Post Meeting Announcement

Expert Panel for Cosmetic Ingredient Safety
160th Meeting (March 7-8, 2022) - Findings

March 11, 2022

● Final Safety Assessments

- **Acrylamide/Acrylate Copolymers – 6 ingredients – Safe**
- **Methicones – 30 ingredients – Split (safe with qualifications; insufficient data for airbrush use)**
- ***Rosa damascena* – 10 ingredients – Safe with qualifications**
- **Ubiquinone – 4 ingredients – Safe**

● Tentative Safety Assessments

- **Barley – 16 ingredients – Split (5 safe; 11 insufficient)**
- **Diatomaceous Earth – 1 ingredient – Safe**
- **Glucosamine – 4 ingredients – Safe with qualifications**
- **Glyceryl Acrylates – 4 ingredients – Safe**
- **Glycolactones – 5 ingredients – Split (1 safe; 4 insufficient)**
- **Hydroxyacetophenone – 1 ingredient – Safe**
- ***Portulaca oleracea* – 4 ingredients – Safe with qualifications**
- **Starch Phosphates – 4 ingredients – Safe**
- **Zeolites – 6 ingredients - Safe**

● Insufficient Data Announcements

- **Clays – 7 ingredients**
- ***Rosa centifolia* – 12 ingredients**

● 160th Meeting Notes

- **Director's Report**
- **Presentation – Skin Sensitization**
- **Methacrylate Ester Monomers – Re-Review Summary**
- **2023 Draft Priorities**
- **Strategy Memo – Yeast**
- **Airbrush Discussion – and Boilerplate**
- **Scientific Literature Reviews – available or under development**
- **Next Expert Panel Meeting – Thursday and Friday, June 16-17, 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 Unpublished data cited as references in CIR safety assessments are available for review.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.

Acrylamide/Acrylate Copolymers

The Expert Panel for Cosmetic Ingredient Safety (Panel) issued a Final Report with the conclusion that the following 16 acrylamide/acrylate copolymer ingredients are safe as used in cosmetics in the present practices of use and concentrations as described in the safety assessment. Formulators of these ingredients should ensure that the final monomer concentrations do not exceed 5 ppm. The Panel was made aware of the use of Acrylates/Octylacrylamide Copolymer in airbrush devices from sources outside of the FDA's Voluntary Cosmetic Registration Program (VCRP) and concentration survey processes conducted by the Personal Care Product Council (Council). The Panel determined that there were insufficient data to conclude on the safety of these acrylamide/acrylate copolymer ingredients when used in airbrush devices.

Acrylamide/Ammonium Acrylate Copolymer
Acrylamide/Sodium Acrylate Copolymer
Acrylates/Acrylamide Copolymer
Acrylates/t-Butylacrylamide Copolymer
Acrylates/Methacrylamide Copolymer
Acrylates/Octylacrylamide Copolymer
AMP-Acrylates/C1-18 Alkyl Acrylate/C1-8 Alkyl Acrylamide Copolymer
AMP-Acrylates/C1-18 Alkyl Acrylate/C1-8 Alkyl Acrylamide/Hydroxyethylacrylate Copolymer*
t-Butylacrylamide/Dimethylacrylamide/PEG-14 Diacrylate Crosspolymer*
Butyl Acrylate/Isopropylacrylamide/PEG-18 Dimethacrylate Crosspolymer*
Corn Starch/Acrylamide/Sodium Acrylate Copolymer
Dimethyl Acrylamide/Hydroxyethyl Acrylate/Methoxyethyl Acrylate Copolymer
Dimethylacrylamide/Lauryl Methacrylate Copolymer
Potassium Acrylates/Acrylamide Copolymer*
Sodium Acrylate/Hydroxyethyl Acrylamide Copolymer*
Starch/Acrylates/Acrylamide Copolymer*

**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.*

Methicones

The Panel issued a Final Amended Report with a split conclusion for these 30 ingredients. Specifically, the Panel concluded that these ingredients are safe as used in cosmetics in the present practices of use and concentration as described in the report when formulated to be non-irritating, with the exception that the data are insufficient to make a determination of safety for use of these ingredients in products that may be incidentally inhaled when applied using airbrush devices.

Amino Bispropyl Dimethicone
Aminopropyl Dimethicone
Amodimethicone
Amodimethicone Hydroxystearate*
Behenoxy Dimethicone
C20-24 Alkyl Dimethicone
C20-24 Alkyl Methicone*
C24-28 Alkyl Dimethicone*
C24-28 Alkyl Methicone
C26-28 Alkyl Dimethicone
C26-28 Alkyl Methicone*
C30-45 Alkyl Dimethicone
C30-45 Alkyl Methicone
C30-60 Alkyl Dimethicone
C32 Alkyl Dimethicone*
Capryl Dimethicone
Caprylyl Methicone
Cetearyl Methicone
Cetyl Dimethicone
Dimethicone
Dimethoxysilyl Ethylenediaminopropyl Dimethicone
Hexyl Dimethicone
Hexyl Methicone*
Hydroxypropyldimethicone*
Methicone
Stearamidopropyl Dimethicone*
Stearoxy Dimethicone
Stearyl Dimethicone
Stearyl Methicone
Vinyl Dimethicone

**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 agreed that methods of use, including concentration of use and exposure duration and frequency, for these ingredients in products applied using airbrush devices are still lacking. Particle size distribution, as well as additional data, are still needed to make a determination of safety for the use of these ingredients in products delivered via airbrush technology. Additional data needs include information on the regulation of spray, or other, delivery systems for cosmetics applied via airbrush technology; and methods of use, including concentration of use and exposure duration and frequency, for all cosmetics applied via airbrush technology Thus, the Panel deemed the available data insufficient to make a determination of safety for this product category.

Rosa damascena

The Panel issued a Final Report with the conclusion that the following 10 ingredients are safe as used in cosmetics in the present practices of use and concentration described in the safety assessment when formulated to be non-sensitizing.

Hydrolyzed Rosa Damascena Flower Extract*
Rosa Damascena Bud Extract*
Rosa Damascena Extract
Rosa Damascena Flower
Rosa Damascena Flower Extract
Rosa Damascena Flower Oil
Rosa Damascena Flower Powder
Rosa Damascena Flower Water
Rosa Damascena Flower Water Extract
Rosa Damascena Flower Wax

**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 acknowledged the presence of potentially sensitizing constituents in the composition of these ingredients; accordingly, the Panel stated that because final product formulations may contain multiple botanicals, each possibly containing the same constituents of concern, formulators are advised to be aware of these constituents and to avoid reaching levels that may be hazardous to consumers. According to 2022 VCRP data, Rosa Damascena Flower Water has 302 reported

uses, Rosa Damascena Flower Extract has 293 reported uses, and Rosa Damascena Flower Oil has 229 reported uses. Additionally, updated results from the 2019 Council survey also indicate that the highest reported maximum use concentration for these ingredients (Rosa Damascena Flower Oil at up to 10.8% in other skincare preparations) is an essential oil which is sold with instructions to dilute before use; the second highest reported concentration of use is for Rosa Damascena Flower Water, at up to 1.9% in foundations.

Ubiquinone

The Panel issued a Final Report with the conclusion that the following 4 ingredients are safe as used in cosmetics in the present practices of use and concentrations described in the safety assessment. The safety of these ingredients was supported by the available oral toxicity, developmental and reproductive toxicity, genotoxicity, carcinogenicity, and irritation/sensitization data, as well as by the natural presence of ubiquinone in the body and widespread use as a dietary supplement.

Disodium Ubiquinone | Hydroxydecyl Ubiquinone* | Ubiquinol | Ubiquinone

**Concentrations of use were not reported. Were this ingredient found to be used in the future, the expectation is that it would be used in product categories and at concentrations comparable to the other ingredients.*

According to 2022 VCRP data, Ubiquinone, is reported to be used in 221 formulations (208 of which are leave-on formulations). Results from concentration of use surveys, conducted by Council in 2018 and 2020, indicate that Ubiquinone also has the highest reported concentration of use, at up to 0.05% in body and hand products.

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* ***June 16-17, 2022*** *meeting. However, some of the tentative safety assessments below may be posted later (with an appropriate 60-day comment period) and likely be scheduled for review by the Panel at its* ***September 2022*** *meeting.*

Barley

The Panel issued a Tentative Report for public comment with the conclusion that the following 5 barley-derived ingredients are safe as used 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 larger systemic exposures than those from use in cosmetic products. The potential for systemic exposure from the absorption of these ingredients through the skin is much less than the potential for systemic exposure from absorption through oral exposures. 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, additional data, such as developmental and reproductive toxicity and genotoxicity data, may be needed
    - 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

Diatomaceous Earth

The Panel issued a Tentative Report for public comment with the conclusion that Diatomaceous Earth is safe as used in cosmetics in the present practices of use and concentration described in this safety assessment. Diatomaceous Earth is a polymorph of silica, or silicon dioxide, and is naturally-occurring. The Panel understands that Diatomaceous Earth, whether unprocessed (natural) or heat-processed (calcined or flux-calcined), can contain crystalline silica, a known respiratory carcinogen. However, the Panel noted that chronic inhalation studies of flux-calcined Diatomaceous Earth (which may comprise up to 60% crystalline

silica) were negative for fibrosis or tumors in rats and guinea pigs. This data, coupled with the fact that Diatomaceous Earth is used as relatively low concentrations in cosmetics, mitigated concerns about use in products that may be incidentally inhaled, including face masks which may flake during drying.

Glucosamine

The Panel issued a Tentative Report for public comment with the conclusion that Acetyl Glucosamine, Glucosamine, Glucosamine HCl, and Glucosamine Sulfate* are safe as used in cosmetics in the present practices of use and concentration, when formulated to be non-irritating. The Panel noted the mild cumulative irritation during the induction phase of a human repeat insult patch test (HRIPT) evaluating an eye lotion containing 2% Acetyl Glucosamine. Because this irritation was observed at a concentration of 2%, and the maximum concentration of use of Acetyl Glucosamine in cosmetics is reported to be 5%, formulators should ensure that products containing these glucosamine ingredients are formulated to be non-irritating. In addition, the Panel considered the lack of human sensitization data at the maximum use concentration of 5%; however, the available in vitro and in vivo sensitization data coupled with the Panel's clinical experience and a lack of sensitization case reports, mitigated this concern. The safety of these ingredients is further supported by their use as dietary supplements/debulking agents, and the available systemic toxicity data.

**Not reported to be in current use. Were this 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.*

Glyceryl Acrylates

The Panel issued a Tentative Report for public comment with the conclusion that the Caprylyl Glycol/Glycerin/Polyacrylic Acid Copolymer, Glyceryl Acrylate/Acrylic Acid Copolymer, Glyceryl Polyacrylate, and Glyceryl Polymethacrylate are safe as used in cosmetics in the present practices of use and concentrations described in the safety assessment. The Panel determined that the available data were sufficient to support the safety of all 4 glyceryl acrylates. Representative data on method of manufacturing and impurities were adequate for evaluating the entire group of ingredients. Safety was further supported by the large molecular weights of these ingredients. Glyceryl Polyacrylate, for example, has a molecular weight greater than 500,000 Da. The other polymers are also very large, which precludes dermal absorption.

Glycolactones

The Panel issued a Tentative Report for public comment with the conclusion that Gluconolactone is safe as used in cosmetics in the present practices of use and concentration as described in the safety assessment. The Panel also concluded that the available data are insufficient to make a determination that the remaining ingredients (i.e., Galactonolactone, Glucarolactone, Glucoheptonolactone, and Ribonolactone, none of which are reported to be in use) are safe under the intended conditions of use in cosmetic formulations. To conclude on the safety of Glucarolactone, and Glucoheptonolactone, the Panel requires impurities and cosmetic-specific method of manufacturing data. In addition, impurities data are required to determine the safety of Galactonolactone and Ribonolactone.

Hydroxyacetophenone

The Panel issued a Tentative Report for public comment with the conclusion that this ingredient is safe as used in cosmetics in the present practices of use and concentration described in the safety assessment. The Panel noted that Hydroxyacetophenone is conferred a generally recognized as safe (GRAS) status as a food flavoring substance by the Flavoring, Extract, and Manufacturing Association (FEMA). Additionally, the Panel noted reported purity of 99.5%, low concentrations of use in cosmetics, a favorable toxicological profile, and lack of chemical structure alerts for this ingredient; the Panel agreed that these considerations mitigated systemic toxicity concerns. The Panel noted positive ocular irritation data and considered that the ingredient was tested undiluted and at a much higher concentration than possible based the reported maximum use concentration near the eye, at up to 0.23% in eye lotions and eye makeup removers. Hence, the Panel stated that manufacturers should be aware of the potential for ocular irritation and assure that these products are formulated to be non-irritating.

Portulaca oleracea

The Panel issued a Tentative Report for public comment with the conclusion that the following 4 *Portulaca oleracea*-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:

Portulaca Oleracea Extract	Portulaca Oleracea Juice*
Portulaca Oleracea Flower/Leaf/Stem Extract*	Portulaca Oleracea 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.*

After reviewing scientific literature that confirmed the use of the whole *Portulaca oleracea* plant as a food, the Panel's previous concerns regarding systemic toxicity were mitigated. The potential for systemic exposure from the absorption of these ingredients through the skin is much less than the potential for systemic exposure from absorption through consumption. This fact, coupled with negative findings in human dermal irritation and sensitization studies on the whole plant extract, led the Panel to determine that *Portulaca oleracea*-derived ingredients are safe for use in cosmetic products. The Panel identified the presence of potentially sensitizing constituents in the composition of these ingredients; accordingly, the Panel stated that because final product formulations may contain multiple botanicals, each possibly containing the same constituents of concern, formulators are advised to be aware of these constituents and to avoid reaching levels that may be hazardous to consumers.

Starch Phosphates

The Panel issued a Tentative Report for public comment with the conclusion that these 4 starch phosphates are safe as used in cosmetics in the present practices of use and concentration described in the safety assessment.

Distarch Phosphate	Hydroxypropyl Starch Phosphate
Distarch Phosphate Acetate*	Sodium Hydroxypropyl Starch Phosphate

**Not reported to be in current use. Were this 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 Panel removed Sodium Dimaltodextrin Phosphate from the ingredient list. The Panel concluded that even though Sodium Dimaltodextrin Phosphate is made from the same monomer (α 1-4 glucose), the polymerized chains of this molecule are much shorter than the other ingredients in this report; therefore, Sodium Dimaltodextrin Phosphate is chemically different from the other ingredients, including being freely water soluble.

Zeolites

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

Ammonium Silver Zeolite*	Silver Copper Zeolite*	Zeolite
Gold Zeolite*	Titanium 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 erionite (and by comparison, asbestos) is fibrous). 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 are unavailable (i.e., not easily released) due to the nature of the zeolite framework. The zeolites are also not likely to absorb through the skin. Although other heavy metals may be present during mining, those should be readily avoidable/separable. Accordingly, the Panel stressed that the cosmetics industry should continue to use current good manufacturing processes (cGMPs) to ensure erionite and available heavy metals are not present in cosmetic formulations.

Insufficient Data Announcements

For these insufficient data announcements, 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 May 10, 2022, for full consideration****.* ***Submissions received thereafter might not be considered by the Panel at their next meeting.*** *These reports may be scheduled for review by the Panel as soon as the* ***June 16-17, 2022*** *meeting.*

Clays

The Panel issued an Insufficient Data Announcement (IDA) for these 7 clay ingredients.

Attapulgite*	Fuller's Earth*	Montmorillonite*
Bentonite*	Hectorite*	
Clay	Kaolin*	

**Previously reviewed by the Panel.*

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

- Particle size distribution (mean and range) on all ingredients, except Bentonite
- Chronic inhalation data on all ingredients, except Attapulgite and Kaolin
- Human dermal irritation and sensitization data at maximum use concentrations

Rosa centifolia

The Panel issued an IDA for these 12 *Rosa centifolia*-derived ingredients.

Rosa Centifolia Bud Extract	Rosa Centifolia Flower Oil
Rosa Centifolia Callus Culture Extract	Rosa Centifolia Flower Powder
Rosa Centifolia Extract	Rosa Centifolia Flower Water
Rosa Centifolia Flower	Rosa Centifolia Flower Wax
Rosa Centifolia Flower Extract	Rosa Centifolia Leaf Cell Extract
Rosa Centifolia Flower Juice	Rosa Centifolia Stem Extract

The additional data needed to determine safety for these cosmetic ingredients and address data insufficiencies include:

- Method of manufacturing
- Composition and impurities data for all, except the flower and bud ingredients
- Dermal toxicity (28-day dermal)
    - If positive, other toxicological endpoints (e.g., developmental and reproductive toxicity, genotoxicity, carcinogenicity, etc.) may be needed

160th Meeting Notes

Director's Report

Dr. Heldreth expressed gratitude for the Panel's and other stakeholders' continued support of the CIR program. With the conclusion of the December meeting, the Panel determined the safety of almost 6,000 ingredients since its conception in 1976. He noted that, sadly, Dr. Lisa Peterson retired from the Panel. A meeting of the CIR Steering Committee is scheduled for the following week to vote on nominees to fill the vacancy. Accordingly, Dr. Heldreth requested that candidates be

nominated as soon as possible. Nominees need not be chemists, as there have been multiple proposals to instead supplement the Panel's expertise with backgrounds in new alternative methods, inhalation toxicology, and the like.

Presentation

Additionally, Dr. Don Bjerke, of the Proctor & Gamble company and also the chair of the CIR Science and Support Committee, provided a very informative presentation, "Skin Sensitization Next Generation Risk Assessment Framework and Case Study." The presentation detailed vetted, alternative tests and strategies to assessing the skin sensitization potential of cosmetic ingredients. The presentation is available on the meeting page, https://www.cir-safety.org/sites/default/files/160th%20CIR%20EP%20Skin%20Sensitization%20NAM%20Upate%20Don%20Bjerke%20Final%20updated.pdf.

Methacrylate Ester Monomers – Rereview Summary

The Panel determined that the published final report on methacrylate ester monomers should not be reopened and that the original conclusion on these ingredients remains valid. It was agreed that an updated search of the published literature did not reveal toxicity data that warrant re-evaluation of the safety of these ingredients in cosmetic products. The Panel affirmed the written summary as presented.

2023 Draft Priorities

The CIR Procedures require preparation of the 2023 Draft Priority List for public comment by June 1, 2022. However, it is advantageous for the 2023 Draft Priority List to be issued for public comment earlier (March 2022) in the process to allow more time for the acquisition of data. The priority list is typically based on stakeholder requests (e.g., a hair dye) and frequency of use (FOU) data from FDA's VCRP; this year, VCRP data were received from the FDA on January 11 (in response to a Freedom of Information Act request).

While the list below includes only the lead ingredients, groupings of ingredients, drafted by CIR Staff, can be found in the Panel meeting book (https://www.cir-safety.org/sites/default/files/Admin_Priorities.pdf). There are 15 reports proposed, covering 60 ingredients, on the 2023 Draft Priorities List (2 of the ingredients on this list are proposed to be grouped together in 1 report). Once a proposal of a hair dye for assessment has been received from the PCPC Hair Color Technical Committee, 16 new reports in total will be proposed for the 2023 docket. Reports previously prioritized and on the CIR docket at the end of 2022, as well as an extensive number of re-reviews of previous assessments, will supplement the total number of reports to be assessed in 2023.

Information was provided that certain prostaglandins analogs might be in use in cosmetics. However, the Panel agrees that such is the purview of the FDA, as these are known drug uses. Thus, the proposed priorities for 2023 are:

Ingredients	Frequency of Use (FOU) Data Year 2022
For cause	
To be determined **– a hair dye**	-
Per FOU	
Sodium Hydrosulfite	**246**
Pelargonium Graveolens Flower Oil	**236**
Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate	**234**
Diglycerin	**211**
Polyglycerin-3	**208**
Sigesbeckia Orientalis Extract	**202**
Houttuynia Cordata Extract	**201**
Malva Sylvestris (Mallow) Extract	**198**
Palmitoyl Pentapeptide-4	**198**
Salix Alba (Willow) Bark Extract	**197**
Centaurea Cyanus Flower Extract	**196**
Lactobacillus Ferment	**196**
Copper Gluconate	**192**
Inositol	**190**
Paeonia Suffruticosa Root Extract	**189**
Nelumbo Nucifera Flower Extract	**182**

Strategy Memo - Yeast

In February 2022, data were received suggesting the use of various genus and species of yeasts in the preparation of Yeast Extract, other than *Saccharomyces cerevisiae*. Because of this, and the broad and uninformative definition of Yeast in the *Dictionary*, CIR requested the guidance of the Panel in the handling of this report, and the ingredients therein. The Panel suggested the preparation of another strategy memo, to be reviewed at a future meeting, including all yeast ingredients currently listed in the *Dictionary*, along with notations of whether or not these ingredients (or their corresponding species) are used in foods, and their frequency of use. The Panel also requested the guidance of an expert with knowledge regarding the classification and general biology of yeasts. In addition, information is requested from industry verifying which species of yeast are used in the manufacturing of Yeast and Yeast Extract.

Airbrush Discussion

The Panel expressed concerns on validation of information sources that identify cosmetic formulas associated with airbrush delivery, in consideration of Women's Voices for the Earth (WVE)'s memo, which presented the usage of Kaolin and Acrylates/Octylacrylamide Copolymer in airbrush products. The Panel re-emphasized that data identification process requires transparency and consistency; therefore, data included in CIR reports should come from sources that can be

easily validated and verified (e.g., frequency and concentration of use data are crucial in justifying exposure patterns and duration of discrete ingredient use contained in a specific formula) and need to be cited in a way that meets CIR report format requirements.

In addition, the Panel discussed the jurisdictions between different federal agencies regarding the categorization and safety management of consumer products applied with airbrush technologies. The Panel further discussed its purview in a safety evaluation process that requires addressing hazards involving both airbrush device use and exposure of discrete ingredients through sprayable applications, based upon responses recently received from US Consumer Product Safety Commission (CPSC), US FDA Center for Devices and Radiological Health, as well as the Office of Cosmetics and Colors. The Panel re-stated that the data are currently insufficient to assess the inhalation safety of each ingredient in relation to the unintended exposure resulting from the intended use of the finished products delivered by airbrush system.

The Panel determined the following boilerplate language should be included under the Cosmetic Use section of each report that is about to be reviewed at upcoming Panel meetings:

> The safety of the cosmetic ingredients addressed in this assessment is evaluated based on data received from the US Food and Drug Administration (FDA) and the cosmetics industry on the expected use of these ingredients in cosmetics. Use frequencies of individual ingredients in cosmetics are collected from manufacturers and reported by cosmetic product category in the FDA Voluntary Cosmetic Registration Program (VCRP) database. The cosmetic product categories named in the VCRP database, indicate the intended uses of a cosmetic ingredient, and are identified in 21 CFR Part 720. Data are submitted by the cosmetic industry in response to a survey conducted by the Personal Care Products Council (Council), of maximum reported use concentrations, also by product categories. Neither the categories provided by the VCRP nor those provided by the Council survey, include a designation for use via airbrush application. Airbrush devices, alone, are within the purview of the US Consumer Product Safety Commission (CPSC), while ingredients as used in airbrush devices are within the jurisdiction of the FDA. As airbrush technology use for cosmetics has neither been evaluated by the CPSC, nor the use of cosmetic ingredients in airbrush technology by the FDA, no US regulatory authority has evaluated the safety of this delivery methodology for cosmetic ingredients. Moreover, no consumer habits and practices data are available to evaluate the risks associated with this use type.

In addition, when discussing potential safety concerns raised by specific routes of exposure (such as incidental ingestion, eye area, inhalation, etc.), the following paragraph is to be included in reports:

> Additionally, although products containing some of these ingredients may be marketed for use with airbrush technology, this information is not available from the VCRP or the Council survey. Without information regarding the frequency and concentrations of use of these ingredients (and without consumer habits and practices data related to this use technology), the data are insufficient to evaluate the safety thereof in airbrush applications.

The Panel further determined the following statement should go into the Discussion section when the Panel is informed through alternative sources other than the FDA VCRP or the Council survey:

> The Panel acknowledges that some cosmetic ingredients may be used in products marketed for airbrush application. However, the available data are insufficient to make a determination of safety for use of these ingredients in products that may be incidentally inhaled when applied using airbrush devices. The Panel's respiratory exposure resource document (available here: https://www.cir-safety.org/cir-findings) notes that airbrush technology presents a potential safety concern, and that no data are available for consumer habits and practices thereof. Thus, the data do not support the safety of the ingredients named in this report if applied via airbrush technology.

Scientific Literature Reviews

The following Scientific Literature Reviews (SLRs), and SLR Notices to Proceed (NTP), are posted at the CIR website, or are currently under development and may be posted imminently. (An NTP is prepared when an intensive search of the published information results in insufficient data to justify preparation of a formal SLR.) These may then be presented to the Panel for their review (as Draft Reports) during the next few meetings.

- Basic Yellow 87
- Charcoal ingredients
- Hyaluronates
- *Olea europaea* (Olive)-derived ingredients
- Phenyl-Substituted Methicones
- Phytosteryl Glutamates
- Polyhydroxystearic Acid
- Pyridoxine and Pyridoxine HCl
- Sodium Lauroamphoacetate group
- Trisodium Ethylenediamine Disuccinate
- *Zanthoxylum piperitum* – derived ingredients

Next Expert Panel Meeting

Thursday and Friday, June 16-17, 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 161st meeting page of the CIR website. https://www.cir-safety.org/