Post Meeting Announcement

Expert Panel for Cosmetic Ingredient Safety
161st Meeting (June 16-17, 2022) - Findings

June 24, 2022

● Final Safety Assessments

- **Acryloyloxyethyl Phosphorylcholine Polymers - 8 ingredients - Safe**
- **Barley – 16 ingredients – Split (5 safe; 11 insufficient)**
- **Glucosamine – 4 ingredients - Safe with qualifications**
- **Glyceryl Acrylates – 4 ingredients – Safe**
- **Radish Root – 7 ingredients - Safe with qualifications**
- **Sage – 12 ingredients - Split (6 safe; 6 insufficient)**
- **Zeolites – 6 ingredients – Safe**

● Tentative Safety Assessments

- **Fatty Esters End-Capped Alkoxylates – 14 ingredients – Split (1 safe; 13 insufficient)**
- **Fatty Ethers – 8 ingredients – Safe**
- **Ginger – 9 ingredients - Split (7 safe with qualifications; 2 insufficient)**

● Insufficient Data Announcements

- **Phytosteryl Glutamates – 3 ingredients**

● 161st Meeting Notes

- **Director's Report**
- **Re-Reviews – 2 re-opened; 7 conclusions reaffirmed**
- **Strategy Memos - Prostaglandins/Kojic Acid/Aluminum**
- **Use Table Format**
- **GRAS Food Status Discussion**
- **Airbrush Boilerplate Discussion**
- **Scientific Literature Reviews – available or under development**
- **Next Expert Panel Meeting – Monday and Tuesday, September 26-27, 2022**

Final Safety Assessments

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 Unpublished data cited as references in CIR safety assessments are available for review.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.

Acryloyloxyethyl Phosphorylcholine Polymers

The Panel issued a Final Report with the conclusion that the following 8 ingredients are safe in cosmetics in the present practices of use and concentrations described in the safety assessment.

Acrylic Acid/Phosphorylcholine Glycol Acrylate Crosspolymer
C4-18 Alkyl Methacrylate/Methacryloyloxyethyl Phosphorylcholine Copolymer*
Hydroxyethylcellulose/Phosphorylcholine Glycol Acrylate Copolymer*
Phosphorylcholine Glycol Methacrylate/PEG-10 dimethacrylate Crosspolymer*
Polyphosphorylcholine Glycol Acrylate
Polyquaternium-10/Phosphorylcholine Glycol Acrylate Copolymer*
Polyquaternium-51
Polyquaternium-61

**Not reported to be in current use. Were ingredients in this group not in current use to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in this group.*

The Panel considered the available data to be adequate to determine safety for the use of these ingredients as reported to be used in cosmetics. The Panel's respiratory exposure resource document (https://www.cir-safety.org/cir-findings) notes that airbrush delivery systems present a potential safety concern, and that no data are available for consumer habits and practices thereof. As a result of deficiencies in these critical data needs, the risk and safety of cosmetic ingredients applied by airbrush delivery systems cannot be assessed by the Panel. Therefore, the Panel has found the data insufficient to support the safe use of cosmetic ingredients applied via an airbrush delivery system.

Barley

The Panel issued a Final Report with the conclusion that the following 5 barley-derived ingredients are safe in cosmetics in the present practices of use and concentrations described in this safety assessment:

Hordeum Distichon (Barley) Seed Flour*
Hordeum Vulgare Seed Extract
Hordeum Vulgare Seed Flour
Hordeum Vulgare Seed Water*
Hordeum Vulgare Sprout Extract*

**Not reported to be in current use. Were ingredients in this group not in current use to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in this group.*

The Panel noted that the barley seed- and sprout-derived ingredients that are reviewed in this safety assessment are found in foods that are consumed daily, and daily exposure from food use would result in much greater systemic exposures than those from use in cosmetic products. This fact, coupled with negative findings in human dermal irritation and sensitization studies on whole plant extracts and seed extracts, led the Panel to determine that barley seed- and sprout-derived ingredients are safe for use in cosmetic products.

However, the Panel also concluded that the available data are insufficient to make a determination of safety on the following 11 barley-derived ingredients:

Hordeum Distichon (Barley) Extract
Hordeum Vulgare Extract
Hordeum Vulgare Flower/Leaf/Stem Juice**
Hordeum Vulgare Juice**
Hordeum Vulgare Leaf Extract
Hordeum Vulgare Leaf Juice
Hordeum Vulgare Leaf Powder**
Hordeum Vulgare Leaf/Stem Powder**
Hordeum Vulgare Powder**
Hordeum Vulgare Root Extract
Hordeum Vulgare Stem Water**

***There are currently no uses reported for these ingredients.*

The additional data needed to determine safety for these cosmetic ingredients are:

- Explanation of the plant parts used to make the whole plant extracts, Hordeum Distichon (Barley) Extract and Hordeum Vulgare Extract
- Method of manufacturing for Hordeum Distichon (Barley) Extract and Hordeum Vulgare Extract
- Composition and impurities data for Hordeum Distichon (Barley) Extract and Hordeum Vulgare Extract
- 28-day dermal toxicity data on the whole plant extract Hordeum Distichon (Barley) Extract and Hordeum Vulgare Extract
    - If positive, developmental and reproductive toxicity and genotoxicity data
- Alternatively, acceptable evidence of safe use as food for ingredients derived from the flower, leaf, stem, and root
- Dermal irritation and sensitization data for Hordeum Leaf Extract or other leaf ingredients

The Panel's respiratory exposure resource document (https://www.cir-safety.org/cir-findings) notes that airbrush delivery systems present a potential safety concern, and that no data are available for consumer habits and practices thereof. As a result of deficiencies in these critical data needs, the safety of cosmetic ingredients applied by airbrush delivery systems cannot be assessed by the Panel. Therefore, the Panel has found the data insufficient to support the safe use of cosmetic ingredients applied via an airbrush delivery system.

Glucosamine

The Panel issued a Final Report with the conclusion that the following 4 ingredients are safe in the present practices of use and concentration as described in the safety assessment when formulated to be non-irritating.

Acetyl Glucosamine
Glucosamine
Glucosamine HCl
Glucosamine Sulfate*

**Not reported to be in current use. Were the ingredient in this group not in current use to be used in the future, the expectation is that it would be used in product categories and at concentrations comparable to others in this group.*

The safety of these ingredients is supported by available in chemico/in vitro sensitization data, clinical sensitization data, a lack of case reports, systemic toxicity data, and the safe use of these ingredients as dietary supplements and debulking agents.

The Panel's respiratory exposure resource document (https://www.cir-safety.org/cir-findings) notes that airbrush delivery systems present a potential safety concern, and that no data are available for consumer habits and practices thereof. As a result of deficiencies in these critical data needs, the safety of cosmetic ingredients applied by airbrush delivery systems cannot be assessed by the Panel. Therefore, the Panel has found the data insufficient to support the safe use of cosmetic ingredients applied via an airbrush delivery system.

Glyceryl Acrylates

The Panel issued a Final Report with the conclusion that the following 4 ingredients are safe in cosmetics in the present practices of use and concentrations described in the safety assessment.

Caprylyl Glycol/Glycerin/Polyacrylic Acid Copolymer
Glyceryl Acrylate/Acrylic Acid Copolymer
Glyceryl Polyacrylate
Glyceryl Polymethacrylate

The Panel's respiratory exposure resource document (https://www.cir-safety.org/cir-findings) notes that airbrush delivery systems present a potential safety concern, and that no data are available for consumer habits and practices thereof. As a result of deficiencies in these critical data needs, the safety of cosmetic ingredients applied by airbrush delivery systems cannot be assessed by the Panel. Therefore, the Panel has found the data insufficient to support the safe use of cosmetic ingredients applied via an airbrush delivery system.

Radish Root

The Panel issued a Final Report with the conclusion these 7 radish root-derived ingredients are safe as used in the present practices of use and concentration described in the safety assessment when formulated to be non-sensitizing:

Lactobacillus/Radish Root Ferment Extract Filtrate*
Lactobacillus/Radish Root Ferment Filtrate
Leuconostoc/Radish Root Ferment Filtrate
Leuconostoc/Radish Root Ferment Lysate Filtrate*
Raphanus Sativus (Radish) Root Extract
Raphanus Sativus (Radish) Root Juice*
Raphanus Sativus (Radish) Root Powder*

**Not reported to be in current use. Were ingredients in this group not in current use to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in the group*

The Panel considered the available data to be adequate to determine safety for the use of these ingredients as reported to be used in cosmetics. Safety of these ingredients is further supported by the root portion of the *Raphanus sativus* plant being consumed as food, and that foods fermented with lactic acid and *Leuconostoc* bacterial strains have generally recognized as safe (GRAS) status, further mitigating potential systemic toxicity concerns.

The Panel's respiratory exposure resource document (https://www.cir-safety.org/cir-findings) notes that airbrush delivery systems present a potential safety concern, and that no data are available for consumer habits and practices thereof. As a result of deficiencies in these critical data needs, the safety of cosmetic ingredients applied by airbrush delivery systems cannot be assessed by the Panel. Therefore, the Panel has found the data insufficient to support the safe use of cosmetic ingredients applied via an airbrush delivery system.

Sage

The Panel issued a Final Report with the conclusion that the following 6 *Salvia officinalis* (sage)-derived ingredients are safe in cosmetics in the present practices of use and concentration described in the safety assessment when formulated to be non-sensitizing:

Salvia Officinalis (Sage) Leaf
Salvia Officinalis (Sage) Leaf Extract
Salvia Officinalis (Sage) Leaf Oil
Salvia Officinalis (Sage) Leaf Powder*
Salvia Officinalis (Sage) Leaf Water
Salvia Officinalis (Sage) Oil

**Not reported to be in current use. Were this ingredient to be used in the future, the expectation is that it would be used in product categories and at concentrations comparable to others in this group*.

Systemic and dermal toxicity concerns were mitigated by the GRAS status of *Salvia officinalis* (sage) leaves and negative findings from dermal irritation and sensitization studies for leaf-derived ingredients, respectively.

The Panel also concluded that the available data are insufficient to make a determination that the following 6 *Salvia officinalis* (sage)-derived ingredients are safe under the intended conditions of use in cosmetic formulations:

Salvia Officinalis (Sage) Extract
Salvia Officinalis (Sage) Flower/Leaf/Stem Extract**
Salvia Officinalis (Sage) Flower/Leaf/Stem Juice**
Salvia Officinalis (Sage) Flower/Leaf/Stem Water **
Salvia Officinalis (Sage) Root Extract**
Salvia Officinalis (Sage) Water

*** There are currently no uses reported for these ingredients.*

In the absence of additional data, including a 28-day dermal toxicity data for the Salvia Officinalis (Sage) Flower/Leaf/Stem Extract or Root Extract, or the whole plant, the safety of these ingredients could not be determined. Additionally, the Panel discussed the occasional challenge of ascertaining which parts of the *Salvia officinalis* plant were used in the methods of manufacture described in the assessment. The Panel determined that general descriptions of 'aerial' parts being used is not sufficient to confirm the use of flowers or stems to produce these ingredients.

The Panel's respiratory exposure resource document (https://www.cir-safety.org/cir-findings) notes that airbrush delivery systems present a potential safety concern, and that no data are available for consumer habits and practices thereof. As a result of deficiencies in these critical data needs, the safety of cosmetic ingredients applied by airbrush delivery systems cannot be assessed by the Panel. Therefore, the Panel has found the data insufficient to support the safe use of cosmetic ingredients applied via an airbrush delivery system.

Zeolites

The Panel issued a Final Amended Report with the conclusion that the following 6 zeolite ingredients are safe in cosmetics in the present practices of use and concentration described in the safety assessment.

Ammonium Silver Zeolite*
Gold Zeolite*
Silver Copper Zeolite*
Titanium Zeolite*
Zeolite
Zinc Zeolite

**Not reported to be in current use. Were ingredients in this group not in current use to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in this group.*

The Panel noted that erionite is a naturally-occurring fibrous material that is carcinogenic to humans and animals, and is significantly more structurally similar to asbestos than the zeolite ingredients discussed in this report (i.e., the superstructures of the zeolites in this report comprise layered sheets, while those of erionite (and by comparison, asbestos) are fibrous). The Panel stressed that the cosmetics industry should continue to use current good manufacturing processes (cGMPs) to ensure erionite is not present in cosmetic formulations.

The Panel also expressed concern about the presence of heavy metals and free metal ions in zeolite ingredients. The metals in Ammonium Silver Zeolite, Gold Zeolite, Silver Copper Zeolite, Titanium Zeolite, and Zinc Zeolite would have limited metal exchange into solution due to the nature of the zeolite framework. The zeolites are also not likely to absorb through the skin. Although other heavy metals (e.g., lead, nickel, mercury, etc.) may be present during mining, those should be removed through processing. Accordingly, the Panel stressed that the cosmetics industry should continue to use the necessary procedures to limit these impurities in the ingredients before blending into cosmetic formulations.

The Panel's respiratory exposure resource document (https://www.cir-safety.org/cir-findings) notes that airbrush delivery systems present a potential safety concern, and that no data are available for consumer habits and practices thereof. As a result of deficiencies in these critical data needs, the safety of cosmetic ingredients applied by airbrush delivery systems cannot be assessed by the Panel. Therefore, the Panel has found the data insufficient to support the safe use of cosmetic ingredients applied via an airbrush delivery system.

Tentative Safety Assessments

For the tentative safety assessments listed below, to be posted on the CIR website at www.cir-safety.org 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, for full consideration. Submissions received thereafter may be in jeopardy of not being considered by the Panel.*** *The updated reports may be scheduled for review by the Expert Panel as early as at its* ***September 26-27, 2022*** *meeting.*

Fatty Esters End-Capped Alkoxylates

The Panel issued a Tentative Report for public comment with the conclusion that PEG/PPG-8/3 Diisostearate is safe cosmetics in the present practices of use and concentration described in this safety assessment.

The Panel noted the lack of developmental and reproductive toxicity (DART) and genotoxicity studies for fatty ester end-capped alkoxylated ingredients. However, the Panel also noted these ingredients are large molecules (> 1600 Da) and are not likely to absorb readily through the skin. These factors, coupled with the favorable safety profile and lack of structural features associated with genotoxicity, mitigated the need for DART and genotoxicity data.

However, the data are insufficient to make a determination of safety for the following 13 fatty ester end-capped alkoxylate:

PEG-15 Butylene Glycol Diisostearate**
PEG-10 Glyceryl Diisostearate**
PEG-15 Glyceryl Diisostearate**
PEG-20 Glyceryl Diisostearate**
PEG-30 Glyceryl Diisostearate**
PEG-60 Glyceryl Diisostearate**
PEG-12 Glyceryl Dimyristate
PEG-12 Glyceryl Dioleate**
PEG-3 Glyceryl Distearate
PEG-4 Glyceryl Distearate**
PEG-12 Glyceryl Distearate
PEG-23 Glyceryl Distearate**
PEG-4 Polyglyceryl-2 Distearate**

*** There are currently no uses reported for these ingredients.*

The additional data needed to determine safety for these cosmetic ingredients are:

- Method and manufacturing for all ingredients except PEG/PPG-8/3 Diisostearate
- Composition and impurities data for all ingredients except PEG/PPG-8/3 Diisostearate

The Panel's respiratory exposure resource document (https://www.cir-safety.org/cir-findings) notes that airbrush delivery systems present a potential safety concern, and that no data are available for consumer habits and practices thereof. As a result of deficiencies in these critical data needs, the safety of cosmetic ingredients applied by airbrush delivery systems cannot be assessed by the Panel. Therefore, the Panel has found the data insufficient to support the safe use of cosmetic ingredients applied via an airbrush delivery system.

Fatty Ethers

The Panel issued a Tentative Report for public comment with the conclusion that the following 8 ingredients are safe as used in the present practices of use and concentration described in the safety assessment:

Cetyl Dimethylbutyl Ether
Dicaprylyl Ether
Dicetyl Ether*
Didecyl Ether *
Diisononyl Ether*
Dilauryl Ether*
Dimyristyl Ether*
Distearyl Ether

**Not reported to be in current use. Were ingredients in this group not in current use to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in this group.*

Dicaprylyl Ether has 255 reported uses and Distearyl Ether has 6 reported uses; the Panel discussed the absence of method of manufacturing data for ingredients with the highest reported frequencies of use. The Panel noted, however, the data stating that Dicaprylyl Ether and Distearyl Ether were tested at ≥ 99.1% purity. Negative DART data, as well as negative genotoxicity data, a lack of structural alerts, and data demonstrating lack of dermal absorption, mitigated systemic toxicity concerns. Irritation and sensitization study data results further assured the Panel of the dermal safety of these ingredients.

The Panel's respiratory exposure resource document (https://www.cir-safety.org/cir-findings) notes that airbrush delivery systems present a potential safety concern, and that no data are available for consumer habits and practices thereof. As a result of deficiencies in these critical data

needs, the safety of cosmetic ingredients applied by airbrush delivery systems cannot be assessed by the Panel. Therefore, the Panel has found the data insufficient to support the safe use of cosmetic ingredients applied via an airbrush delivery system.

Ginger

The Panel issued a Tentative Report for public comment with the conclusion that the following 7 *Zingiber officinale* (ginger)-derived ingredients are safe as used in the present practices of use and concentration as described in the safety assessment, when formulated to be non-sensitizing:

Zingiber Officinale (Ginger) Rhizome Extract
Zingiber Officinale (Ginger) Root*
Zingiber Officinale (Ginger) Root Extract
Zingiber Officinale (Ginger) Root Juice*
Zingiber Officinale (Ginger) Root Oil
Zingiber Officinale (Ginger) Root Powder
Zingiber Officinale (Ginger) Water

**Not reported to be in current use. Were ingredients in this group not in current use to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in this group.*

The Panel found the available data to be sufficient to conclude on the safety for Zingiber Officinale (Ginger) Water, as this ingredient, according to manufacturers, is reported to be prepared via the distillation of ginger roots.

However, the Panel determined that the data are insufficient to make a determination of safety for the following non-root *Zingiber officinale* (ginger)-derived ingredients

Zingiber Officinale (Ginger) Leaf Cell Extract
Zingiber Officinale (Ginger) Extract**

*** There are currently no uses reported for this ingredient.*

In order evaluate safety, the Panel requested the following data:

- Method of manufacturing, composition, and impurities data for Zingiber Officinale (Ginger) Leaf Cell Extract
  - If the composition of Zingiber Officinale (Ginger) Leaf Cell Extract notably differs from the root-derived ginger ingredients, the following are needed
    - Systemic toxicity data (28-d dermal toxicity, genotoxicity, developmental/reproductive toxicity, and carcinogenicity data)
    - Dermal irritation/sensitization data
- Irritation and sensitization data on Zingiber Officinale (Ginger) Extract at the maximum concentration of use

The Panel's respiratory exposure resource document (https://www.cir-safety.org/cir-findings) notes that airbrush delivery systems present a potential safety concern, and that no data are available for consumer habits and practices thereof. As a result of deficiencies in these critical data needs, the safety of cosmetic ingredients applied by airbrush delivery systems cannot be assessed by the Panel. Therefore, the Panel has found the data insufficient to support the safe use of cosmetic ingredients applied via an airbrush delivery system.

Insufficient Data Announcements

For this insufficient data announcement, 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 August 23, 2022, for full consideration****.* ***Submissions received thereafter might not be considered by the Panel at their next meeting.*** *This report may be scheduled for review by the Panel as soon as the* ***September 26-27, 2022*** *meeting.*

Phytosteryl Glutamates

The Panel issued an Insufficient Data Announcement (IDA) for these 3 phytosterol glutamate ingredients:

Phytosteryl/Behenyl/Octyldodecyl Lauroyl Glutamate
Phytosteryl/Behenyl/Octyldodecyl/Isostearyl Lauroyl Glutamate
Phytosteryl/Octyldodecyl Lauroyl Glutamate

The additional data needed to determine safety for these cosmetic ingredients are:

- Method of manufacturing data
- Impurities data
- 28-day dermal toxicity data
  - If positive, other toxicity data, including DART, genotoxicity, and carcinogenicity data, may be needed
- Irritation and sensitization data for Phytosteryl/Octyldodecyl Lauroyl Glutamate at maximum concentration of use
- ocular irritation data, if available

161st Meeting Notes

Director's Report

Dr. Heldreth remarked on the great fortune to have 2 amazing new Panel members, Drs. Allan Rettie and David Ross, join at this meeting. There was a consensus that they did a splendid job.

Dr. Heldreth stated that he knows Dr. Ron Shank would rather kiss his horse and ride off into the sunset without fanfare, but that all of the Panel and CIR Staff were going to miss this cowboy. Dr. Shank completed his bachelors and doctorate at MIT, achieving the 1st doctorate there in toxicology. He continued his education as a postdoctoral fellow at the Medical Research Council Laboratories in Surrey, England. He returned to MIT as a professor for a time, but then rode out west to the University of California, Irvine, where he served as professor, director, chair, and emeritus professor. Dr. Shank continued on to achieve many accolades, but Dr. Heldreth's favorite is that he joined this Panel in 1984. Thirty-eight years of distinguished serve, wow! Dr. Heldreth just wanted to say thank you Ron, we have learned so much from you. He also noted that we all will miss seeing Ron and Cathy (Ron's wonderful spouse) at these meetings. He wish him all the best in his retirement.

Dr. Heldreth reiterated how fortunate it is to have such an amazing group of clinicians and scientists on this Panel. He noted that every member of this Panel is deserving of many accolades. Indeed, Dr. Bergfeld, after receiving the Master Dermatologist award in 2012, has this year been awarded the Master Clinician award by the Cleveland Clinic.

The CIR Staff have also been busy. Dr. Jinqiu Zhu recently added to the alphabet soup following his name; he had PhD, DABT, ERT, but now he has also achieved DCST, which is the Chinese equivalent of the American board of toxicology diplomat status. And CIR's newest staff member, Regina Tucker, graduated with her Master of Science degree in skin biology, while writing the reports presented at this meeting.

Although we have one more of these virtual meetings in September, he noted how he is looking forward to seeing everyone in-person in December.

Re-Reviews

In accordance with its Procedures, the Panel evaluates the conclusions of previously-issued safety assessments approximately every 15 years. At this meeting, the Panel considered 9 previous assessments for re-review. The Panel determined that the following two reports should be reopened; a Draft Amended Report will be presented to the Panel for each of these safety assessments at a later meeting.

- Acid Orange 3 – 1 ingredient
- Amino Cresols – 6 ingredients

In contrast, the Panel reaffirmed the conclusions reached for the following 7 safety assessments (choosing to no re-open the original reports). A re-review summary will be presented to the Panel for each of these safety assessments at a later meeting, as early as the September meeting.

- Amyl Acetates
- *N,N*-Bis(2-Hydroxyethyl)-*p*-Phenylenediamine Sulfate
- Cottonseed Glycerides
- Glycol Stearate
- PEGS Soy Sterol
- Polyacrylamide
- PPGs Stearyl Ethers

Strategy Memos - Prostaglandins/Kojic Acid/Aluminum

Prostaglandins – at the March Panel meeting, representatives from the FDA were requested to evaluate whether the safety evaluation of products containing prostaglandin ingredients is exclusively within the purview of FDA Drugs, or if the use of such ingredients could be considered within the parameters of cosmetic use. It was determined that for some products containing prostaglandins, drug claims are not made, and therefore, those ingredients could be registered in the VCRP. Accordingly, prostaglandins will be considered at the September meeting for inclusion on the 2023 Priority List.

Kojic Acid – according to the standard 15-year re-review clock, the safety of this ingredient should be reconsidered in 2025. The Panel was asked if the re-review should be accelerated based on the European Commission Scientific Committee on Consumer Safety opinion, issued in March, that Kojic Acid was deemed not safe when used as a skin lightening agent in cosmetic products at concentrations of up to 1%, due to concerns related to potential "endocrine disrupting" properties. The Panel determined to accelerate this re-review.

Aluminum Hydroxide – according to the standard 15-year re-review clock, the safety of these ingredient should be reconsidered in 2031. The Panel was asked if the re-review should be accelerated because aluminum was selected by ACDS as the "Allergen of the Year." Because the issue concern for aluminum is in with use in vaccines, not cosmetics, the Panel determined to not accelerate this re-review.

Use Table Format

The Panel reviewed proposed changes to the Use Table format that is utilized in each report. As a result of their discussions, the Panel has requested that a letter be submitted by CIR to the FDA requesting updates to the VCRP product categories. The requested updates would provide the Panel with additional information regarding exposure. No updates to the use table format were finalized at this meeting.

GRAS Food Status Discussion

The Panel discussed how food and GRAS status should be utilized in the safety assessments. The Panel agreed the draft white paper contributes to develop a weight of evidence (WoE) decision-making approach for considering GRAS status in the safety evaluation of cosmetic ingredients; however, they determined that the document would be better suited as an internal SOP for CIR Staff (i.e., not to be issued as a white paper/resource document). The Panel deliberated as to how to utilize GRAS as an assessment factor in accessing the systemic toxic potential of cosmetic substances. The Panel noted the recognition of GRAS status should relate to the conditions of intended use, and the differences of route exposure between cosmetic and food ingredients (topical vs. oral) warrant careful consideration. The Panel requested formal comments from the US FDA on the document and would reconsider the document with such additional relevant information at an upcoming meeting.

Airbrush Boilerplate Discussion

The Panel discussed the airbrush boilerplate language that has been proposed for addition in all reports. It was the consensus of the Panel that insufficiencies affecting the ability of the Panel to address and conclude on the safety of cosmetic ingredients as used in airbrush delivery systems should be included in the Discussion of all reports. The Panel also edited some of the language proposed by the CIR staff for inclusion in the Cosmetic Use section of each report.

The Panel members expressed great concern that they are not being informed of ingredients that are used in cosmetic formulations that are intended for use with airbrush delivery systems, and queried the FDA about adding a category to the VCRP specifically identifying airbrush use. An FDA representative informed the Panel that there is a specific process that is required for any changes to the VCRP. CIR Staff were tasked with communicating further with the FDA about such a potential change.

Scientific Literature Reviews

The following Scientific Literature Reviews (SLRs) are posted at 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.

Basic Yellow 87
Charcoal Powder
Polyglycerins
Hyaluronates
Malva sylvestris (Mallow)-Derived Ingredients
Olea europaea (Olive)-Derived Ingredients
Phenyl-Substituted Methicones
Polyhydroxystearic Acid
Pyridoxine and Pyridoxine HCl
Sodium Lauroamphoacetate Group
Trisodium Ethylenediamine Disuccinate Group
Zanthoxylum piperitum – Derived Ingredients

Next Expert Panel Meeting

Monday and Tuesday, September 26-27, 2022, to be held virtually via Microsoft Teams.

Please submit a request for an invitation prior to the meeting if you would like to attend. The link will be available approximately a month before the meeting and will be found on the 162nd meeting page of the CIR website. https://www.cir-safety.org/.