Post Meeting Announcement

Expert Panel for Cosmetic Ingredient Safety
177th Meeting (October 5 - 6, 2026) - Findings

October 9, 2026

● Final Safety Assessment

- **2-Bromo-2-Nitropropane-1,3-Diol – 1 ingredient – Safe when formulated to be non-sensitizing**
- **Alkyl Gallates – 4 ingredients – Safe when formulated to be non-irritating/non-sensitizing**
- **Pyrogallol - 1 ingredient – Insufficient data**
- **Polyacrylate-13 – 1 ingredient – Safe**

● Tentative Safety Assessments

- **Kojic Acid – 1 ingredient – Split conclusion (insufficient data for anogenital wipes, douches, and baby products; safe for other uses)**
- **Phthalates – 3 ingredients - Split conclusion (insufficient data for 2 ingredients; safe for 1)**
- **Oxyquinoline & Oxyquinoline Sulfate - 2 ingredients – Split conclusion (1 ingredient safe as used as a hydrogen peroxide stabilizer; both ingredients insufficient data for all other uses)**
- **Phosphine Oxides – 3 ingredients – Safe as used in nail products; insufficient data for non-nail uses**
- **Ethyl Tafluprostamide & Isopropyl Cloprostenate – 2 ingredients - Insufficient data**
- **Willow-derived ingredients – 6 ingredients - Split conclusion (1 ingredient safe in non-baby products; insufficient data for baby product uses of that ingredient and all uses of the other 5 ingredients)**

● Insufficient Data Announcements

- **Sigesbeckia Orientalis Extract – 1 ingredient**
- **Sodium Hyaluronate Crosspolymers – 6 ingredients**
- **Sodium Hydrosulfite - 1 ingredient**
- **Tosylamide/Formaldehyde Resin & Tosylamide/Epoxy Resin - 2 ingredients**

● 177th Meeting Notes

- **Director's Report**
- **Read-Across Best Practices**
- **Propolis**
- **Scientific Literature Reviews – available or under development**
- **Next Expert Panel Meeting – Monday and Tuesday, December 7 - 8, 2026 – *in-person* – The Darcy Hotel, 1515 Rhode Island Avenue, NW, Washington, DC 20005**
    - ***All submissions for this meeting should be received by CIR no later than October 30th, 2026***

Final Safety Assessment

Final safety assessments will be posted on the Cosmetic Ingredient Review (CIR) website at www.cir-safety.org. Unpublished data cited as references in CIR safety assessments are available for review. Any interested person who has sound scientific evidence that a final safety assessment is incorrect may petition the Expert Panel for Cosmetic Ingredient Safety (Panel) to amend the safety assessment.

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

The Panel reviewed the available data and issued a Final Amended Report. The Panel concluded that 2-Bromo-2-Nitropropane-1,3-Diol is safe in cosmetics when formulated to be non-sensitizing, which may be based on a quantitative risk assessment (QRA) or other appropriate methodology.

The concern for possible sensitization is due to the results of a North American Contact Dermatitis Group (NACDG) retrospective cross-sectional study to determine the prevalence of wet wipes as a source of allergy during patch testing. 2-Bromo-2-Nitropropane-1,3-Diol is reported to be used at a maximum concentration of 0.05% in disposable wipes.

The Panel also noted that 2-Bromo-2-Nitropropane-1,3-Diol should not be used in cosmetic products in which *N* nitroso compounds can be formed; it was also noted that antioxidant use in formulations may reduce potential *N*-nitrosating activity in situ. Furthermore, the Panel acknowledged that although the conclusion of the 1984 addendum stated that on absorption, it was possible 2-Bromo-2-Nitropropane-1,3-Diol may contribute to the endogenous formation of *N*-nitrosamines in humans, due to further review and the lack of any supporting information, the Panel stated that it is highly unlikely that such endogenous formation would occur.

2-Bromo-2-Nitropropane-1,3-Diol may release a minimal amount of formaldehyde upon hydrolysis due to its long half-life. However, concern for this issue was mitigated by the fact that this ingredient is reported to be used at concentrations up to 0.05%, which is less than the 0.074% formaldehyde limit established by the Panel in its final safety assessment of formaldehyde.

Alkyl Gallates

The Panel issued a Final Amended Report on 4 alkyl gallates (Caprylyl Gallate, Dodecyl Gallate, Ethylhexyl Gallate, and Propyl Gallate) and with the conclusion that these ingredients are safe as used when formulated to be non-irritating and non-sensitizing. According to 2025 FDA RLD data and the results of the 2024 Council concentration of use survey, Propyl Gallate is reported to be used in 1127 formulations at concentrations up to 0.1%. All other ingredients are reported to be used in 21 formulations or fewer.

Pyrogallol

The Panel issued a Final Amended Report with the conclusion that the available data are insufficient to make a determination of safety for Pyrogallol as used in hair dyes. The additional data needed to determine the safety of this ingredient are maximum concentration of use in hair dye formulations and genotoxicity studies, with metabolic activation, that test for the formation of DNA adducts.

Pyrogallol has been reported to be used in false eyelashes, eyelash and eyebrow adhesives, and nail polish and enamels. However, this ingredient is exempt from certain adulteration and color additive provisions of the FD&C Act only when used as a coal tar hair dye ingredient. Accordingly, because Pyrogallol is not an approved color additive in cosmetic products, use in eye makeup products and manicuring preparations is not permitted in the US. Thus, determination of safety for Pyrogallol outside of use for hair dyes is not within the purview of the Panel. Furthermore, the Panel noted that the RLD reported uses in eyelash and eyebrow dyes, and reiterated that hair dyes, such as those containing Pyrogallol, should not be applied to the eyebrows and eyelashes in that such use can result in lost or permanently damaged vision.

The Panel noted the carcinogenic activity observed in mice in both the National Toxicology Program (NTP) study and a co-carcinogenicity study, as well as the positive findings in Ames tests and other in vitro genotoxicity studies conducted with and without metabolic activation. Although tumor formation at the site of dermal application was likely driven primarily by chronic irritation and subsequent inflammatory and regenerative processes given the absence of systemic carcinogenic effects, the confinement of tumors to the site of application, and the increased incidence of non-neoplastic inflammatory and proliferative skin lesions, the possibility of a genotoxic mode of action could not be excluded. The in vivo genotoxicity results (e.g., micronucleus assay) were negative; however, without additional data demonstrating whether Pyrogallol can or cannot react with DNA (e.g., through in vitro evaluation of DNA adduct formation), concerns regarding the mode of action underlying the carcinogenic findings could not be fully alleviated.

Polyacrylate-13

The Panel reviewed the available data and issued a Final Report with the conclusion that Polyacrylate-13 is safe in cosmetics in the present practices of use and concentration described in this safety assessment. According to 2025 RLD, Polyacrylate-13 is reported to be used in 1807 total formulations. Based on a 2025 concentration of use survey conducted by the Council, this ingredient is used at concentrations up to 3.4% in leave on face and neck products (not spray). The Panel discussed that Polyacrylate-13 is used in baby products, where concentration of use regarding this category is not reported. Given the high molecular weight of Polyacrylate-13, absorption is likely to be minimal, and the concern over the absence of a reported maximum concentration of use for this category is mitigated.

Tentative Safety Assessments

For the tentative safety assessments listed below, to be posted on the CIR website in the near future, interested persons are given 60 days from the posting date to comment, provide information, and/or request an oral hearing before the Panel. Information may be submitted without identifying the source or the trade name of the cosmetic product containing the ingredient. All unpublished data submitted to CIR will be discussed in open meetings and are available for review by any interested party. Please submit data and/or comments to CIR ***as soon as possible, but no later than 60 days from the actual posting date of the report, for full consideration. Submissions received thereafter may be in jeopardy of not being considered by the Panel at the next review.*** *The updated reports may be scheduled for review by the Panel as early as the* ***March 8 - 9, 2027 meeting.***

Kojic Acid

The Panel issued a Tentative Amended Report for public comment with the conclusion that the available data are insufficient to make a determination of safety for use of Kojic Acid in anogenital wipes, douches, and baby products. The Panel also found that Kojic Acid is safe in cosmetics in the other present practices of use and concentration described in this safety assessment. The additional data needed to determine the safety of this ingredient for use in anogenital wipes, douches, and baby products are maximum concentration of use for products with anogenital applications (i.e., wipes and douches) and maximum concentration of use for baby products.

The Panel noted that uses were reported in anogenital applications and in baby products. The Panel was concerned for the potential for irritation and sensitization and increased absorption in baby skin and mucosal skin that may be occluded. Concentrations of use are needed to determine the margin of exposure (MOE) for these types of use. Concentrations reported for analogous adult products should not be assumed to represent concentrations in baby products without supporting information.

The Panel also noted that liver, thyroid, and adrenal tumors were observed in rodent studies. However, these effects are considered not relevant to human cancer risk due to well-characterized species differences in mode of action. Liver tumors are associated with CAR-mediated enzyme induction, which is a rodent-specific mechanism not operative in humans. Thyroid effects are linked to disruption of hormone homeostasis, to which rodents are particularly sensitive due to differences in thyroid hormone metabolism and regulation. Adrenal tumors observed in rats also involve mechanisms not predictive of human risk. Given these species-specific responses, the Panel stated that the observed tumorigenic effects do not indicate a significant carcinogenic risk to humans under cosmetic use conditions.

Data included in this report indicate that Kojic Acid may have a skin lightening effect. The Panel noted that skin lightening is considered a drug effect in the US and should not occur during the use of cosmetic products. Because of that caveat, as well as the Panel's knowledge of the mechanism of action (i.e., inhibition of tyrosinase activity) and clinical experience, concern for this effect in cosmetics was mitigated. Nevertheless, cosmetic formulators should only use this ingredient in products in a manner that does not cause depigmentation.

Phthalates

The Panel issued a Tentative Amended Report for public comment with the conclusion that Diethyl Phthalate is safe in cosmetics in the present practices of use and concentration described in the safety assessment. However, the Panel also concluded that the data are insufficient to make a determination of safety for Dibutyl Phthalate and Dimethyl Phthalate under the reported conditions of use as cosmetic ingredients. In order to come to a conclusion of safety for these ingredients, the Panel requires maximum concentration of use for both ingredients.

The Panel considered the voluminous data concerning phthalates and endocrine and developmental effects. Significant adverse effects in male reproductive toxicity studies have been observed in phthalates with a carbon chain length of 4 or greater. Based on the MOE, the Panel found that Diethyl Phthalate, with high no-observed-adverse-effect levels (NOAELs) for reproductive endocrine effects, greatly exceeded the safety threshold of 100. Even if absorption was 100%, the MOE would still exceed the safety threshold. While it appears that Dibutyl Phthalate, with a carbon chain length of 4, is linked to many adverse endocrine and developmental effects, the Panel cannot assess the risk from cosmetic exposure without a concentration of use. While Dimethyl Phthalate has a smaller carbon chain length and likely does not pose a significant risk (like Diethyl Phthalate, it has extremely high NOAELs), an MOE calculation cannot be performed without a concentration of use.

Oxyquinoline & Oxyquinoline Sulfate

The Panel issued a Tentative Amended Report for public comment on Oxyquinoline and Oxyquinoline Sulfate with a split conclusion. Oxyquinoline Sulfate was considered safe as a hydrogen peroxide stabilizer in hair products in the present practices of use and concentration described in the safety assessment. The available data are insufficient to make a determination of safety of Oxyquinoline Sulfate for all other uses and of Oxyquinoline for all reported conditions of use in cosmetic formulations.

For Oxyquinoline, the data needs include maximum concentrations of use, ocular irritation data at the maximum concentration of use, phototoxicity/photosensitization data, developmental and reproductive toxicity (DART) data (including an NOAEL suitable for calculation of an MOE), and dermal absorption data. For Oxyquinoline Sulfate in uses other than as a hydrogen peroxide stabilizer, the data needs include maximum concentrations of use, ocular irritation data at the maximum concentration of use, and phototoxicity/photosensitization data. The Panel noted that phototoxicity/photosensitization data for Oxyquinoline Sulfate, including when used as a hydrogen peroxide stabilizer, had previously been requested; however, this data need was mitigated for hydrogen peroxide stabilizer use because the ingredient is expected to be rapidly consumed in this function.

Phosphine Oxides

The Panel issued a Tentative Amended Report for public comment on Bis-Trimethylbenzoyl Phenylphosphine Oxide, Ethyl Trimethylbenzoyl Phenylphosphinate, and Trimethylbenzoyl Diphenylphosphine Oxide with a split conclusion. These ingredients are safe in nail products in the present practices of use and concentration described in this safety assessment, but the available data are insufficient to make a determination of safety for under the reported conditions of use for all other product types. For non-nail uses of all 3 ingredients, the Panel requested sensitization data at the maximum concentrations of use, phototoxicity/photosensitization data, and concentrations of use. In addition, method of manufacturing data are needed for Bis-Trimethylbenzoyl Phenylphosphine Oxide and Ethyl Trimethylbenzoyl Phenylphosphinate, and dermal irritation data at the maximum concentration of use are needed for Trimethylbenzoyl Diphenylphosphine Oxide.

Ethyl Tafluprostamide & Isopropyl Cloprostenate

The Panel issued a Tentative Report for public comment on Ethyl Tafluprostamide and Isopropyl Cloprostenate with the conclusion that the available data are insufficient to make a determination of safety under the reported conditions of use in cosmetic formulations. The Panel accepted in whole the recommendations of the Read Across Working Group (RAWG) that the previously proposed read-across molecules, the same as those considered by the SCCS (tafluprost and travoprost), are not appropriate read-across sources for the two target ingredients in this report. Accordingly, because the risk calculations presented in the report relied on points of departure (PODs) derived from these read-across sources, these calculations could not be used to support the safety assessment of the cosmetic uses of Ethyl Tafluprostamide and Isopropyl Cloprostenate. With the exclusion of these read-across sources, the available toxicity data on the target ingredients are insufficient, and additional data are needed to determine the safety of these ingredients. For Ethyl Tafluprostamide, the data needs include repeated dose toxicity, DART, and unequivocal genotoxicity data. For Isopropyl Cloprostenate, the data needs include acute toxicity, repeated dose toxicity, DART, unequivocal genotoxicity, data on local ocular effects (including intraocular pressure, iris color change, and periorbital fat loss) at the current maximum concentration of use (0.0075%), data regarding targets and mechanisms of action, and information regarding potential receptors, potency, and Ki values.

Salix alba (Willow)-derived ingredients

The Panel issued a Tentative Report for public comment on 6 *Salix alba* (willow)-derived ingredients and issued a split conclusion. Salix Alba (Willow) Bark Extract is safe in the present practices of use and concentration described in the safety assessment in non-baby products; however, the data are insufficient to determine the safety of this ingredient in baby products. The available data are also insufficient to make a determination of safety for Salix Alba (Willow) Bark Powder, Salix Alba (Willow) Bark Water, Salix Alba (Willow) Extract, Salix Alba (Willow) Flower Extract, and Salix Alba (Willow) Leaf Extract under the reported conditions of use in cosmetic formulations.

For Salix Alba (Willow) Bark Extract as used in baby products, the maximum concentration of use in these products is needed. For Salix Alba (Willow) Leaf Extract, dermal absorption data are needed and, if the ingredient is absorbed, DART data are also needed. For Salix Alba (Willow) Bark Powder, Salix Alba (Willow) Bark Water, Salix Alba (Willow) Extract, and Salix Alba (Willow) Flower Extract, the data needs include method of manufacturing, composition and impurities, dermal absorption (and if absorbed, DART and genotoxicity data may be needed), and dermal irritation and sensitization, and ocular irritation data a maximum use concentrations.

The Panel noted the previous request for photoallergenicity data for this ingredient group. This data need was mitigated based on the high salicylate content of these ingredients and data presented in the 2025 CIR safety assessment of salicylate ingredients, indicating that salicylates are neither phototoxic nor photoallergenic.

Insufficient Data Announcements

For these Insufficient Data Announcements (IDAs), interested persons are given an opportunity to comment, provide information, and/or request an oral hearing before the Panel. Information may be submitted without identifying the source or the trade name of the cosmetic product containing the ingredient. All unpublished data submitted to CIR will be discussed in open meetings and are available for review by any interested party. Please submit data and/or comments to CIR ***as soon as possible, but no later than December 8th, 2026, for full consideration****.* ***Submissions received thereafter might not be considered by the Panel at their next meeting.*** *These reports may be scheduled for review by the Panel as soon as the* ***March 8 - 9, 2027 meeting****.*

Sigesbeckia Orientalis Extract

The Panel reviewed the Draft Report on Sigesbeckia Orientalis Extract and issued an IDA. The additional data needed to determine the safety of this ingredient are:

- Methods of manufacturing and impurities data
- Absorption data
    - If absorbed, DART data may be needed
- Genotoxicity data
- Dermal irritation and sensitization data at maximum concentration of use
- Ocular irritation data at maximum concentration of use

Sodium Hyaluronate Crosspolymers

The Panel reviewed the Draft Report on Sodium Hyaluronate Crosspolymer, Sodium Hyaluronate Crosspolymer-2, Sodium Hyaluronate Crosspolymer-3, Sodium Hyaluronate Crosspolymer-4, Sodium Hyaluronate Crosspolymer-6, Sodium Hyaluronate Crosspolymer-7, and issued an IDA for all 6 ingredients. The following data are necessary to determine the safety:

- Methods of manufacture for all ingredients
- Impurities data, including residual monomer, for all ingredients
- Ocular irritation studies for all that may be used in formulations applied near the eye
- A POD for risk assessment of Sodium Hyaluronate Crosspolymer-6
- Maximum concentration of use for all that are used in baby products
- Maximum concentrations of use for Sodium Hyaluronate Crosspolymer-2, Sodium Hyaluronate Crosspolymer-3, Sodium Hyaluronate Crosspolymer-4, Sodium Hyaluronate Crosspolymer-6, and Sodium Hyaluronate Crosspolymer-7

Sodium Hydrosulfite

The Panel reviewed the Draft Report on Sodium Hydrosulfite and issued an IDA. The additional data needed to determine the safety of this ingredient are:

- Concentration of use data
- Dermal irritation and sensitization data at maximum concentration of use
- Ocular irritation data at maximum concentration of use

Tosylamide/Formaldehyde Resin & Tosylamide/Epoxy Resin

The Panel reviewed the Draft Amended Report on Tosylamide/Formaldehyde Resin and Tosylamide/Epoxy Resin and issued an IDA for these 2 ingredients. The following data are necessary to determine the safety of these ingredients:

Tosylamide/Formaldehyde Resin

- Impurities (residual monomers)
- Maximum concentration of use in non-nail formulations
- Mucous membrane irritation studies

Tosylamide/Epoxy Resin

- Method of manufacture
- Impurities (residual monomers)
- Maximum concentration of use in non-nail formulations
- Suitable toxicity data to calculate a MOE
- Genotoxicity studies
- Ocular irritation studies
- Mucous membrane irritation studies

177th Meeting Notes



Director's Report

Dr. Heldreth thanked the members of, and liaisons to, the Panel for their tireless efforts to protect consumers over the past 50 years of CIR. Dr. Heldreth also venerated Peter Hutt, who played a significant role in CIR's origin story.

Among many other things, Peter was the Chief Counsel of the US FDA from 1971 to 1975. Therein, he modernized the agency by shifting its regulatory approach from enforcement to rulemaking. He also defined regulation of over-the-counter drugs, was responsible for legislation governing medical devices, promoted regulations to define "imitation" foods, brought the FDA into compliance with the Freedom of Information Act, legitimized off-label drug use, and helped establish foundational policies that continue to shape the cosmetics industry.

In 1975, Peter drafted the first CIR Procedures, laying out the tenants of the CIR processes and formation of the Staff, the CIR Science and Support Committee, the CIR Steering Committee, and this very Panel. With the help of Peter's efforts, CIR was established in 1976 by the then-named CTFA, now PCPC, along with collegial support of the CFA and the US FDA. This was the first of its kind, independent cosmetic ingredient safety review process, with active US FDA and consumer advocacy participation.

Read-Across Best Practices



Dr. Donna Macmillan, Director of Outreach and Capacity Building, ICCS, provided the Panel with an overview of the ICCS Best Practice Guidance Document - Read-Across. This guidance document provides insights into using a read-across approach for human and environmental health decisions with the primary goal to inform hazard and safety assessments without the need for new animal testing. The full guidance is freely available here: https://www.iccs-cosmetics.org/education/best-practice-guidance/bpg-read-across. In addition to introducing the 10-step read-across work-flow, Dr. Macmillian utilized a case study to demonstrate real-world use thereof.



Propolis

The Panel reviewed the Strategy Memo on propolis-derived ingredients and provided direction regarding the inclusion of published studies in the safety assessment. Studies on presumably-relevant, characterized Propolis (i.e., Brazilian, Chinese, and poplar-type propolis), will be included, while studies on generically identified propolis will be set aside.

Scientific Literature Reviews

The following Scientific Literature Reviews (SLRs) or Notices to Proceed Without the Preparation of an SLR (NTP) are either posted on the CIR website or are currently under development and may be posted imminently. These may then be presented to the Panel for their review (as Draft Reports) during the next few meetings.

Cannabidiol
HC Blue No. 15
Pelargonium graveolens-Derived Ingredients
Perfluorohexylethyl Triethoxysilane
Phytosphingosines
Polygonum cuspidatum-Derived Ingredients
Propolis-Derived Ingredients
Pyridoxine and Pyridoxine HCl
Sophora flavescens-Derived Ingredients
Xylitylglucoside

Next Expert Panel Meeting

Monday and Tuesday, December 7 - 8, 2026, to be held ***in-person***, at the Darcy Hotel, Washington, DC. All submissions for this meeting should be received by CIR no later than October 30th, 2026. Please check the CIR website for details as the meeting approaches. https://www.cir-safety.org/