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AGENDA

MINUTES

EXPERT PANEL MEETING

JUNE 15-16, 2026

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MEMORANDUM

To: The Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Bart Heldreth, Ph.D., Executive Director, Cosmetic Ingredient Review
Subject: 176th Meeting of the Panel — Monday and Tuesday, June 15th - 16th, 2026
Date: May 22nd, 2026

Welcome to the second Panel Meeting of 2026! The agenda and accompanying materials for the 176th Expert Panel Meeting, to be held on June 15th - 16th, 2026, are now available. ***The location is different from the one in March*** – and it is at the **Darcy Hotel, 1515 Rhode Island Avenue, NW, Washington, DC 20005**. ***The meeting will start on both days, promptly, at 8:30 AM EDT***. The meeting is open to the public; no prior registration is required. While participation in this meeting will be exclusively in-person, audience members may view the meeting live, via MS Teams (note: there will be no option to participate in the discussions virtually). Invitations (3) to join the virtual component of the meeting may be received by request in advance of the meeting at the meeting page:

https://www.cir-safety.org/meeting/176th-expert-panel-meeting

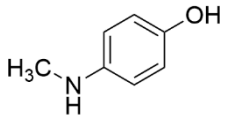
The meeting agenda includes the consideration of 13 reports advancing in the review process, including 5 draft final reports, 4 draft tentative reports, and 4 draft reports (one of which is a re-opened review). There is also 1 administrative item, comprising a genotoxicity studies boilerplate and a discussion of such studies that are no longer considered valid/relevant for assessing cosmetic ingredient safety.

As we continue with our efforts to reduce the quantity of late-breaking information, we are making a cutoff for most information sent to the Panel. The exception to this cutoff is any pertinent information relevant to a Draft Final Report. (For this meeting, the reports that fall into this category are Fatty Amphocarboxylates, *Acacia senegal*-Derived Ingredients, Butoxyethanol, Dimer Dilinoleates, and 2-Nitro-*p*-Phenylenediamine.) ***Submissions received on non-final reports, but not in time for inclusion in the Wave 2 supplement on June 5th, will be held back until the next Panel review of those reports.***

Finally, CIR is excited to announce **the newest member of the Expert Panel for Cosmetic Ingredient Safety, Dr. Bruce A. Brod, MD, MHCI, FAAD!** The CIR Steering Committee met on April 27th, and voted to elect Dr. Brod, who is currently Clinical Professor of Dermatology, Director of Occupational and Contact Dermatitis Clinic, and Associate Dean of Continuing Medical Education and Interprofessional Collaboration at the University of Pennsylvania Perelman School of Medicine. He has also served on, and led, numerous professional and scientific associations and committees, including the American Contact Dermatitis Society, where he served as President, the American Academy of Dermatology, where he serves on the Executive Committee and Board of Directors, and the Accreditation Council for Continuing Medical Education, where he served as Chair of the Accreditation Review Committee.

Draft Reports - There are 4 draft reports for review. Sufficient data to proceed to a tentative

conclusion, or issue an Insufficient Data Announcement (IDA)?

1. <u>*p*-Methylaminophenol</u> – DAR (Christina) – ***Dr. Brod reports on day 2*** – 

The Panel first published the Final Report on the Safety Assessment of *p*-Methylaminophenol Sulfate in 1991 and added *p*-Methylaminophenol in a 2007 rereview, both with a conclusion of safe as a cosmetic ingredient in the present practices of use and concentration. Because more than 15 years have passed since the Panel last reviewed this report and because the 2007 report was never published, this amended safety assessment on *p*-Methylaminophenol and *p*-Methylaminophenol Sulfate is presented to the Panel herein as a Draft Amended Report.

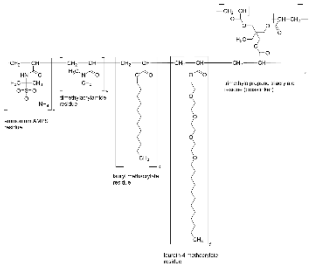
   According to the US FDA Registration and Listing Data (RLD) that CIR received in 2025, *p*-Methylaminophenol is used in 1 hair tint. Additionally, the RLD reported *p*-Methylaminophenol Sulfate is used in 1759 cosmetic formulations, with the majority reported as hair dyes and colors. One use was reported for an eyelash and eyebrow dye. No concentrations of use were submitted for either ingredient in response to the survey conducted by the Council in 2025. In our analysis of each product reported in the RLD with a categorization of "(17) other preparations (i.e., those preparations that do not fit another category)," all 81 products were co-categorized as "(07) hair coloring preparations." Thus, all of these products have already been accounted for in the use table of this report as various hair coloring preparations. Thereby, there are effectively no reported products of unknown category in this report.

   In the US FDA Voluntary Cosmetic Registration Program (VCRP) data submitted to CIR in 2023, *p*-Methylaminophenol Sulfate was reported to be used in 3 hair dyes and colors. When comparing this data to that last reviewed by the Panel in 2007, the frequencies of use for *p*-Methylaminophenol Sulfate have greatly decreased. In the 2007 re-review, this ingredient was reported to have 112 uses in hair dyes and colors. No uses were reported in the VCRP for the free base in 2007 or 2023. In the 2007 re-review, the maximum concentration of use range for *p*-Methylaminophenol Sulfate was 0.1 - 0.7% in hair dyes and colors, and *p*-Methylaminophenol was reported to have a maximum concentration of use of 0.7% in hair dyes and colors.

   Based on the equivocal relevance of certain genotoxicity study methods, CIR staff have excluded an in vivo unscheduled DNA synthesis assay in rats that was reported by the Scientific Committee on Consumer Products in 2006.

   If no further data are needed, the Panel should formulate an updated Discussion and issue a Tentative Amended Report. However, if additional data are required, the Panel should be prepared to identify those needs and issue an IDA.

2. <u>Polyacrylate Crosspolymer-6</u> – DR (Temima) – ***Dr. Brod reports on day 2*** – This is the first time the Panel is seeing this safety assessment. The Scientific Literature Review (SLR) was issued by CIR on November 14, 2025.



   According to RLD obtained from the FDA in 2025, Polyacrylate Crosspolymer-6 is reported to be used in 2771 formulations. In 2025, the concentration of use survey conducted by the Council reported the highest maximum concentration of use is 5% in mascaras. Polyacrylate Crosspolymer-6 is used in products that are applied near the eye (e.g., mascaras up to 5%), that can be incidentally ingested (e.g., lipsticks and lip glosses at up to 1.6%), and in products that result in mucous membrane exposure (e.g., bath soaps and body washes up to 0.7%). Additionally, Polyacrylate Crosspolymer-6 is used in sprays (e.g., cologne and toilet waters up to 0.89%; deodorants, concentration of use not reported) and could therefore be incidentally inhaled.

   In our analysis of each product reported in the RLD with a categorization of "(17) Other preparations (i.e., those preparations that do not fit another category)," 11 of the 23 products were co-categorized as either "(01) Baby products," "(06) Hair preparations (non-coloring)," or "(14) Skin care preparations, (creams, lotions, powder, and sprays)." According to the submitted names, 3 products are an eyelash product, body glitter makeup kit, and a hair spray. However, for the 9 remaining reported formulations exclusively categorized as "(17) Other preparations," neither the product type nor the area/route of exposure is obvious from the information submitted to the RLD.

Also, since the issuing of the SLR, data on the method of manufacturing, impurities, and skin sensitization using a Sens-Is assay and human cell line activation test (h-CLAT) for Polyacrylate Crosspolymer-6 were submitted. There was also a summary of a human repeated insult patch test (HRIPT) on a product containing 1.1% Polyacrylate-Crosspolymer-6 provided. Additionally, studies on an eye cream containing 0.5% Polyacrylate Crosspolymer-6 evaluating dermal irritation and sensitization and ocular irritation potential through an HRIPT and EpiOcular™ screening assay, respectively, were included in this report.

If no further data are needed, the Panel should formulate an updated Discussion and issue a Tentative Report. However, if additional data are required, the Panel should be prepared to identify those needs and issue an IDA.

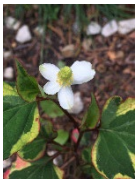
3. *Centaurea cyanus* Flower – DR (Litta) – ***Dr. Brod reports on day 2*** – This is the first time the Panel is reviewing this report on the following 3 ingredients: Centaurea Cyanus Flower, Centaurea Cyanus Flower Extract, and Centaurea Cyanus Flower Water. The SLR for these ingredients was issued by CIR on March 24, 2026.

According to RLD obtained from the FDA in 2025, Centaurea Cyanus Flower Extract has the highest frequency of use, and is reported to be used in 800 formulations. According to concentration of use data submitted in 2025 in response to the Council survey, Centaurea Cyanus Flower Water has the highest concentration of use, at up to 6.1% in eye makeup removers and at 5% in leave-on face and neck preparations. Some of these ingredients may be incidentally ingested as they are used in products used near the mouth (e.g., Centaurea Cyanus Flower Water is used in lipstick and lip glosses; concentration not reported). In addition, these ingredients may be used near the eye area (e.g., Centaurea Cyanus Flower Water is used in eye makeup remover at up to 6.1%) or result in mucous membrane exposure (e.g., Centaurea Cyanus Flower Water is used in douches; concentration not reported). These ingredients are reported to be used in baby products (e.g., Centaurea Cyanus Flower Extract is used in rinse-off "other" baby products at 0.003%). Lastly, cosmetic products containing *Centaurea cyanus* flower-derived ingredients may be incidentally inhaled as they are used in spray (e.g., Centaurea Cyanus Flower Water is used in perfume; concentration not reported) and powder (e.g., Centaurea Cyanus Flower Extract is used in face powders; concentration not reported) formulations.

In our analysis of each product reported in the RLD with a categorization of "(17) Other preparations (i.e., those preparations that do not fit another category)," the product names were useful in determining the product type for some, but not all, formulations. Thereby, of the 2 products containing Centaurea Cyanus Flower reported as "other," one is a body oil. However, for the other reported formulations exclusively categorized as "(17) Other preparations," neither the product type nor the area/route of exposure is obvious from the information submitted to the RLD. Among 13 products containing Centaurea Cyanus Flower Extract categorized as "(17) Other preparations (i.e., those preparations that do not fit another category)," a few were co-categorized as "(06) Hair preparations (non-coloring)" or "(14) Skin care preparations (creams, lotions, powder, and sprays)." For the remaining products, the product names thereof were useful in determining the product type; they were hair removal creams, sheet masks, face serums, lip oils, a calming mask, a cleansing cloth, and a lip mask. The 3 products containing Centaurea Cyanus Flower Water, categorized as "(17) Other preparations (i.e., those preparations that do not fit another category)" were a make-up remover, an eye mask, and a face mask.

In addition, since the issuing of the SLR, various data were received and incorporated into this report, including an HRIPT on a serum containing 0.0014% Centaurea Cyanus Flower Extract. If no further data are needed, the Panel should formulate an updated Discussion and issue a Tentative Report. However, if additional data are required, the Panel should be prepared to identify those needs and issue an IDA.

4. *Houttuynia cordata* – DR (Litta) – ***Dr. Belsito reports on day 2*** – This is the first time the Panel is reviewing this report on the following 6 ingredients: Houttuynia Cordata Extract, Houttuynia Cordata Leaf Water, Houttuynia Cordata Flower/Leaf/Stem Water, Houttuynia Cordata Powder, Houttuynia Cordata Leaf Extract, and Houttuynia Cordata Water. The SLR was announced December 16, 2025.



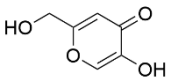
According to RLD obtained from the FDA in 2025 and concentration of use data submitted in 2025 in response to the Council survey, Houttuynia Cordata Extract has the highest frequency and concentration of use; it is reported to be used in 2285 formulations at up to 1.5% in leave-on face and neck products. The other 5 ingredients had 39 or fewer uses reported, and did not have any concentration of use reported. Some of these ingredients may be incidentally ingested as they are used in products used near the mouth (e.g., Houttuynia Cordata Extract is used in lipsticks and lip glosses; concentration not reported). In addition, these ingredients may be used near the eye area (e.g., Houttuynia Cordata Extract is used in eye lotion at up to 0.0027%) or result in mucous membrane exposure (e.g., Houttuynia Cordata Extract is used in bath oils, tablets and salts at 0.004%). These ingredients are also reported to be used in baby products (e.g., Houttuynia Cordata Extract is used in baby lotions/oils/powders/creams; concentration not reported). Lastly, cosmetic products containing *Houttuynia cordata*-derived ingredients may be incidentally inhaled as they are used in spray and powder formulations (e.g., Houttuynia Cordata Extract is used in hair sprays and face powders; concentrations not reported).

In our analysis of each product reported in the RLD with a categorization of "(17) Other preparations (i.e., those preparations that do not fit another category)," several products containing Houttuynia Cordata Extract were co-categorized as "(03) Eye makeup preparations (other than children's eye makeup preparations)," "(06) Hair preparations (non-coloring)," or "(14) Skin care preparations (creams, lotions, powder, and sprays)." For a few of the remaining products, the product names thereof were useful in determining the product type. There were several were eye and face patches, face masks, eye rollers, a serum, and a soothing cream. Information reported for the remainder of the products categorized as "(17) Other preparations," suggests that those submitted products might not be considered to be cosmetic products in the US. We have sent a request to our colleagues in the FDA's OCAC for clarification. One product containing Houttuynia Cordata Powder, categorized as "(17) Other preparations (i.e., those preparations that do not fit another category)" was a face mask.

Since the issuance of the SLR, various data were received, including HRIPT data on an emulsion containing 0.0048% Houttuynia Cordata Extract. If no further data are needed, the Panel should formulate an updated Discussion and issue a Tentative Report. However, if additional data are required, the Panel should be prepared to identify those needs and issue an IDA.

Draft Tentative Reports - There are 4 draft tentative reports for consideration. Issue a tentative conclusion?

1. Kojic Acid – TAR (Christina) – ***Dr. Brod reports on day 2*** – At the September 2025 meeting, the Panel issued a second Insufficient Data Announcement (IDA) for Kojic Acid. The additional data needed to determine the safety of this ingredient are:



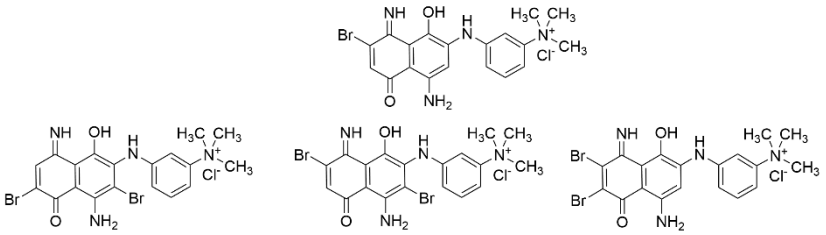
   - Maximum concentration of use for baby products and rinse-off skin care products
   - Margin of exposure (MOE) calculations for various exposure scenarios, specifically (e.g., in bath products at 0.05%, rinse-off product, whole body, face and hands, etc.) and toxicity endpoints (developmental and reproductive toxicity, repeated-dose studies, etc.).

   Since the IDA, CIR has received a data submission through the Council. This submission contains an additional MOE calculation for rinse-off products applied on the whole body. In addition, CIR staff performed new MOE calculations, now included in this report.

   Additionally, the use table has been updated with RLD obtained from the FDA in 2025. Kojic Acid is reported to be used in 3726 formulations (increased from 1114 uses reported in 2024), with the majority of the uses reported in personal cleanliness products (867 in bath soaps and body washes) and skin care preparations (822 in face and neck products). In our analysis of each product reported in the RLD with a categorization of "(17) Other preparations (i.e., those preparations that do not fit another category)," the product names thereof were mostly useful in determining the product type. Many products were serums, peels, cleansers, soaps, wipes, lotions, or masks to be applied to the face. Several products were to be applied as body lotions, or serums or oils for the eye area or lips. Numerous products were described as skin whiteners or dark spot removers, with a few products appearing to be targeted for use in sensitive skin areas (e.g. the genital or rectal areas).

   The Panel should carefully consider and discuss the data (or lack thereof), and issue a Tentative Amended Report with a safe, safe with qualifications, insufficient data, unsafe, or split conclusion, and identify any additional items for inclusion in the Discussion.

2. Basic Blue 99 – TAR (Christina) – ***Dr. Belsito reports on day 2*** – At the March 2023 meeting, the Panel issued an IDA for Basic Blue 99. The additional data needed to determine the safety of this ingredient are:



- Method of manufacturing
- Composition and impurities data
    - Depending on the results of these data, additional information on toxicological endpoints may be needed

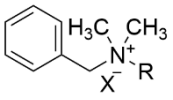
Shortly after the IDA was issued, CIR received a letter from the Basic Blue 99 Consortium requesting a delay of review while the Consortium worked on standardizing a production process for Basic Blue 99 to reduce variability and to better characterize the physical/chemical definition of this substance. Results of the work would then be submitted to the SCCS for review. A second letter from the Consortium was received by CIR in February 2024 requesting further delay of review and providing an update on the work it was performing and a potential timeline for review by the SCCS. Subsequently, the work was reviewed by the SCCS, and the SCCS published a new opinion on Basic Blue 99 in February 2026. All relevant data found in the updated SCCS opinion have been incorporated into the Draft Tentative Amended Report for Basic Blue 99. According to the ingredient manufacturer's submissions provided to the EU SCCS in the 2026 opinion, Basic Blue 99 also comprises 4 other major constituents, including a regio isomer of the mono-brominated naphthoquinoneimine provided in the *Dictionary* monograph and three different dibrominated analogues.

Additionally, the use table has been updated with RLD obtained from the FDA in 2025. Basic Blue 99 is reported to be used in 856 formulations, with the majority of the uses reported in hair coloring preparations (246 in hair dyes and colors, 121 in hair tints, and 226 in hair rinses). RLD also indicated that Basic Blue 99 is used in non-coloring hair preparations (78 formulations) and has 1 use in a rinse-off personal cleanliness product. The results of an updated concentration of use survey conducted by the Council in 2025 indicate Basic Blue 99 is used at up to 0.88% in hair dyes and colors.

In our analysis of each product reported in the RLD with a categorization of "(17) Other preparations (i.e., those preparations that do not fit another category)," all 19 products were co-categorized as "(07) Hair coloring preparations." Thus, all of these products have already been accounted for in the use table of this report as various hair coloring preparations. Thereby, there are effectively no reported products of unknown category in this report.

Based on the equivocal relevance of certain genotoxicity study methods, CIR staff have excluded an unscheduled DNA synthesis assay from this report. The Panel should carefully consider and discuss the data (or lack thereof), and issue a Tentative Amended Report with a safe, safe with qualifications, insufficient data, unsafe, or split conclusion, and identify any additional items for inclusion in the Discussion.

3. Alkonium Chlorides and Bromides – TAR (Priya) – ***Dr. Belsito reports on day 2*** – At the September 2025 meeting, the Panel determined that the data were insufficient to support the safety of these cosmetic ingredients and issued an Insufficient Data Annoucement (IDA) with the following data needs:



- Impurities data on Behenalkonium Chloride, Benzalkonium Bromide, Cetearalkonium Bromide, and Lauralkonium Chloride
- HRIPT on Benzalkonium Chloride at maximum use concentration
- Concentration of use of Benzalkonium Chloride and Stearalkonium Chloride in baby products
- Concentration of use of Stearalkonium Chloride in products applied near the eye
- Ocular irritation data on Stearalkonium Chloride at maximum concentration of use

Since the issuing of the IDA, the following data have been received and incorporated into the report:

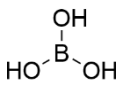
- Japanese specifications and use information in medicinal products on Benzalkonium Chloride

- Impurities data on Stearalkonium Chloride
- Summary impurities information, in vitro dermal irritation, and in vitro ocular irritation data on Stearalkonium Chloride

Behenalkonium Chloride, Benzalkonium Chloride, and Stearalkonium Chloride were reported to have uses under category "(17) Other preparations (i.e., those preparations that do not fit another category)" in 2025 RLD. Twenty-six products for Benzalkonium Chloride were co-categorized as either eye makeup preparations (not children's), personal cleanliness products, skin care preparations, or hair preparations (non-coloring). In addition, in several instances, products were only categorized in RLD with a categorization of "(17) Other preparations;" however, the product names were useful in determining product type. For Behenalkonium Chloride, this product type was a hair conditioner. For Benzalkonium Chloride, these product types include makeup removers, moisturizers, toners, disposable wipes, hair masks, shampoos, hair creams, and deodorant. For one product containing Benzalkonium Chloride, neither the product type nor the area/route of exposure is obvious from the information submitted to the RLD. Lastly, information reported for some of the "(17) Other preparations" for Benzalkonium Chloride and Stearalkonium Chloride suggests that those submitted products might not be considered cosmetic products in the US. We have sent a request to our colleagues in the FDA's OCAC for clarification.

A draft Abstract and Discussion have been included in this report version. The Panel should carefully consider and discuss the data (or lack thereof), and issue a Tentative Amended Report with a safe, safe with qualifications, insufficient data, unsafe, or split conclusion, and identify any additional items for inclusion in the Discussion.

4. Sodium Borate – TAR (Temima) – ***Dr. Belsito reports on day 2*** – At the September 2025 meeting, the Panel determined that the data were insufficient to support the safety of these cosmetic ingredients, and issued an IDA with the following data needs:



- MOE calculations for cosmetic uses that result in mucosal and vaginal exposures.
- Mucosal absorption data
- Vaginal absorption and total application surface area data
- Maximum concentration for Sodium Borate in products applied near the eye area, that result in mucous membrane exposure, and in douches
- Maximum concentration for Boric Acid when used in products applied near the eye

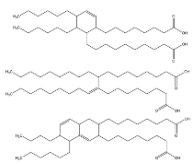
Since the IDA was issued, CIR has not received any of the requested data..

In our analysis of each product reported in the RLD with a categorization of "(17) Other preparations (i.e., those preparations that do not fit another category)," Boric Acid and Sodium Borate both had 1 product that was co-categorized as "(03) Eye makeup preparations (other than children's eye makeup preparations)." According to the submitted names, 4 of the Boric Acid products consist of a cuticle oil, gel polish remover, gel polish remover and cuticle oil, and a nail treatment. However, for 5 of the reported formulations exclusively categorized as '(17) Other preparations,' neither the product type nor the area/route of exposure is obvious from the information submitted to the RLD. For 3 of the Sodium Borate products, the submitted names indicate the products consist of 2 teeth whitening products and a powdered hand cleaner. Information reported for 4 Boric Acid and 6 Sodium Borate products in the '(17) Other preparations,' category suggests that those submitted products might not be considered to be cosmetic products in the US. We have sent a request to our colleagues in the FDA's OCAC for clarification.

Based on the equivocal relevance of certain genotoxicity study methods, CIR staff have excluded sister chromatid exchange (SCE) assays from this report. A draft Abstract and Discussion have been included in this report version. The Panel should carefully consider and discuss the data (or lack thereof) and be prepared to issue a Tentative Amended Report with a safe, safe with qualifications, insufficient data, unsafe, or split conclusion, and identify any additional items for inclusion in the Discussion.

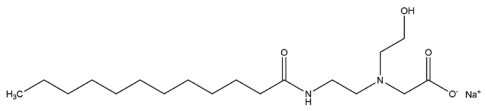
Draft Final Reports - There are 5 Draft Final Reports for consideration. Review these drafts, especially the rationale provided in the Discussion sections, and issue final reports, as appropriate.

1. Dimer Dilinoleates – FR (Christina) – ***Dr. Brod reports on day 2*** – At the March 2026 meeting, the Panel issued a Tentative Report with the conclusion that these 7 dimer dilinoleate ingredients are safe in cosmetics in the present practices of use and concentration described in this safety assessment. No additional data have been received since the March meeting.



In our analysis of each product reported in the RLD with a categorization of "(17) Other preparations (i.e., those preparations that do not fit another category)," the product names thereof were useful in determining the product type. The majority of entries for the dimer dilinoleates in category 17 were for lip care products. Other entries include uses in skin care products, a tanning product, and a makeup product. The Panel should carefully review the Abstract, Discussion, and Conclusion, and issue a Final Report.

2. Fatty Amphocarboxylates – FR (Priya) – ***Dr. Belsito reports on day 2*** – At the September 2025 meeting, the Panel issued a Tentative Report with the conclusion that the 11 fatty amphocarboxylates are safe in cosmetics in the present practices of use and concentration described in the safety assessment when formulated to be non-sensitizing, based on a quantitative risk assessment (QRA) or other appropriate methodology.



Since the September 2025 meeting, an HRIPT on a product containing 2.04% Disodium Lauroamphodiacetate (final test concentration: 0.02% Disodium Lauroamphodiacetate) was received. In addition, a study was found in the published literature assessing the ocular irritation potential of Disodium Cocoamphodiacetate, Sodium Cocoamphoacetate, and Sodium Lauroamphoacetate in rabbits. These data have been incorporated into the report.

Also, since the September meeting, CIR has updated the use data with RLD obtained from the FDA in 2025. According to these data, Disodium Cocoamphodiacetate has the highest frequency of use (it is reported to be used in 3010 formulations). The results of the concentration of use survey conducted by the Council in 2025 indicate that Sodium Cocoamphoacetate has the highest concentration of use in leave-on products (it is used at up to 3% in leave-on face and neck (not spray) and body and hand products (not spray)) and Disodium Cocoamphodipropionate has the highest concentration of use overall, in rinse-off products (it is used at up to 14.8% in rinse-off non-coloring shampoos).

Disodium Cocoamphodiacetate, Sodium Cocoamphoacetate, and Sodium Lauroamphoacetate were reported to have uses under category “(17) Other preparations (i.e., those preparations that do not fit another category)” in 2025 RLD. Twelve products for Disodium Cocoamphodiacetate were co-categorized as either bath preparations, manicuring preparations, skincare preparations, or hair preparations (coloring and non-coloring). One product for Sodium Cocoamphoacetate was co-categorized as a non-coloring hair preparation, and one product for Sodium Lauroamphoacetate was co-categorized as a personal cleanliness product. In addition, in several instances, products were only categorized in RLD with a categorization of “(17) Other preparations;” however, the product names were useful in determining product type. For Disodium Cocoamphodiacetate, these products include makeup remover wipes, facial cleansers, cleansing pads, micellar waters, makeup brush cleaning wipes, face masks, and beard and face scrubs. For Sodium Cocoamphoacetate, these product types include face wash and shampoo bars. For one product containing Disodium Cocoamphodiacetate, neither the product type nor the area/route of exposure is obvious from the information submitted to the RLD. Lastly, information reported for some of the “(17) Other preparations” suggests that those submitted products might not be considered cosmetic products in the US. We have sent a request to our colleagues in the FDA’s OCAC for clarification.

The Panel should carefully review the Abstract, Discussion, and Conclusion, and issue a Final Report.

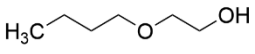
3. *Acacia senegal* – FAR (Monice) – ***Dr. Brod reports on day 2*** – At the September 2025 meeting, the Panel issued a Tentative Amended Report, reaffirming the conclusion that Acacia Senegal Gum and Acacia Senegal Gum Extract are safe in cosmetics in the present practices of use and concentration described in this safety assessment. Since the September meeting, CIR has updated the report with use data obtained in 2025 from the FDA RLD. Frequencies of use have increased since reported in 2024. In 2024, Acacia Senegal Gum was reported to have 1833 uses, and Acacia Senegal Gum Extract 92; in 2025, Acacia Senegal Gum has 2938 uses and Acacia Senegal Gum Extract has 149.

The RLD for Acacia Senegal Gum lists 54 products under category "(17) other preparations (i.e., those preparations that do not fit another category)." In our analysis of these products, 5 were co-categorized with eye makeup preparations, 18 with non-coloring hair preparations, 1 with personal cleanliness products, and 3 with skin care preparations. The 27 remaining formulations were only listed as category 17, and the product names were useful in determining some (but not all) of the product types; e.g., 4 were face masks, 6 were skin care preparations, 1 was an eye cream, 1 was a mascara, and 10 were face paint products. However, for 5 of the products, the product type nor the area/route of exposure is obvious from the information submitted to the RLD, and some of those submitted products might not be considered to be cosmetic products in the US. We have sent a request to our colleagues in the FDA's OCAC for clarification.

For Acacia Senegal Gum Extract, 12 products reported in the RLD were listed under category (17). In our analysis of these products, all but one were co-categorized: 8 with non-coloring hair preparations, 1 with personal cleanliness products, and 2 with skin care preparations. The product type and the area/route of exposure, or whether it is a cosmetic product, is not clear for the 1 remaining category 17 entry.

No additional data have been received. The Panel should carefully review the Abstract, Discussion, and Conclusion, and issue a Final Amended Report.

4. Butoxyethanol – FAR (Christina) – ***Dr. Belsito reports on day 2*** – At the September 2025 meeting, the Panel issued a Tentative Amended Report with the conclusion that the available data are insufficient to make a determination of safety under the intended conditions of use as a cosmetic ingredient. The additional data needs are:



- Maximum concentration of use in hair dye formulations
- Maximum concentration of use in non-hair dye formulations

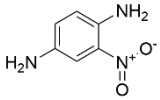
Since the September meeting, CIR has updated the use data with the RLD obtained from the FDA in 2025. Butoxyethanol is used in 103 formulations, with 82 uses reported in hair coloring preparations. Uses were also reported in eye makeup preparations, non-coloring hair preparations, makeup preparations, and skin care preparations.

In our analysis of each product reported in the RLD with a categorization of "(17) Other preparations (i.e., those preparations that do not fit another category)," the product names thereof were useful in determining the product type. Thereby, of the 3 products reported as "other," one is a lip balm, one is a lipstick, and one is a decorative sticker intended for application to the face.

CIR staff reviewed the available genotoxicity studies, noting that some genotoxicity studies are now considered obsolete. Based on the equivocal relevance of certain genotoxicity study methods, CIR staff have excluded in vitro SCE and unscheduled DNA synthesis (UDS) assays that were reported in the original 1996 safety assessment.

No additional data have been received. The Panel should carefully review the Abstract, Discussion, and Conclusion, and issue a Final Amended Report.

5. 2-Nitro-*p*-Phenylenediamine – FAR (Christina) – ***Dr. Belsito reports on day 2*** – At the September 2025 meeting, the Panel issued a Tentative Amended Report with a revised conclusion stating that the available data are insufficient to make a determination of safety for 2-Nitro-*p*-Phenylenediamine under the intended conditions of use as a hair dye ingredient. In order to come to a conclusion of safety for this ingredient, the following additional data are needed:



- Maximum concentration of use in hair dye formulations
- A 90-d oral repeated-dose study with a no-observed-adverse-effect level (NOAEL) that shows a dose-response relationship

Since the September meeting, CIR has updated the use data with RLD obtained from the FDA in 2025. 2-Nitro-*p*-Phenylenediamine is now reported to be used in 4 hair dyes and colors (1 additional use from that previously reported).

Based on the equivocal relevance of certain genotoxicity study methods, CIR staff have excluded from the report a mutagenicity study using *S. cerevisiae*, SCE assays, an *E. coli* K-12 uvrB/recA DNA repair host-mediated assay, and an immunological DNA synthesis-inhibition test.

No additional data have been received. The Panel should carefully review the Abstract, Discussion, and Conclusion, and issue a Final Amended Report.

Administrative Item - there is 1 administrative item.

1. Genotoxicity Boilerplate – Admin – (Jinqiu) – ***Dr. Brod reports on day 2*** – At the March Panel meeting, the Panel discussed the limitations, interpretability, and current regulatory relevance of several historical genotoxicity assays, such as SCE assays, UDS assays, the mouse spot test, and other older or non-standard assays that have appeared in published literature and prior CIR safety assessments. The Panel noted that these assays are no longer considered acceptable for evaluating genotoxic potential in light of updated OECD guidance and the availability of current guideline-based approaches for evaluating gene mutation, chromosomal damage, and other relevant genotoxicity endpoints. The Panel determined that a standard boilerplate statement should be included in the genotoxicity section of CIR reports to clarify how obsolete genotoxicity assays are handled.

   Based on the Panel meeting discussion, boilerplate language has been proposed. Additionally, the Panel should note that CIR staff have excluded such obsolete genotoxicity assays from the reports at this meeting. The Panel is requested to discuss whether to adopt the proposed genotoxicity boilerplate language; review the studies proposed for omission; and to provide direction on whether citations to historical/obsolete genotoxicity assays should be omitted or retained in the genotoxicity section.

Full Panel Meeting

The Panel will consider 5 dossiers to potentially issue as Final Reports, followed by the remaining reports advancing in the process (i.e., the Tentative Reports and Draft Reports). In addition, a consensus should be reached for the genotoxicity boilerplate.

Please remember, the meeting starts at 8:30 AM EDT on day 1 and day 2.

Looking forward to seeing you all ***in-person***!

Agenda
176th Meeting of the Expert Panel for Cosmetic Ingredient Safety
June 15-16, 2026

Monday, June 15, 2026

8:30 AM EDT	**WELCOME TO THE 176th EXPERT PANEL TEAM MEETINGS**	**Drs. Bergfeld/Heldreth**
8:45 AM - 12 PM	**TEAM MEETINGS**	**Drs. Belsito/Brod**
12 PM – 1 PM	**Lunch break**	
1:00 PM - 5 PM	**TEAM MEETINGS (continued)**	**Drs. Belsito/Brod**

Dr. Belsito's Team*	
FAR (CB)	Butoxyethanol
FR (CB)	Dimer Dilinoleates
FAR (CB)	2-Nitro-*p*-Phenylenediamine
TAR (CB)	Kojic Acid
TAR (CB)	Basic Blue 99
DAR (CB)	*p*-Methylaminophenol
FAR (MF)	*Acacia senegal*-derived ingredients
FR (PF)	Fatty Amphocarboxylates
TAR (PF)	Alkonium Chlorides
TAR (TN)	Sodium Borate
DR (TN)	Polyacrylate Crosspolymer-6
DR (LP)	*Centaurea cyanus*
DR (LP)	*Houttuynia cordata*
Admin (JZ)	Genotoxicity boilerplate

Dr. Brod's Team	
FR (PF)	Fatty Amphocarboxylates
TAR (PF)	Alkonium Chlorides
TAR (TN)	Sodium Borate
DR (TN)	Polyacrylate Crosspolymer-6
DR (LP)	*Centaurea cyanus*
DR (LP)	*Houttuynia cordata*
FAR (MF)	*Acacia senegal*-derived ingredients
Admin (JZ)	Genotoxicity boilerplate
FAR (CB)	Butoxyethanol
FR (CB)	Dimer Dilinoleates
FAR (CB)	2-Nitro-*p*-Phenylenediamine
TAR (CB)	Kojic Acid
TAR (CB)	Basic Blue 99
DAR (CB)	*p*-Methylaminophenol

The purpose of the Cosmetic Ingredient Review and the Expert Panel for Cosmetic Ingredient Safety is to determine those cosmetic ingredients for which there is a reasonable certainty, in the judgment of competent scientists, that the ingredients are safe under intended conditions of use.

FR: Final Report || FAR: Final Amended Report || TR: Tentative Report || TAR: Tentative Amended Report || DR: Draft Report || DAR: Draft Amended Report || RR: Re-Review || RRsum: Re-Review Summary || Rev: Revised || SM: Strategy Memo || Admin: Administrative item

BH: Bart Heldreth || MF: Monice Fiume || CB: Christina Burnett || PF: Priya Ferguson || TN: Temima Nguyen || LP: Litta Paulson || JZ: Jinqiu Zhu

*Team moves to the breakout room.

Cosmetic Ingredient Review

Tuesday, June 16, 2026			
8:30 AM EDT	**WELCOME TO THE 176th FULL EXPERT PANEL MEETING**		**Dr. Bergfeld**
8:40 AM	Admin **MINUTES OF THE MARCH 2026 EXPERT PANEL MEETING**		**Dr. Bergfeld**
8:45 AM	**DIRECTOR'S REPORT**		**Dr. Heldreth**
9:00 AM	**FINAL REPORTS, REPORTS ADVANCING TO THE NEXT LEVEL, OTHER ITEMS**		
	Final Reports		
	FR (PF)	Fatty Amphocarboxylates - ***Dr. Belsito reports***	
	FAR (MF)	*Acacia senegal*-derived ingredients – ***Dr. Brod reports***	
	FAR (CB)	Butoxyethanol - ***Dr. Belsito reports***	
	FR (CB)	Dimer Dilinoleates – ***Dr. Brod reports***	
	FAR (CB)	2-Nitro-*p*-Phenylenediamine - ***Dr. Belsito reports***	
	Reports Advancing		
	TAR (CB)	Kojic Acid – ***Dr. Brod reports***	
	TAR (CB)	Basic Blue 99 – ***Dr. Belsito reports***	
	DAR (CB)	*p*-Methylaminophenol – ***Dr. Brod reports***	
	TAR (PF)	Alkonium Chlorides and Bromides – ***Dr. Belsito reports***	
	DR (TN)	Polyacrylate Crosspolymer-6 – ***Dr. Brod reports***	
	TAR (TN)	Sodium Borate – ***Dr. Belsito reports***	
	DR (LP)	*Centaurea cyanus* flower-derived ingredients – ***Dr. Brod reports***	
	DR (LP)	*Houttuynia cordata*-derived ingredients – ***Dr. Belsito reports***	
	Other Items		
	Admin (JZ)	Genotoxicity boilerplate – ***Dr. Brod reports***	

ADJOURN – – *The next meeting will be held in-person on Monday and Tuesday,* ***October 5-6, 2026****, at The Darcy Hotel, 1515 Rhode Island Avenue, NW, Washington, DC 20005. Please check the CIR website for details as the meeting approaches.*

On the basis of all data and information submitted, and after following all of the Procedures (https://www.cir-safety.org/supplementaldoc/cir-procedures), the Expert Panel shall determine whether each ingredient, under each relevant condition of use, is safe, safe with qualifications, unsafe, or there are insufficient data or information to make a determination of safety. Upon making such a determination, the Expert Panel shall issue a conclusion and/or announcement.

FR: Final Report || FAR: Final Amended Report || TR: Tentative Report || TAR: Tentative Amended Report || DR: Draft Report || DAR: Draft Amended Report || RR: Re-Review || RRsum: Re-Review Summary || Rev: Revised || SM: Strategy Memo || Admin: Administrative item

BH: Bart Heldreth || MF: Monice Fiume || CB: Christina Burnett || PF: Priya Ferguson || TN: Temima Nguyen || LP: Litta Paulson || JZ: Jinqiu Zhu

ONE HUNDRED SEVENTY-FIFTH MEETING

OF THE

EXPERT PANEL FOR COSMETIC INGREDIENT SAFETY

March 12-13, 2026

Microsoft Teams Virtual Meeting

Expert Panel Members

Wilma F. Bergfeld, M.D., Chairperson

Donald V. Belsito, M.D., Teamleader

David E. Cohen, M.D., Teamleader

Samuel M. Cohen, M.D., Ph.D.

Curtis D. Klaassen, Ph.D.

Allan E. Rettie, Ph.D., RAWG leader

David Ross, Ph.D.

Paul W. Snyder, D.V.M., Ph.D.

Susan Tilton, Ph.D.

Liaison Representatives

Consumer

Courtney Griffin, J.D.

Industry

Jaap Venema, Ph.D.

Government

Prashiela Manga, Ph.D. (Acting)

Jannavi Srinivasan, Ph.D.

Janet Zang, Ph.D.

Hong Xie, Ph.D.

Adopted (Date)

Wilma F. Bergfeld, M.D.

CIR Staff

Administration
Bart Heldreth, PhD - Executive Director

Monice Fiume, MBA - Senior Director

Carla Jackson - Administrative Coordinator

Subject Matter Expertise
Jinqiu Zhu, PhD, DABT, ERT, DCST - Toxicologist

Analysis
Christina L. Burnett, MSES - Senior Scientific Analyst

Priya Ferguson, MS – Associate Toxicologist & Senior Scientific Analyst

Temima Nguyen, MS - Scientific Analyst

Litta Paulson, MPH - Scientific Analyst

Information Services
Kevin Stone Fries, MLS - Information Services Manager

Other Virtual Attendees

Name	Organization
Ayodele Ajayi	June Jacobs Labs
Jay Ansell	EAS Consulting Group
Melanie Buser	RHP Risk Management, Inc.
Travis Cook	Beiersdorf
George Daston	Procter & Gamble
Silvia Pérez Damonte	CLAIM
Carol Eisenmann	Personal Care Products Council
Enrico Gilberti	L'Oreal & CIR SSC
Linda Giles	Transcription Etc.
Dave Gossai	L'Oreal
Chaira Lazzari	Celanese
Donna MacMillan	ICCS
Sarvin Moghaddam	FDA
Lauren Nardella	HBW Insight
Jeff Nicolai	J Nicolai Law
Kim Norman	Personal Care Products Council
Allison Schafer	Procter & Gamble
Alexandra Gorman Scranton	Weaving Voices for Health & Justice
Brenda Shinyashiki	Edgewell Personal Care
Kathy Stanton	Personal Care Products Council
Patra Volarath	FDA
Zemin Wang	FDA
Teresa Washington	FDA
Zhenning Yang	Henkel Corp.
Leah Yip	Unilever

CHAIRPERSON'S OPENING REMARKS

Dr. Bergfeld welcomed the attendees to the 175h meeting of the Expert Panel for Cosmetic Ingredient Safety. Dr. Bergfeld thanked everyone for their patience and consideration of the postponement of the December meeting. She also thanked the CIR staff, the Council, the CIR Science and Support Committee, Weaving Voices for Health & Justice (previously known as Women's Voice for the Earth), and the Panel for all of their efforts in preparing for this meeting.

Dr. Bergfeld noted that the Panel was reviewing 14 documents which consisted of 2 final reports, 4 tentative reports, 4 draft reports, a re-review summary, and 3 administrative documents. There were also 2 presentations on the agenda for the meeting: an overview of skin sensitization best practice guidance and insights on data interpretation relevant to the report on Phthalates.

APPROVAL OF MINUTES

The minutes of the September 8-9, 2025 (174th) Expert Panel meeting were approved.

DIRECTOR'S REPORT

Dr. Heldreth thanked the members of, and liaisons to, the Panel for their tireless efforts to protect consumers. He also thanked Dr. David Cohen for years of expert service on the Panel, as Dr. Cohen is retiring from this Panel effective immediately. While Dr. Cohen is not replaceable, the Panel now has an immediate vacancy to fill. Please send nominations to fill this vacancy directly to heldrethb@cir-safety.org ASAP; nominees should be well-known experts in dermatology and have no financial conflicts of interest with the cosmetics industry, per the statement herein: https://ingredientsafetyexpertpanel.org/conflict-of-interest-statement/.

Dr. Heldreth also enumerated on the ways CIR and the Panel have been valuable over the past 50 years, and continue to be, to consumers and industry alike. He also provided a brief recall of the history of those participating in the program since 1976.

This meeting was the first for new CIR Staff member, Litta Paulson, who joined CIR just a few months prior as a Scientific Analyst. Litta holds a bachelor's degree in Biology and a master's degree in Public Health from Virginia Commonwealth University. Before coming to CIR, she worked in regulatory affairs as a scientific literature specialist, supporting FDA product submissions.

FINAL SAFETY ASSESSMENTS

Cocoyl Hydrolyzed Collagens

The Panel reviewed the available data and issued a Final Amended Report concluding that Potassium Cocoyl Hydrolyzed Collagen, TEA-Cocoyl Hydrolyzed Collagen, Cocoyl Hydrolyzed Collagen, and Sodium Cocoyl Hydrolyzed Collagen are safe in cosmetics in the present practices of use and concentration described in the safety assessment. The Panel noted there were no concentrations of use reported for Cocoyl Hydrolyzed Collagen or TEA-Cocoyl Hydrolyzed Collagen; the expectation is that they would be used at concentrations comparable to others in this group.

The Panel noted that the ingredients named in this group are derived from animal sources, and stressed the cosmetics industry should continue to use necessary procedures to limit infectious agents and/or biologically-derived impurities (e.g., nucleic acids, proteins, endotoxins). Additionally, the Panel cautioned that TEA-Cocoyl Hydrolyzed Collagen should not be used in cosmetic products in which *N*-nitroso compounds can be formed.

TENTATIVE SAFETY ASSESSMENTS

Alkyl Gallates

The Panel reviewed the Draft Amended Report on Caprylyl Gallate, Dodecyl Gallate, Ethylhexyl Gallate, and Propyl Gallate, and issued a Tentative Amended Report for public comment with the conclusion that these ingredients are safe as used when formulated to be non-irritating and non-sensitizing. Safety for this group was supported by the fact that most of these ingredients are approved by the US FDA for use as antioxidants/preservatives in food, and Propyl Gallate is also used in approved oral and topical drug products. Additional support for safety included negative results from a 2-year carcinogenicity study and a multigenerational reproductive toxicity study of Propyl Gallate.

The Panel also discussed several in vitro studies reporting estrogenic activity for Propyl Gallate; however, concern for these effects was considered mitigated as the doses and routes of exposure in those studies are not relevant to cosmetic use. Lastly, the Panel considered a case report describing skin depigmentation following use of products containing gallates, but determined that the effect represented post-inflammatory hypopigmentation resulting from the severity of the reaction rather than a direct effect on melanogenesis.

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

The Panel reviewed the available data and issued a revised Tentative Amended Report for public comment. 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 prompted the revision and stemmed from 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. In patients that had a positive patch, 0.9% had an allergic reaction to a wet wipe source, and the reaction rate to 2-Bromo-2-Nitropropane-1,3-Diol in these subjects was 27.4%. 2-Bromo-2-Nitropropane-1,3-Diol is reported to be used at a maximum concentration of 0.05% in disposable wipes.

The Panel noted that 2-Bromo-2-Nitropropane-1,3-Diol may act as a formaldehyde-releaser. However, based on the low maximum concentration of use of 2-Bromo-2-Nitropropane-1,3-Diol in cosmetics, along with the low amount of formaldehyde that could be potentially be released from this ingredient, concerns about this ingredient as a formaldehyde-releaser were mitigated; specifically, the Panel determined that the potential amount of formaldehyde resulting from the cosmetic use of this ingredient would be below the level of concern in their previous safety assessment of formaldehyde as a cosmetic ingredient. The Panel also noted that 2-Bromo-2-Nitropropane-1,3-Diol is a known *N*-nitrosating agent and should not be used in cosmetic products in which *N*-nitroso compounds can be formed.

Dimer Dilinoleates

The Panel reviewed the following 7 dimer dilinoleates and issued a Tentative Report for public comment with the conclusion that these ingredients are safe in cosmetics in the present practices of use and concentration described in the safety assessment.

Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate
Bis-Behenyl/Phytosteryl Dimer Dilinoleate
Dimer Dilinoleyl Dimer Dilinoleate
Octyldodecyl/PPG-3 Myristyl Ether Dimer Dilinoleate
Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate
Phytosteryl Isostearyl Dimer Dilinoleate
Stearyl/PPG-3 Myristyl Ether Dimer Dilinoleate

The Panel noted that it had previously concluded that dilinoleic acid is safe in the present practice of use and concentration described in that safety assessment when formulated to be non-irritating and non-sensitizing; other components of the ingredients found in this report have also been found to be safe as used as cosmetic ingredients. While toxicokinetics data are lacking, significant dermal absorption for these dimer dilinoleate ingredients is not expected. The Panel also noted that heavy metals may be present in these ingredients and stressed that the cosmetics industry should continue to use the necessary procedures to minimize impurities in cosmetic formulations according to limits set by the US FDA and EPA.

Polyacrylate-13

The Panel reviewed the available data and issued a Tentative Report for public comment with the conclusion that Polyacrylate-13 is safe in cosmetics in the present practices of use and concentration described in the safety assessment. Polyacrylate-13 is reported to be used in 1807 cosmetic formulations at up to a maximum concentration of 3.4%. Due to its large average molecular weight, dermal absorption is expected to be minimal; thus, the need for further systemic toxicity data is mitigated. The European Union established limits that Polyacrylate-13 can be used in body leave-on products and other products up to a maximum residual acrylamide content of 0.1 and 0.5 mg/kg, respectively. A trade mixture containing Polyacrylate-13 was reported to comprise < 1 ppm (~1 mg/kg) of residual acrylamide impurities. Since Polyacrylate-13 is comprised in part of acrylamide monomers, manufacturers formulating with Polyacrylate-13 should continue to use current good manufacturing practices (cGMPs) to limit residual acrylamide contamination.

Pyrogallol

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 Pyrogallol. The additional data needed to determine the safety of this ingredient are:

- Maximum concentration of use in hair dye formulations
- Genotoxicity studies, with metabolic activation, that test for the formation of DNA adducts

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.

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 cosmetics products, use in eye makeup products and manicuring preparations is not permitted in the US. Furthermore, 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.

INSUFFICIENT DATA ANNOUNCEMENTS (IDA)

Oxyquinoline and Oxyquinoline Sulfate

The Panel reviewed the draft Tentative Amended Report on Oxyquinoline and Oxyquinoline Sulfate and issued a second IDA. The insufficiencies are as follows:

For Oxyquinoline:

- Impurities
- Maximum concentrations of use
- Photoirritation/photosensitization data
- Dermal absorption
- Developmental and reproductive toxicity (DART) data, including a no-observed-adverse-effect-level (NOAEL) on Oxyquinoline
- Clarification regarding use around the eye (specifically whether the reported uses in "eyebrow and eye preparations" include eyebrow and/or eyelash dye products)

For Oxyquinoline Sulfate:

- Method of manufacturing
- Composition and impurities
- Photoirritation/photosensitization data at maximum use concentrations

In lieu of photoirritation/photosensitization data, evidence demonstrating that photoabsorption is not significant may be submitted.

Phosphinate Ingredients

The Panel reviewed the draft Tentative Report on Bis-Trimethylbenzoyl Phenylphosphine Oxide, Ethyl Trimethylbenzoyl Phenylphosphinate, and Trimethylbenzoyl Diphenylphosphine Oxide and issued an IDA. The insufficiencies are as follows:

For all:

- Sensitization data at maximum use concentrations
- Phototoxicity/photosensitization data (for nail products)
- Concentrations of use in non-nail products

For Bis-Trimethylbenzoyl Phenylphosphine Oxide and Ethyl Trimethylbenzoyl Phenylphosphinate:

- Impurities
- Method of manufacturing

For Trimethylbenzoyl Diphenylphosphine Oxide:

- Dermal irritation data at maximum concentration of use

Phthalates

The Panel issued an IDA for Dibutyl Phthalate, Diethyl Phthalate, and Dimethyl Phthalate. The additional data needed to determine the safety of these ingredients are:

- Clarification on the type of current uses and maximum concentration of use for Dibutyl Phthalate
- Maximum concentration of use for Dimethyl Phthalate

***Salix alba* (Willow) – Derived Ingredients**

The Panel reviewed the Draft Report on 6 *Salix alba*–derived ingredients and issued an IDA. The insufficiencies are as follows:

For Salix Alba (Willow) Bark Extract:

- Concentration of use in baby products
- Photoallergenicity data

For Salix Alba (Willow) Leaf Extract:

- DART data
- Photoallergenicity data

For Salix Alba (Willow) Bark Powder, Salix Alba (Willow) Bark Water, Salix Alba (Willow) Extract, and Salix Alba (Willow) Flower Extract:

- Methods of manufacturing
- Composition and impurities

- 28-day dermal toxicity
    - if absorbed, DART and genotoxicity data may be needed
- Dermal sensitization and irritation data at maximum use concentrations
- Phototoxicity/photosensitization data

Additionally, the Panel requested information on particle size and particle size distribution, habits and practices related to airbrush use, and ocular irritation at maximum use concentrations.

RE-REVIEW SUMMARY

In accordance with its Procedures, the Panel evaluates the conclusions of previously-issued safety assessments approximately every 15 years. At this meeting, 1 re-review summary was considered. The Panel reaffirmed the conclusion of the safety assessment of Fossil & Synthetic Waxes (8 ingredients).

OTHER ITEMS & DOCUMENTS

Presentations

Dr. Donna Macmillan, Director of Outreach and Capacity Building, ICCS, provided the Panel with an overview of the ICCS Skin Sensitization Best Practice Guidance and walked through a case study thereof. This guidance utilizes the integration of in silico, in chemico, and in vitro methods, including those aligned with OECD Test Guidelines. The full guidance is freely available here:

https://www.iccs-cosmetics.org/education/best-practice-guidance/bpg-skin-sensitization-assessment-using-new-approach-methods

Dr. George Daston, VMS Research Fellow, Proctor & Gamble, also made a presentation to the Panel. He provided insights on data interpretation relevant to the report on Phthalates, specifically with regard to developmental and reproductive toxicities, and endocrine activation

Airbrush

Prior to the mandatory reporting of ingredients used in formulations that employ airbrush application, the Panel acknowledged in the Cosmetic Use section of our reports that the data are insufficient to evaluate the exposure resulting from cosmetics applied via airbrush delivery systems. Subsequently, it is restated in the Discussion that the data are insufficient to support the safe use of cosmetic ingredients applied via an airbrush delivery system. However, with the advent of the Modernization of Cosmetics Reform Act of 2022 (MoCRA), it is now known if an ingredient is included in a formulation that uses airbrush application. Accordingly, the Panel was asked to consider stating in the Conclusion that data are insufficient to determine safety in products applied via airbrush application when such use types are reported in the FDA RLD or in response to the Council concentration of use survey. The Panel unanimously responded in the affirmative.

Genotoxicity

The Panel discussed the limitations and current scientific validity of several historical genotoxicity assays, such as the sister chromatid exchange (SCE) assay, unscheduled DNA synthesis (UDS) test, and mouse spot test. These assays are no longer considered acceptable for genotoxicity testing according to updated OECD guidelines. The Panel determined that a standard disclaimer should be included in the genotoxicity section of CIR reports. This disclaimer would clarify that although results from these assays are reported in the published literature, their scientific reliability and regulatory relevance are limited; therefore, such studies will no longer be routinely summarized or used to support the safety evaluation in CIR assessments.

In addition, the Panel discussed the increasing importance of New Approach Methodologies (NAMs) in genotoxicity assessment. The Panel recognized that, when integrated with established guideline studies and existing toxicological data, NAMs can strengthen a weight-of-evidence (WoE) framework for evaluating genotoxic potential and are expected to play an increasingly important role in current genotoxicity testing strategies.

Use Tables

In the past, the use tables in CIR reports were based on the categories used in the Voluntary Cosmetic Registration Program (VCRP). However, with the advent of MoCRA, there have been changes, updates, and additions to the product categories. Accordingly, CIR has updated the use table template utilized by the scientific analysts. The Panel and other stakeholders present were asked for input as to whether the updated tables meet their needs. A consensus was achieved on some changes to the arrangement, but this template will remain a living document, adaptable to changing data sources and stakeholder needs. Additionally, since the Panel determined that evaluating the safety of ingredients as used in tattoo preparations is not within their purview, such uses will not be included in future CIR use tables.