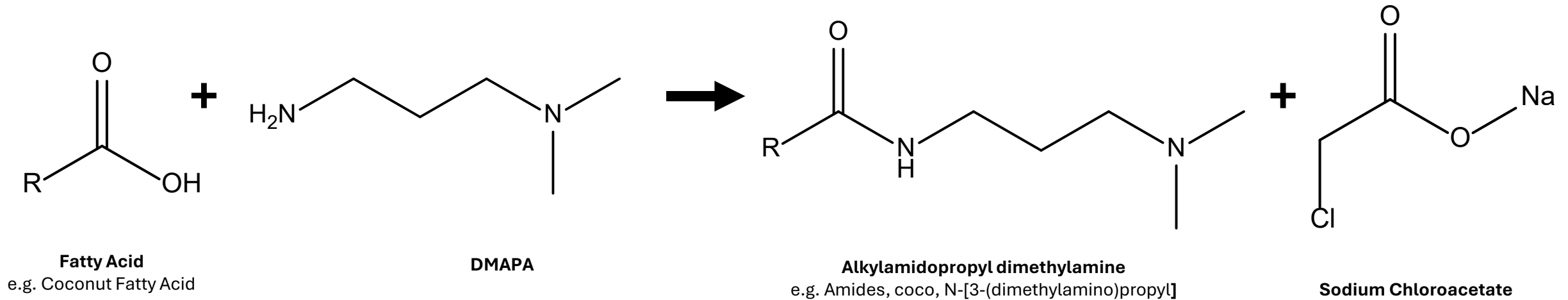
SUBJECT: Fatty Amphocarboxylates

EU Alkylamphoacetates Consortium. 2025. Comparison of the Method of Manufacture and Impurities for Amphoacetates Versus Alkylamidopropyl Betaines, e.g. CAPB.

Amphoacetate Manufacturing Process

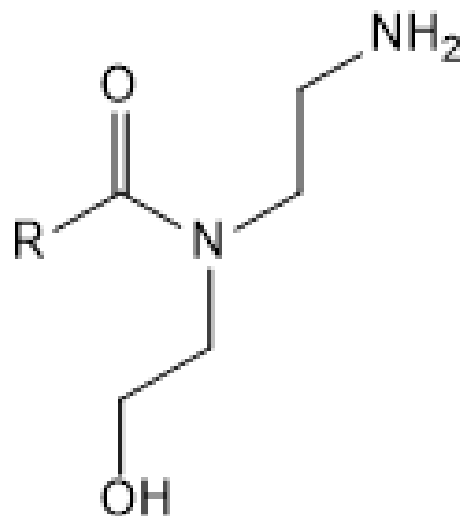
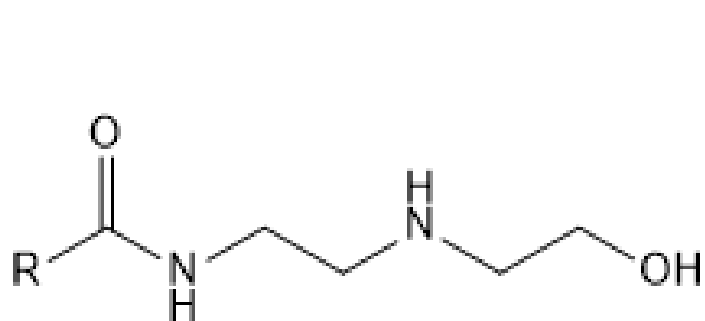


AAPB Manufacturing Process

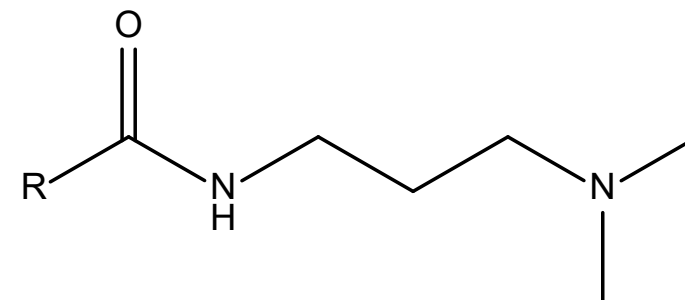


Impurities

Amidoamine in amphotoacetates (Amido Hydroxyethyl Ethylenediamines)



Amidoamine in AAPB (Amidopropyl dimethylamines)



Amides, coco, N-[3-(dimethylamino)propyl]
CAS 68140-01-2; EC 268-771-8
Skin Sens. 1B, H317



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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
 From: Jinqiu Zhu, Ph.D., DABT, ERT, DCST, CIR Toxicologist
 Date: August 28, 2025
 Subject: Response to comments on Hair Dye Epidemiology Resource Document submitted by WVE

Enclosed are comments dated August 27, 2025 from Women’s Voices for the Earth (WVE) on the Hair Dye Epidemiology Resource Document (identified as *WVEcomments_HairDyeDocument_Wave2_092025*). In the comments, WVE re-iterates their concern that the Resource Document’s conclusion – current hair dye epidemiology data do not provide sufficient evidence to support a causal relationship between personal hair dye use and cancer – is overly broad and potentially misleading, giving that “*at least one statistically significant positive association between hair dye use and cancer was reported in the majority of studies reviewed by the CIR.*” In addition, WVE comments more generally on the issue of “asymmetrical evaluation of evidence” in regulatory contexts, noting that study limitations tend to be emphasized primarily for studies with positive findings but not for those reporting null results, which may create an impression of bias. They recommend adding clarifying language to the conclusion and ensuring a more balanced discussion of study limitations to maintain scientific integrity.

In response to the first comment, while several epidemiological studies report statistically significant positive associations between personal hair dye use and specific cancer types, it is essential to emphasize that association does not imply causation. A statistically significant association merely indicates that two variables occur together more often than would be expected by chance – it does not establish any causal link.

Regarding the second comment, epidemiological studies, by design, have inherent limitations that complicate causal interpretation. These include reliance on observational rather than experimental data, potential for recall bias (particularly in case-control studies), selection bias, exposure misclassification, and uncontrolled confounding variables. For example, self-reported hair dye use may be imprecise, and important risk factors – such as smoking history, occupational chemical exposures, or genetic predispositions – may not be fully adjusted for. Additionally, small sample sizes for certain cancer types may limit statistical power, and inconsistent findings across populations raise concerns about the reproducibility and generalizability of observed associations. Such inherent limitations may be addressed in the discussion of methodology for each original study, especially when the findings report a null or negative association. However, an extended discussion of these limitations for every study is not considered necessary within the scope of the current Resource Document. Instead, a brief discussion of key elements of study design – such as whether the study includes information on the type of hair dyes used, as well as important exposure details like shade, frequency, and duration of use – is included, as these elements are essential for understanding the Rollison et al. (2006) scale to evaluate the quality of hair dye exposure assessment in epidemiological studies, giving that causal inference requires more than statistical significance; it also depends on the consistency of findings, the strength and dose-response of the association, and the specificity of the observed effect.

It is worth noting that the results of a meta-analysis can be heavily influenced by the inclusion and exclusion criteria determined by the authors, as well as the types of epidemiological studies considered. Although these limitations are not always elaborated in the main text, they are documented in the tables of the Resource Document. For example, Gera et al. (2018) conducted a meta-analysis of 8 case-control studies and reported a borderline increased risk of breast cancer associated with hair dye use (RR = 1.18; 95% CI: 1.03-1.37). However, as the authors noted in the paper, of the 24 studies initially deemed relevant, 5 prospective studies that did not show any association were excluded from the final analysis. Such exclusions may substantially affect the overall findings, and therefore the limitations and exclusion criteria are explicitly noted in the relevant table (see PDF page 41 at https://www.cir-safety.org/sites/default/files/Admin_HairDyeEpi_092025.pdf). Similarly, as mentioned in WVE’s comments, the Mendelsohn et al. (2009) study was limited by small case numbers for certain cancer types. This limitation was recorded in the corresponding table (see PDF page 28 at https://www.cir-safety.org/sites/default/files/Admin_HairDyeEpi_092025.pdf) but not discussed in the main text. Nonetheless, the main text clearly indicates that “*exposure assessment was rated low quality (+) according to*

the Rollison et al. (2006) scale,” meaning that this study might be appropriately considered of low weight in the overall evaluation.

WVE continues to draw analogies between personal hair dye use and well-established carcinogens such as ultraviolet (UV) radiation, radon, and diethylstilbestrol (DES), emphasizing the supposed rarity of causal determinations made by authoritative bodies. As CIR staff have previously explained (see PDF page 7 at https://www.cir-safety.org/sites/default/files/DataSupplement_Wave2_062025.pdf), this comparison is misleading. Unlike the epidemiological data on personal hair dye use – which remain inconclusive and are constrained by confounders, exposure misclassification, and study heterogeneity – the causal link between UV exposure and cancer, specifically skin cancers such as malignant melanoma and squamous cell carcinoma, has been firmly established. The International Agency for Research on Cancer (IARC) of the World Health Organization (WHO) has classified solar radiation, radon, and DES as **Group 1** carcinogens, reflecting **sufficient** evidence of carcinogenicity in humans. These agents represent clear exceptions supported by robust data and broad scientific consensus, rather than typical cases of scientific uncertainty. Therefore, equating the state of evidence on personal hair dye use with the well-substantiated evidence on UV radiation, radon or DES undermines the critical differences in data strength, disease specificity, and the degree of global scientific consensus.

Furthermore, as outlined in the Introduction section of the Resource Document, IARC concluded that while certain animal studies suggested limited evidence for the carcinogenicity of hair colorants, the overall data lacked sufficient quality, consistency, and statistical power to establish a causal relationship between personal hair dye use and cancer. Accordingly, IARC classified personal hair dye use as “not classifiable as to its carcinogenicity to humans” (**Group 3**). (For comparison, coffee and tea, when consumed as beverages, are also classified as Group 3 by the IARC.) In contrast, occupational exposure among hairdressers, barbers, and beauticians – who experience more frequent and prolonged contact with hair dyes – was classified as “probably carcinogenic to humans” (**Group 2A**), based primarily on limited evidence for bladder cancer. Evidence regarding other cancer types was **inconsistent or inadequate**. Importantly, occupational safety assessments fall outside the scope of the Expert Panel’s review. To date, the US FDA has similarly concluded that no reliable evidence has demonstrated a causal link between cancer and the use of currently marketed coal-tar hair dyes.

Although positive associations may serve as a signal to prompt further investigation, they cannot be interpreted as evidence of a causal relationship without a more comprehensive and consistent body of supporting evidence. This distinction is critical in regulatory science and public health communication to ensure scientific credibility and avoid overstating potential risks. It should also be noted that the draft Resource Document is intended for submission to an academic journal with high impact factor, where it will undergo peer review by experts in the fields of cancer research, toxicology, and epidemiology. Feedback from the journal reviewers will inform subsequent updates of the document before its release to the public.

The Panel is asked to review the WVE’s comments submitted and, if deemed necessary, consider whether revisions to the conclusion and discussion sections of the Resource Document are warranted.



August 27, 2025

Re: Comments on Hair Dye Epidemiology report

To the CIR:

The following comments are submitted on behalf of Women's Voices for the Earth.

I appreciate the effort to make the hair dye epidemiology work more publicly available by crafting it as an article to be published in a journal. All the more so, I believe the CIR should be concerned and aware of the potential impact on the CIR's credibility and reputation from making this a much more publicly available document.

1.) Overly broad conclusion of the report may be misleading

As I have commented before, I am concerned that the overly broad conclusion of the paper is unclear and may be seen as misleading.

When the CIR concludes that,

"...current hair dye epidemiology data do not provide sufficient evidence to support a causal relationship between personal hair dye use and cancer."

it is unclear what exactly is being implied. This claim could be interpreted to mean that there is not sufficient evidence to support a causal relationship between personal hair dye use and "all cancer morbidity and mortality." Or the conclusion could be interpreted to mean that the CIR is claiming there is not even sufficient evidence to support a causal relationship between personal hair dye use and any single type of cancer or in any particular subpopulation.

Reading through the whole report, it is clear that the CIR has identified considerable evidence of significant associations between personal hair dye use for some types of cancer, especially in certain subpopulations. By my count, **at least one statistically significant positive association between hair dye use and cancer was reported in the majority of studies reviewed by the CIR.**

Specifically, a statistically significant positive association was reported in:

6 out of 8 cohort studies reviewedⁱ
19 out of 30 case-control studies reviewedⁱⁱ and
10 out of 13 meta-analyses reviewedⁱⁱⁱ.

The use of language in the abstract and conclusion which could be misinterpreted to mean there is little or no evidence of positive associations between hair dye use and cancer would be misleading. I strongly suggest some additional language be added to both the conclusion and the abstract to better explain the nuance and meaning of your conclusion, in light of the evidence presented in the report.

The impact of a misinterpretation of your intended meaning could have serious implications. After all, if one is only referring to “all cancer morbidity and mortality” collectively it is also scientifically accurate to say,

“There is no causal relationship between...

...UV exposure and cancer
...Radon and cancer
...Diethylbestrol (DES) and cancer

But the reputational risks of making such broad claims are obvious. UV exposure is well-known as a carcinogen that causes skin cancer (but not other cancers). Radon is well known to cause lung cancer (but not other cancers), etc. Making a broad statement that appears to claim these chemicals/exposures don't cause cancer would strain the credibility of the claimant. I am concerned that, as written, the article places the CIR at risk of putting forward a very public conclusion in a peer-reviewed journal that would come across as similar to one of the three statements above, and be viewed as a discredit to the reputation of the CIR.

2.) Asymmetric evaluations of scientific evidence indicating harm

In reading through the paper, I recognized that there was a distinct bias towards reporting and discussing the limitations/weaknesses of studies only for those studies which found significant positive associations between personal hair dye use and cancer. Where studies reported null results, no limitations or weaknesses were discussed (which could have contributed to an inadvertent false null conclusion.) This asymmetrical evaluation of scientific evidence comes across as a bias – as if the CIR wholly trusts those studies showing no association with cancer without question, but when a study shows a significant positive association, only then does the CIR choose to add qualifying language to cast doubt on the verity of those results. To avoid risk to the CIR's public reputation and credibility, more balance in the reporting of limitations should be added to the paper.

For example, on p. 20 of the .pdf are summaries of two papers (Kogevinas et al. 2006) and (Koutros et al. 2011), both of which reported null associations with use of hair dye and bladder cancer. It is unfortunate that there is no mention here that both studies also suffered from the limitation of being based on small numbers of subjects – which clearly would have lowered the statistical power needed to find a significant association. (The limitation of small numbers of subjects is noted for these papers in the table on pp. 36-7, but mentions of these limitations are inexplicably absent from the summaries in the text.)

Similarly, on p.12 of the .pdf is a summary of a cohort study (Mendelsohn et al., 2009) stating “no increased risk was observed for site-specific cancers.” Again, missing from the text is any mention of the limitation noted in the table on p. 29 which states “*the study is limited by small numbers for certain cancer types.*” The lack of increased risk for site-specific cancers could well be due to those small numbers.

In fact, reading through the paper, I could not find a single instance in which study limitations were mentioned for a study which reported solely null findings. In comparison, there were 11 studies which reported statistically significant positive associations with cancer in which the study limitations and weaknesses were formally addressed. (Zhang 2020, Thun 1994. Eberle 2020, White, Gregorire 2021, Dianatinasab 2017, Llanos 2017, Heikkinen 2015, White, Sandler 2021, Parodi 2016, Lim 2022 and Tai 2016.)

This same asymmetrical evaluation of scientific evidence has recently been called out publicly in a 2025 peer-reviewed journal article titled “Asymmetric evaluations of scientific evidence indicating harm compared to evidence indicating an absence of harm in regulatory appraisals.”

van Zwanenberg, P., Millstone, E. & Ortolani, A.L. **Asymmetric evaluations of scientific evidence indicating harm compared to evidence indicating an absence of harm in regulatory appraisals.** Environ Sci Eur 37, 138 (2025). <https://doi.org/10.1186/s12302-025-01176-9>
<https://enveurope.springeropen.com/articles/10.1186/s12302-025-01176-9>

The authors of this article concluded:

“...the types of evaluative asymmetry we have identified are not only anti-precautionary, some are also scientifically defective. They are scientifically defective, because they violate indispensable scientific requirements for making valid inferences and reaching well-founded conclusions. This is important but also revealing, because it highlights some of the ways in which groups of scientists recruited to serve policy-makers can violate some of the basic norms of professional science.”

Adding greater balance to the reporting of study limitations in this paper could help the CIR avoid similar critiques of being “scientifically defective” in the future. There is considerably greater risk of this type of public critique once the CIR publishes this report in a peer-reviewed journal in comparison to self-publishing the resource on the CIR website.

Thank you for your consideration of these comments.

A handwritten signature in black ink, appearing to read "Alexandra Scranton". The signature is written in a cursive, flowing style.

Alexandra Scranton
Director of Science and Research
Women's Voices for the Earth

ⁱ **Cohort studies** reporting at least one positive association between hair dye use and cancer include: Zhang (2020), Thun (1994), Eberle (2020), White, Gregoire (2021), White, Sandler (2021) and Lim (2022).

ⁱⁱ **Case-control studies** reporting at least one positive association between hair dye use and cancer include: Heikkininen (2015), Dianatinasab 2017, Llanos 2017, Rao 2022, Zhang (2004), Morton (2007), Chang (2010), Lv (2011), Parodi (2016), Arshad (2018), Gao (2018) Shakhssalim (2010), Koutros (2011), Tai (2016), Spitz (1990), Gago-Dominguez (2003), Morton (2007), Zhang (2009) and Guo (2014).

ⁱⁱⁱ **Meta-analyses** reporting at least one positive association between hair dye use and cancer include: Xu (2021), Farooq (2024), Takkouche (2005), Zhang (2008), Linet (2014), Carhan (2014), Towle (2017), Qin (2019), Oduola (2020), Ahmadi (2022).



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To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Thushara Diyabalanage, Ph.D., Scientific Analyst/ Writer, CIR
Date: August 28, 2025
Subject: Wave 2 - Safety Assessment of *Nelumbo nucifera*-Derived Ingredients as Used in Cosmetics

Please find attached comments of the Personal Care Products Council on the Draft Final Report of the Safety Assessment of *Nelumbo nucifera*-Derived Ingredients as Used in Cosmetics (*PCPCcomments_NelumboNucifera_Wave2_092025*). The Panel should review the comments expressed on the insufficient data conclusion for *Nelumbo Nucifera* Germ Extract and provide guidance for any updated to the Discussion.

Also, please find the following attached information submitted by industry. However, please note that the toxicity data are reported in an extremely summarized form with no detailed information about the study protocols and results.

- Anonymous. 2025. Maximum concentration of use data for *Nelumbo Nucifera* Germ Extract (*data1_NelumboNucifera_Wave2_092025*)
- Anonymous. 2025. Summary Information on *Nelumbo Nucifera* Germ Extract (*data2_NelumboNucifera_Wave2_092025*)



Memorandum

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

FROM: Kimberly Norman, Ph.D., DABT, ERT
Industry Liaison to the CIR Expert Panel

DATE: August 25, 2025

SUBJECT: Draft Final Report: Safety Assessment of *Nelumbo nucifera*-Derived Ingredients as Used in Cosmetics (draft prepared for the September 8-9, 2025, meeting)

The Personal Care Products Council respectfully submits the following comments on the draft final report, Safety Assessment of *Nelumbo nucifera*-Derived Ingredients as Used in Cosmetics.

Key Issues

Discussion – The listed data needs in the Discussion need to be revised. Method of manufacture and composition information has already been received for some ingredients and is included in the report. One example is the Germ Extract which is an ethanolic extract comprised of tannins and flavonoids or tannins and saccharides. UV absorption spectra have been provided for these Germ Extract ingredients, as well as a negative *in vitro* eye irritation assay. The report already includes dermal irritation and sensitization data on these Germ Extracts. A recent submission reports a maximum use of 0.001% in face and neck products for the Germ Extract.

Based on the information in the report and the additional information provided, is the insufficient data conclusion for the Germ Extract as described in the report still appropriate?

Additional Considerations

Method of Manufacture, *Nelumbo Nucifera* Leaf Extract – Please delete “and then” in “the soluble phase was filtered and then using sterilized membrane filtration.”

Composition and Impurities, *Nelumbo Nucifera* Flower Oil – In the studies on the composition of the flower oil, were any alkaloids identified?

UV Absorption – Stating that “two of the three were identified as lotus germ extract” suggests that the third was not a “lotus germ extract”. It should also state that the third was identified as “*Nelumbo Nucifera* Germ Extract”.



Memorandum

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

FROM: Carol Eisenmann, Ph.D.
Personal Care Products Council

DATE: August 22, 2025

SUBJECT: Nelumbo Nucifera Germ Extract Maximum Concentration of Use

Anonymous. 2025. Maximum Concentration of Use Nelumbo Nucifera Germ Extract.

A company reports use of Nelumbo Nucifera Germ Extract in leave-on face and neck products (serum) at a maximum use concentration of 0.001%.



Memorandum

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

FROM: Carol Eisenmann, Ph.D.
Personal Care Products Council

DATE: August 27, 2025

SUBJECT: Nelumbo Nucifera Germ Extract

Anonymous. 2025. Summary information Nelumbo Nucifera Germ Extract.

Nelumbo Nucifera Germ Extract

*We would like to provide you with some information regarding Nelumbo Nucifera Germ Extract

1. Method of manufacture, composition, impurities data for these ingredients as used in cosmetics

• **Method of manufacture**

Dried raw material ⇒ extract with ethanolic solution ⇒ concentration ⇒ add dextrin ⇒ drying ⇒ packaging

• **Composition**

Polyphenol

• **Impurities**

Heavy metals : not more than 20 ppm

Arsenic : not more than 2 ppm

2. Repeated dose oral toxicity studies

(Concentration of the germ extract : 25%)

Test Item	Dose	NOAEL	Method
28-day oral toxicity test	2500mg/kg/d	2500mg/kg/d	10 Rats (5 male and 5 female) in each group

3. Acute oral toxicity studies

(Concentration of the germ extract : 100%)

Test Item	Result	Method
Acute toxicity	LD ₅₀ > 5000mg/kg	10 Mice (5 male and 5 female) in each group

4. Genotoxicity studies

(Concentration of the germ extract : 100%)

Test Item	Concentration of test solution	Result	Method
Mutagenicity (Reverse mutation testing using microorganisms)	312.5, 625, 1250, 2500, 5000µg/0.1mL/plate	Negative	Salmonella typhimurium (TA98, TA100, TA1535, TA1537), Escherichia coli (WP2uvrA)

5. Ocular irritation data

We do not have any ocular irritation data.



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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Priya Ferguson, M.S., Senior Scientific Analyst/Writer, CIR
Date: August 28, 2025
Subject: Wave 2 – Amended Safety Assessment of Octoxynols Used in Cosmetics

Please find attached the comments provided by the Personal Care Products Council (Council) on the Draft Final Amended Report on the Safety Assessment of Octoxynols as Used in Cosmetics (*PCPCcomments_Octoxynols_Wave2_092025*). If the Panel is in agreement with the comments, these will be addressed following the September Panel meeting. Also included are a late received email from Women’s Voices for the Earth (WVE) regarding discussion on these ingredients from the March 2025 meeting (*WVEcomments1_Octoxynols_Wave2_092025*) and comments submitted for the September 2025 meeting on the Draft Final Amended Report (*WVE2comments2_Octoxynols_Wave2_092025*).

In WVE’s comments, it was noted that while the RLD does not report the use of Octoxynols in vaginal or baby products, some currently marketed formulations still list octoxynols as ingredients in products that could lead to such exposures. They suggested the Panel consider this information in the context of reported frequency and concentration of use, relevant toxicological endpoints for mucosal and infant exposures, and the potential for these products to represent a significant source of ongoing consumer exposure. They also recommended that the Panel’s conclusion specifically address whether the available data are sufficient to support a conclusion of safety for potential mucosal exposures, including vaginal use, or baby products.

Additionally, WVE identified an error in the 2004 CIR report concerning an in vitro study on the effects of Octoxynol-9 on sperm motility. Upon review of the original study by Furuse, Ishizeki, and Iwahara (1983), CIR staff confirmed that “the effective concentration of Octoxynol-9 for totally immobilizing all human spermatozoa within 20 seconds in vitro was 0.24 mg/ml.” This correction will be incorporated into the next iteration of the report.



Memorandum

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

FROM: Kimberly Norman, Ph.D., DABT, ERT
Industry Liaison to the CIR Expert Panel

DATE: August 25, 2025

SUBJECT: Draft Final Amended Report: Amended Safety Assessment of Octoxynols as Used in Cosmetics (draft prepared for the September 8-9, 2025, meeting)

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

Key Issues

The report (Use section, Table 3) should make it clear that the 2022 concentration of use survey (3 use concentrations reported) was completed using VCRP cosmetic product categories, while the 2025 concentration of use survey (2 use concentrations reported) was completed using MoCRA cosmetic product categories which included some categories, e.g., disposable wipes, that were not included in the VCRP cosmetic product categories. Because the categories are different, it is not appropriate to combine the surveys into the same column in Table 3.

Cosmetic Use – Although the Octoxynols are not specifically listed in in the EU cosmetic regulations, under ECHA they are considered “substances of very high concern” based on toxicity to aquatic life with long lasting effects. Therefore, in Europe use of these ingredients, including in cosmetics requires authorization.

Additional Considerations

Introduction – As this report is moving to a final report, the word “proposed” should be deleted from “as proposed read-across sources”.

Acute, Inhalation, old report summary – The inhalation exposure lung burden is given in units of $\mu\text{g/g}$ lung, while the units for lung burden following lavage exposure are stated as μg . For the LD_{50} values, the units are stated as $\mu\text{g/g}$ lung for inhalation exposure and $\mu\text{g/g}$? for lavage exposure. Please check the units. Should the values for lavage also be stated as $\mu\text{g/g}$ lung?

Exposure Assessment – Rather than noting the acute dermal toxicity study in guinea pigs for a lack of dermal absorption, it would be better to mention the in vitro study using human skin that

found a dermal penetration of about 0.5% for Nonoxynol-9.

Summary – Saying “Results from a 2022/2025 concentration of use survey conducted by the Council” suggests only one survey was conducted. It should state: “Results from concentration of use surveys (2022 VCRP product categories, 2025 MoCRA product categories) conducted by the Council”.

Discussion – Please delete “some of” in “because some of these ingredients are ethoxylated” as all the ingredients in this report are ethoxylated.

Table 3 – The current limited use of Octoxynol ingredients gets lost in this table with so many NR and blank cells. Is this the most appropriate table for publication? It is also confusing that the VCRP information and the 2022 concentration of use survey were done using the VCRP product categories while the RLD and 2025 concentration of use survey were done using MoCRA product categories. If the RLD data are not being summarized by likely duration and exposure, the 2025 survey data should not be summarized by likely duration and exposure.

From: [Alexandra Gorman Scranton](#)
To: [Bart Heldreth](#); subraw@cir-safety.org; [Courtney Griffin](#)
Subject: Request to clarify misunderstanding on Octoxynols
Date: Thursday, March 13, 2025 9:48:05 AM

Dear Drs. Heldreth and Bergfeld,

I have been listening in to the CIR discussions today on Octoxynols and want to bring a concern forward on what I believe is a misunderstanding of the data. I realize I am not given the opportunity to comment at the meeting – but I am hoping you can at least bring these points to the panel today and tomorrow– just as you occasionally allow manufacturer representatives to further explain their comments, where relevant, when they attend your meetings.

This morning several of the members of the panel in Dr. Cohen’s group stated that they saw no vaginal use of Octoxynols in cosmetics reported in the RLD data. I strongly disagree.

The safety assessment Use section states:

“RLD indicate that mucous membrane exposure to Octoxynol-9 may occur, as it is used in bath soaps and body washes and disposable wipes (concentrations not stated).”

The categories of body washes and disposable wipes include products such as **feminine/vaginal washes** and **feminine wipes**. Both of which would clearly have vaginal/vulvar mucous membrane exposure.

I hope it can be made clear to the panel that vaginal exposure to Octoxynols from present practices and use of cosmetics cannot be ruled out by the RLD data. Given the potential harm from vaginal exposure that I described in my submitted comments, the safety of Octoxynols used in vaginal products should be specifically included in the discussion and conclusion.

I think it would be more effective and efficient for the panel to clarify this misunderstanding now, rather than waiting for comments submitted to the next version of the report.

Thanks very much for your consideration of these comments.

Alexandra Scranton

(Pronouns: She/Her)

Director of Science and Research

Women's Voices for the Earth

www.womensvoices.org

Direct – 720-667-8778



August 27, 2025

Re: Comments on the Amended Safety Assessment of Octoxynols as Used in Cosmetics

To the CIR:

The following comments are submitted on behalf of Women's Voices for the Earth.

- **Octoxynols are still present in vaginally applied products and baby products, despite not being represented in the RLD. The discussion should reflect this fact, and the conclusion should address the CIR's safety concerns with Octoxynols in these product categories.**
- **Data on the spermicidal potency of Octoxynols is relevant and should still be included in the current draft of the safety assessment of the report. (Including this data will also serve to correct the numerical mistake made in the 2004 CIR Report.)**

1) Octoxynols are still present in vaginally applied products and baby products, despite not being represented in the RLD. The discussion should reflect this fact, and the conclusion should address the CIR's safety concerns with Octoxynols in these product categories.

Unfortunately, there are at least two vaginally applied products currently on the market which still contain Octoxynols: CareOne douche and Saforelle intimate cleansing wash.

- CareOne Fresh Scent Douche

This product is a "generic" brand most commonly sold in dollar stores. It is basically a cheaper copy of Summer's Eve douche (which we recently learned no longer contains Octoxynol-9). The front package of CareOne douche even states "Compare to Summer's Eve" as a marketing ploy. The ingredients of this product, however, imitate the old Summer's Eve formulation, and still contains Octoxynol-9. It is of particular concern that low-income women shopping at dollar stores will be exposed to this product.

CareOne Fresh Scent Douche

<https://1source.com/products/careone-feminine-douche-fresh-scent>

Purified Water, **Octoxynol-9**, Citric Acid, Sodium Benzoate, Disodium EDTA, Fragrance.

CareOne Fresh Scent Douche (SmartLabel ingredient disclosure)

<https://smartlabel.peapod.com/upc/41520022295#ingredients>

Purified Water, Sodium Benzoate, Disodium EDTA, Citric Acid, **Octoxynol-9**, Fragrance.



Commented [DE1]: Be sure to format so picture doesn't cover words or break paragraph

- Saforelle Intimate wash – Gentle Cleansing Care

Saforelle is an intimate wash marketed as “*ideal for daily use in the event of irritation, protecting the natural balance of the intimate area.*”

<https://en.saforelle.com/gentle-cleansing-care-v7696.html>

Ingredients : Aqua, Cocamidopropyl betaine, Cocamide dea, Sodium chloride, Peg-6 caprylic/capric glycerides, Parfum, Citronellol, Coumarin, Geraniol, Limonene, Linalool, Propylene glycol, Stearamine oxide, **Octoxynol-12**, Lavandula angustifolia oil, Tetrasodium edta, Polysorbate 20, Sodium hydroxide, Arctium lappa root extract, Dimethyl stearamine.

There is at least one baby product on the market which contains Octoxynol-9. (This may be the product reflected in the VCRP data?)

- PMB – para mi bebé: Baby Moisturizing Body Wash

<http://www.pmb-paramibebe.com/en/products/pmb-para-mi-bebe-baby-moisturizing-body-wash/>

<https://www.amazon.com/P-M-B-Jabon-Liquido-Infantil-Moisuturizing/dp/B006QX924K>

Ingredients : Aqua (Water), Sodium Laureth Sulfate, Cocamidopropyl Betaine, Disodium Cocoamphodiacetate, Peg-4 Rapeseed Amide, Peg-7 Glyceryl Cocoate, Peg-75 Lanolin, Poliquaternium-7, Parfum (Fragrance), Citronellol, Coumarin, Geraniol, Hydroxycitronellal, Limonene, Linalool, Sodium Chloride, Citric Acid, Benzyl Alcohol, Dmdm Hydantoin, Tetrasodium Edta, Styrene-Acrylate Copolymer (And) Sodium Lauryl Sulfate (and) **Octoxynol-9**, Sodium Laureth Sulfate (and) Cocamide Mea (and) Glycol Stearate.

Given this information on Octoxynol-containing products currently on the market, the following sentence in the discussion,

“However, it should be noted that these ingredients are no longer reported to be used in categories/products of concern (baby products and vaginal douches) according to 2024 RLD.”

should be amended to indicate that additional information indicating that octoxynols are still used in these categories/products of concern has been provided to the CIR panel.

As there are products of concern containing Octoxynols – and given that the CIR reopened this ingredient due to concerns about vaginal irritation and vaginal cytotoxicity from octoxynol exposure and inclusion in baby products, **the discussion and conclusion should both discuss those concerns and include a statement on whether the CIR believes octoxynols are safe as used in vaginally applied products and baby products.**

Commented [DE2]: to that end, should we provide citations indicating we believe their conclusion should be that they are NOT safe?

- 2) Data on the spermicidal potency of Octoxynols is relevant and should still be included in the current draft of the safety assessment of the report. (Including this data will also serve to correct the numerical mistake made in the 2004 CIR Report.)

I submitted comments for the March meeting suggesting that data on the spermicidal potency of Octoxynols be included in the current draft (as it had in the previous 2004 CIR safety assessment). This is still relevant, as spermicidal potency could be an adverse effect for someone intending to get pregnant who uses a vaginally-applied product containing Octoxynol-9, as these products are commonly used immediately before or after sexual activity. There seems to have been some confusion with CIR staff, as their response to my original comments claimed that the spermicidal potency data pertained only to Nonoxynols (not Octoxynols). This is incorrect.

The 2004 CIR report included spermicidal potency data for both nonoxynols **and** octoxynols. Found on Page 119 of the current Octoxynols .pdf, the 2004 CIR assessment states:

"In Vitro Studies

Octoxynol-9

Furuse, Ishizeki, and Iwahara (1983) reported that the effective concentration of Octoxynol-9 for totally immobilizing all spermatozoa (human) within 20 s in vitro was 0.12 mg/ml."...

"Nonoxynols

Furuse, Ishizeki, and Iwahara (1983) reported that the effective concentration of Nonoxynol-9 for totally immobilizing all spermatozoa (human) within 20 s in vitro was 0.24 mg/ml."

These numbers, however, were misquoted from the original paper. In my original comments, I referred to the data from the original Furuse (1983) paper which states that the effective spermicidal concentration for Octoxynol-9 was reported as 0.24 mg/dl (not 0.12 mg/dl as stated in the 2004 CIR report) and the effective spermicidal concentration for Nonoxynol-9 was reported as 0.12 mg/dl (not 0.24mg/dl). Specifically, the quote from Furuse (1983) says:

"...the effective concentrations for menfegol (TS-88), nonoxynol-9 and octoxynol-9** for total immobilizing all spermatozoa within 20 s were 0.38 mg/ml, 0.12 mg/ml and 0.24 mg/ml respectively." (p.363-4)*

This corrected information should be included in the current draft safety assessment of Octoxynols, and its relevance discussed by the CIR Expert Panel. I am happy to share a copy of the original Furuse (1983) paper if that would be helpful.

Thank you for your consideration of these comments.



Alexandra Scranton
Director of Science and Research
Women's Voices for the Earth

Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Jinqiu Zhu, Ph.D., DABT, ERT, DCST, CIR Toxicologist
Temima Nguyen, M.S., Scientific Analyst/Writer, CIR
Date: August 28, 2025
Subject: Wave 2 – WVE’s comments on the Amended Safety Assessment of Sodium Borate and Boric Acid as Used in Cosmetics

Attached are comments on the Draft Amended Report on the Safety Assessment of Sodium Borate and Boric Acid as Used in Cosmetics, submitted by Women’s Voices for the Earth (WVE) (identified as *WVEcomments_Sodium_Borate_Wave2_092025* in the pdf). These comments were originally submitted on May 30, 2024, for consideration of the Re-Review of these ingredients at the June 2024 meeting but were received after the deadline. While the request to reopen the safety assessment is no longer applicable, the comments were resubmitted on August 27, 2025, for the Panel’s review.

In their comments, WVE referenced a case-control study (Ács et al., 2006) and a review paper (Mittelstaedt et al., 2021), that addressed the therapeutic use of intravaginal Boric Acid for treatingazole-resistant vulvovaginal candidiasis (VVC) or recurrent bacterial vaginosis (BV). The study by Ács et al. (2006) reported a 2.8-fold increased risk of congenital anomalies among children of women who received intravaginal boric acid treatment during pregnancy. In contrast, the review by Mittelstaedt et al. (2021) concluded that available evidence suggests low systemic absorption of Boric Acid with 600 mg suppositories, and further indicated *available data suggest intravaginal Boric Acid use is safe, at least when used in doses commonly described in the literature as being prescribed by clinicians.*

It should be noted that two of the individual studies cited in the review paper by Mittelstaedt et al. (2021) (i.e., Duydu et al. (2018) and Hjelm et al. (2019, cited as Harari by WVE)) have already been incorporated into the draft amended report. In addition, the following original studies were also included in either the previous 1983 CIR report or the 2006 re-review summary on Sodium Borate and Boric Acid: Linden et al. (1986); Ishii et al. (1993); Price (1997); Heindel et al. (1994); Swate and Weed (1974, cited as Swate by WVE); Van Slyke et al. (1981); and Weir et al. (1972).

WVE also identified several feminine foam wash and cleanser products currently on the market that contain Boric Acid, and expressed concern their use may adversely impact reproductive health – particularly if applied to damaged skin or if used during pregnancy. WVE’s comments cite Ács et al. (2006) as evidence of potential teratogenicity following intravaginal Boric Acid exposure. However, it is critical to recognize that this study evaluated therapeutic drug use rather than cosmetic exposures: *“in most cases, treatment consisted of two vaginal tablets of 30 mg each daily for 7 days.”* This represents a short-term prescription drug therapy context, designed to treat vulvovaginal candidiasis, and is not comparable to the far lower, intermittent exposures expected from cosmetic use. According to the 2025 Council survey, reported concentrations of use for cosmetics were limited to rinse-off products. The maximum reported concentration was 0.00016% Boric Acid in shampoos and body/hand wash products, all of which are rinse-off formulations, resulting in substantially lower systemic exposure. Unlike a retained vaginal tablet or suppository, cosmetic use does not provide prolonged mucosal contact or sustained release. Nevertheless, RLD indicate that Boric Acid has also been used in several categories of personal cleanliness/intimate care products, such as douches, feminine deodorants (both leave-on and rinse-off), and disposable wipes. In light of these reported uses, the relevance of new studies on the reproductive and developmental toxicity of Boric Acid warrant careful consideration when assessing safety for potential feminine care applications.

References:

- Ács, N., Bánhidly, F., Puhó, E., & Czeizel, A. E. Teratogenic effects of vaginal boric acid treatment during pregnancy. *International Journal of Gynecology & Obstetrics*, 2006; 93(1), 55–56.
- Duydu Y, Başaran N, Üstündağ A, et al. Birth weights of newborns and pregnancy outcomes of environmentally boron-exposed females in Turkey. *Archives of Toxicology*. 2018;92(8):2475–2485.
- Heindel, J J , C J Price, and BA Schwetz. Developmental Toxicity of Boric Acid in Mice, Rats, and Rabbits. *Environ Health Persp*. 1994;102(suppl 7):107-112
- Hjelm C, Harari F, Vahter M. Pre- and postnatal environmental boron exposure and infant growth: Results from a mother-child cohort in northern Argentina. *Environmental Research*. 2019;171:60–68.
- Ishii, Y, N Fujizuka, T. Takahashi, K. Shimizu, A Tuchida, S Yano, T. Naruse, and T Chishiro. A fatal case of acute boric acid poisoning. *J. Toxicol Clin. Toxicol*. 1993;31 345-352
- Linden, CH, AH. Hall, KW Kulig, and B H Rumack. Acute ingestions of boric acid. *J. Toxicol Clin. Toxicol*. 1986;24 269-280.
- Mittelstaedt R, Kretz A, Levine M, Handa VL, Ghanem KG, Sobel JD, Powell A, Tuddenham S. Data on Safety of Intravaginal Boric Acid Use in Pregnant and Nonpregnant Women: A Narrative Review. *Sex Transm Dis*. 2021 Dec1;48(12):e241-e247.
- Personal Care Products Council. 2025. Concentration of Use by FDA Product Category: Sodium Borate and Boric Acid. [Unpublished data submitted by the Personal Care Products Council on March 31st, 2025].
- Price, CJ, PL Strong, F.J Murray, and MM Goldberg. Blood boron concentrations in pregnant rats fed boric acid throughout gestation. *Reprod Toxicol*. 1997;11 833-842.
- Swate, T.E and Weed, J.C. Boric acid treatment of vulvovaginal candidiasis. *Obstet. Gynecol*. 1974;43(6), 893-5.
- Van Slyke, K.K., Michel, V.P., and Rein, M.F. Treatment of vulvovaginal candidiasis with boric acid powder. *Am J. Obstet. Gynecol*. 1981;141, 145-8.
- Weir, Jr., R.J. and Fisher, R.S. Toxicological studies on borax and boric acid. *Toxicol. Appl. Pharmacol*. 1972;23, 351-64.

May 30, 2024

To the CIR:

I am writing on behalf of Women's Voices for the Earth to offer comments on the Re-Review of the Safety Assessment of Boric Acid and Sodium Borate as Used in Cosmetics.

We strongly encourage the CIR Expert Panel to re-open these ingredients for review.

Our comments include the following points:

1. Significant new research on potential health impacts of boric acid and sodium borate is available and should be included in a re-review of the ingredient.
2. Reproductive and developmental toxicity data specifically has led to the EU classification of boric acid and sodium borate as reproductive toxicants. This is the reason for the ban in the European Union on the use of boric acid and sodium borate in cosmetics.
3. Specifically, exposure to vaginally-applied boric acid during pregnancy has been linked to significantly increased birth defects.
4. Several new vaginally-applied intimate washes containing boric acid have come on the market in the United States. These products do not contain any label warnings against use during pregnancy.

Significant new research on potential health impacts of boric acid and sodium borate is available and should be included in a re-review of the ingredient.

The draft re-review document prepared for the CIR's June 3rd meeting includes numerous new studies on potential health impacts of boric acid and sodium borate that have not been previously considered. The extent of this new data clearly merits re-opening these ingredients for review.

Reproductive and developmental toxicity data specifically has led to the EU classification of boric acid and sodium borate as reproductive toxicants. This is the reason for the ban in the European Union on the use of boric acid and sodium borate in cosmetics.

The ban on the use of boric acid and sodium borate in cosmetics in the EU is another compelling reason to re-open the review of this ingredient. The current CIR Safety Assessment of these ingredients from 1983 concludes these ingredients are safe as used at concentrations of 5% or less with restrictions on use on infant or injured skin. This discrepancy of opinion on the safety of these cosmetic ingredients between the CIR and the EU deserves to be formally addressed. The new reproductive and developmental toxicity data should be incorporated into a re-review and discussed by the CIR Expert Panel.

Exposure to vaginally-applied boric acid during pregnancy has been linked to significantly increased birth defects.

There are two papers specifically addressing intravaginal boric acid use not yet included in the Re-Review of the Safety Assessment, which are pertinent to the re-review

Two Relevant Boric Acid studies to include in Safety Assessment

Ács, N., Bánhidly, F., Puhó, E., & Czeizel, A. E. (2006). *Teratogenic effects of vaginal boric acid treatment during pregnancy. International Journal of Gynecology & Obstetrics, 93(1), 55–56.* doi:10.1016/j.ijgo.2005.12.031

This study found a 2.8 fold increase in congenital anomalies in children of women who received vaginal boric acid treatment during pregnancy.

Mittelstaedt R, Kretz A, Levine M, Handa VL, Ghanem KG, Sobel JD, Powell A, Tuddenham S. Data on Safety of Intravaginal Boric Acid Use in Pregnant and Nonpregnant Women: A Narrative Review. *Sex Transm Dis.* 2021 Dec 1;48(12):e241-e247. doi: 10.1097/OLQ.0000000000001562.

This article summarizes additional research on the potential for birth defects from intravaginal boric acid and confirms the existing gynecological recommendations that intravaginal boric acid exposure is not safe during pregnancy.

Several new vaginally-applied intimate washes containing boric acid have come on the market in the United States. These products do not contain any label warnings against use during pregnancy or against use on injured or broken skin.

While the overall numbers of products containing boric acid and sodium borate may have decreased in recent years (at least, according to VCRP data), there are new products coming on the market which are of concern. It is likely these products are not included in the VCRP data, but they are pertinent to the discussion of the safety of these ingredients. (The VCRP provides data on only **eight** cosmetic products total which contain boric acid in 2023, including powders, sprays and eye makeup in addition to personal cleanliness products but I was easily able to identify **ten** currently available boric acid intimate washes.)

There are a number of new vaginally applied cosmetics such as intimate washes which contain boric acid. For example, Summer's Eve, the #1 intimate wash manufacturer in the U.S. has recently launched a new product called Ultimate Odor Protection which prominently features the inclusion of boric acid. These products will naturally involve vaginal exposure to boric acid from regular use. Also, intimate washes are highly likely to come into contact with injured or broken skin. Intimate washes are commonly used by women during and after menstruation, before and after sex, and are used to "self-treat" vaginal symptoms of itchiness, redness or

rash. Many of these situations when intimate wash is used are likely to be associated with injured or broken vaginal and vulvar skin. The new boric acid-containing intimate washes however do not include any warning language about use during pregnancy, or about use on broken or injured skin.

Photos of products:



<https://www.summerseve.com/>

Back label of Summer's Eve with directions (and lack of warning language):





<https://www.phdfemininehealth.com/collections/boric-acid-foam-washes>



<https://yonipeachcare.com/products/boric-fresh%E2%84%A2-ph-balancing-daily-feminine-wash>



<https://www.monistat.com/maintain-boric-acid/feminine-cleanser>



<https://www.amazon.com/Her-Fantasy-Box-Sensitive-Feminine/dp/BOCSKT4XK5>



<https://www.walmart.com/ip/NutraBlast-So-Fresh-Clean-pH-Balance-Feminine-Wash-with-Boric-Acid-10-fl-oz/1405947783>



<https://poisedorganics.com/products/my-fresh-nani-yni-wash-with-boric-acid>



<https://preciousyouskincare.net/products/gentle-boric-acid-feminine-wash>



<https://selfcarefriday.com/products/boric-shower-gel?>



<https://kyemkollections.com/products/yni-phresh>



These products may well be used during pregnancy and on injured skin, with the potential to adversely affect reproductive health. Given this new trend in marketing intimate care washes with boric acid and the new studies on reproductive and developmental toxicity of boric acid, the CIR Safety Assessment should address the potential health implications of this kind of cosmetic exposure.

Given this pertinent new information, Women's Voices for the Earth strongly recommends that the CIR re-open the Safety Assessment of Boric Acid and Sodium Borate for review.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read 'Alexandra Scranton', is displayed on a light gray background.

Alexandra Scranton
Director of Science and Research