Post Meeting Announcement

Cosmetic Ingredient Review Expert Panel
153rd Meeting (December 9-10, 2019) - Findings

December 13, 2019

- Final Safety Assessments
  - Alkyl Amide MIPA – 14 ingredients – Safe with qualifications
  - Capryloyl Salicylic Acid – 1 ingredient – Insufficient for impurities and phototoxicity
  - MCI/MI – 2 ingredients (1 mixture) – Safe with qualifications
  - Mannitol, Sorbitol, & Xylitol – 3 ingredients - Safe

- Tentative Safety Assessments
  - Honey – 7 ingredients – Safe
  - Palm (açaí & jucara) – 8 ingredients – Split conclusion (safe; insufficient for composition)
  - Pomegranate – 18 ingredients – Split conclusion (safe; insufficient for various endpoints)
  - Soy – 28 ingredients – Split conclusion (safe; insufficient for various endpoints)
  - Vanilla – 9 ingredients – Split conclusion (safe; insufficient for various endpoints)

- Insufficient Data Announcements
  - Amino Acid Diacetates – 2 ingredients
  - Coconut – 9 ingredients
  - Glycerin Ethoxylates – 8 ingredients
  - Polysilicone-11 – 1 ingredient

- Tabled Assessment
  - Caprylhydroxamic Acid – 1 ingredient

- Re-Review
  - Methicones – re-open

- 153rd Meeting Notes
  - Director’s Report
  - Strategy Document - Silicates
  - Read-Across Resource Document
  - Re-Review Summaries
    - Sodium Naphthalenesulfonate
    - Isopropyl Lanolate
  - Scientific Literature Reviews – under development
  - Next Expert Panel Meeting – Monday and Tuesday, March 16-17, 2020
Final Safety Assessments

Final safety assessments will be posted on the 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 Unpublished data cited as references in CIR safety assessments are available for review.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 CIR Expert Panel to amend the safety assessment.

Alkyl Amide MIPA

The Panel issued a Final Report with the conclusion that the 14 alkyl amide MIPA ingredients named below are safe in cosmetics in the present practices of use and concentration described in the safety assessment when formulated to be non-irritating.

- Cocamide MIPA
- Linoleamide MIPA *
- Palm Kernelamide MIPA *
- Coconut Oil MIPA Amides *
- MIPA- Myristate *
- Peanatumide MIPA *
- Hydroxyethyl Stearamide-MIPA *
- Myristamide MIPA *
- Ricinoleamide MIPA *
- Isostearamide MIPA *
- Oleamide MIPA
- Stearamide MIPA *
- Lauramide MIPA
- Palmamide MIPA *

*Use not reported in the VCRP and/or concentration of use survey. The expectation is that if used in cosmetic formulations, they would be used in product categories and at concentrations comparable to that reported for others in this group.

The ingredients in this group are fatty amides resulting from amidation with MIPA. Accordingly, the Panel specified that these ingredients should not be used in cosmetic products in which N-nitroso compounds can be formed.

The alkyl amide MIPA ingredients are primarily used in rinse-off formulations. However, leave-on uses are reported, with 0.4% Oleamide MIPA reported as the highest concentration of use in leave-on formulations. The Panel noted that delayed contact hypersensitivity was reported in a guinea pig maximization test (GPMT) performed with high concentrations of Oleamide MIPA (75% for topical induction/50% at challenge), but not in GPMTs on Cocamide MIPA (25% at topical induction/5% at challenge) and Isostearamide MIPA (100% at topical induction/1% at challenge). The Panel stated that the sensitization observed with Oleamide MIPA was most likely a result of the high concentrations and a stressing of the system (as this method of testing utilizes a combination of exposures, including intradermal injections which bypass the stratum corneum). Because the Panel felt that it was appropriate to read-across from Cocamide MIPA and Isostearamide MIPA, concern that Oleamide MIPA would be a sensitizer in cosmetic formulations was mitigated. Nevertheless, the Panel was concerned that the potential exists for dermal or ocular irritation with the use of products formulated with the ingredients named in this assessment. Therefore, the Panel specified that products containing the ingredients listed above must be formulated to be non-irritating.

Published studies were not found, and unpublished data were not submitted, for certain toxicological endpoints on the alkyl amide MIPA ingredients. Nevertheless, because these ingredients are structurally similar to the diethanolamides, the Panel determined that information on diethanolamides of equivalent chain lengths (from a previous CIR report, as well as from European Chemical Agency (ECHA) dossiers) could be used for read-across for the missing data endpoints.

The acyl groups (i.e. fatty acid chain residues) in Peanatumide MIPA are derived from peanut oil. The Panel has previously reviewed the safety of Arachis Hypogaea (Peanut) Oil as used in cosmetics, and discussed therein the relationship between food allergies and exposure to refined oils. Individuals who have food allergies to a plant protein rarely exhibit allergic reactions when exposed to refined oils of the same plant; proteins do not partition into the oil. Additionally, the Panel noted that aflatoxins, which could be associated with peanuts, do not partition into the oil. However, the Panel does caution manufacturers to make certain that Peanatumide MIPA is free from proteins and aflatoxins.

Capryloyl Salicylic Acid

The Panel issued a Final Amended Report with the conclusion that the data are insufficient to make a determination that Capryloyl Salicylic Acid is safe under the intended concentrations of use in cosmetic formulations. The data needs are:

- Impurities
- Phototoxicity

The Panel discussed the issue of skin sensitization potential for this ingredient, ultimately noting very little to no concern relating to this endpoint. Capryloyl Salicylic Acid induced skin sensitization in GPMTs at challenge concentrations of 0.5%, 2%, and 5%, but not at 1%. However, in human repeated insult patch tests (HRIPts), cosmetic products containing 0.5% or 2% Capryloyl Salicylic Acid were classified as non-sensitizing. After reviewing the HRIPt results and considering that the highest reported maximum use concentration of Capryloyl Salicylic Acid is 0.5% in leave-on cosmetic products, the Panel was reassured that the sensitization potential of exposure to this ingredient via cosmetic use is not a risk.

In response to the Panel’s data requests, the results of an in vitro 3T3 neutral red uptake (NRU) phototoxicity test were provided by the Council. The study was performed in accordance with the Organization for Economic Co-operation and Development (OECD) Guideline for Testing of Chemicals Draft Proposal for a New Guideline (draft document, dated February 2000). According to the evaluation criteria that were used, a test article was considered to be phototoxic in this assay if a marked decrease in cell viability (as measured by OD340 in the NRU) was observed in the presence of long-wave ultraviolet light (UVa; by comparison with the viability seen in the absence of UVa) such that photo-irritation factors (PIF) of ≥ 5 were obtained. Furthermore, a test article was considered to be non-phototoxic in this assay if there was no marked decrease in cell viability when cells were exposed to the test article in the absence and presence of UVa, or if similar toxic profiles were observed in the absence and presence of UVa (PIF < 5). The test yielded PIF’s of 4 and 2.6 - 1.7 in separate experiments that were performed. Based on these PIF values, the author concluded that, according to the proposed OECD guideline evaluation criteria, Capryloyl Salicylic Acid was not phototoxic in the in vitro 3T3 NRU phototoxicity test. However, the Panel noted that, according to OECD Test Guideline (TG) 432 (adopted April 13, 2004), the results of this test are to be interpreted based on the following criteria: a test substance with a PIF of < 2 predicts “no phototoxicity,” a PIF of > 2 and < 5 predicts “probable phototoxicity,” and a PIF of > 5 predicts “phototoxicity.” Thus, the Panel agreed that Capryloyl Salicylic Acid (PIFs of 4 and 2.6 - 1.7) should have been classified as probably phototoxic in the in vitro 3T3 NRU phototoxicity test. Furthermore, the Panel agreed that because this test is prone to false positives, additional data would be needed in order to evaluate the phototoxicity potential of Capryloyl Salicylic Acid. The reactive oxygen species test for phototoxicity was mentioned as one of the phototoxicity tests that could be performed.

The Panel also noted that impurities data were not provided, and that the need for these data remains.
MCU/MI

The Panel issued a Final Amended Report with the conclusion that the ingredient mixture MCU/MI is safe in cosmetics when formulated to be non-sensitizing, based on the results of a quantitative risk assessment (QRA) or similar methodology. Concentrations of use may not exceed 15 ppm in rinse-off products or 7.5 ppm in leave-on products.

The Panel noted the results of a QRA for skin sensitization performed by the CIR Science and Support Committee. The results indicated that some leave-on products comprising MCU/MI at the recommended maximum safe concentration of 7.5 ppm may yet increase the risk of inducing dermal sensitization. In most rinse-off products, 15 ppm MCU/MI was not associated with a potential increased risk of skin sensitization induction. Individuals previously sensitized to MCU/MI should avoid products that contain this ingredient mixture.

The Panel received the requested inhalation study of at least 3 months in duration that is in accordance with the OECD TG 413. This request had been in response to reports of adverse events observed in infants following inhalation exposure to humidifier disinfectants that contained this preservative mixture. The Panel determined that the data sufficiently support safety of the use of this ingredient mixture at the concentrations that could be incidentally inhaled following use in cosmetic products. The concentrations used in the humidifier disinfectants were orders of magnitude greater than those found in cosmetics.

Mannitol, Sorbitol, & Xylitol

The Panel issued a Final Report with the conclusion that Mannitol, Sorbitol, and Xylitol are safe in cosmetics in the present practices of use and concentration described in the safety assessment. The lack of adverse clinical reports after ingestion of foods containing these ingredients, as well as negative sensitization and phototoxicity assays, support the safety of this ingredient group.

According to 2019 VCRP Data, Sorbitol, Xylitol, and Mannitol are used in 1976, 472, and 404 formulations, respectively. The results of the concentration of use survey conducted by the Council indicate that Sorbitol has the highest concentration of use; it is used at up to 70% in dentifrices. The highest concentration of use reported for products resulting in leave-on dermal exposure is 60.5% Mannitol in other skin care preparations.

Tentative Safety Assessments

For those tentative safety assessments below posted on the CIR website at www.cir-safety.org on or before December 20, 2019, interested persons are given 60 days from the posting date (February 18, 2020) to comment, provide information, and/or request an oral hearing before the CIR Expert 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 February 18, 2020 for full consideration. The updated reports may be scheduled for review by the Expert Panel as early as at its March 16-17, 2020 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 Expert Panel at its June 8-9, 2020 meeting.

Honey

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

- Honey
- Honey Cocosates
- Honey Powder
- Honey Extract
- Hydrogenated Honey
- Hydrolyzed Honey
- Hydrolyzed Honey Protein

*Use not reported in the VCRP and/or concentration of use survey. The expectation is that if used in cosmetic formulations, these ingredients would be used in product categories and at concentrations comparable to those reported for others in this group.

The Panel noted the lack of sensitization data for six of the seven ingredients, but determined that the available sensitization data on Honey Extract could be used to support safety for the remaining ingredients. The safety of these ingredients was also supported by their frequent medical use in wound dressings and historical food use, without reported adverse events. In addition, the Panel suggested the inclusion of language suggesting limitations of pesticides and endotoxins, as well as avoiding the use of honey derived from toxic plant sources (e.g., oleander) when formulating with these ingredients.

According to 2019 VCRP survey data, Honey and Honey Extract are reported to be used in 1002 and 359 formulations, respectively. The results of a 2018 concentration of use survey conducted by Council indicate that Honey has the highest reported concentration of use; it is used at up to 22% in rinse-off formulations. The highest concentration of use reported for leave-on products was in formulations containing Honey Extract at up to 7% in body and hand products.

Palm (açaí and jucara)-Derived Ingredients

The Panel issued a Revised Tentative Report with the conclusion that the following ingredients are safe in the present practices of use and concentration described in the safety assessment:

- Euterpe Edulis Fruit Extract
- Euterpe Edulis Juice Extract
- Euterpe Oleracea Fruit Extract
- Euterpe Oleracea Juice
- Euterpe Oleracea Pulp Powder
- Euterpe Oleracea Seed Powder
- Hydrolyzed Euterpe Oleracea Fruit
- Hydrolyzed Euterpe Oleracea Juice
- Hydrolyzed Euterpe Oleracea Pulp Powder
- Hydrolyzed Euterpe Oleracea Seed Powder

*Use not reported in the VCRP and/or concentration of use survey. The expectation is that if used in cosmetic formulations, these ingredients would be used in product categories and at concentrations comparable to those reported for others in this group.

The Panel noted similarities in composition for the two species; accordingly, data on Euterpe oleracea was found to be applicable for determining safety of similar Euterpe edulis ingredients. This conclusion was found to be applicable to Hydrolyzed Euterpe Oleracea Fruit in the absence of composition data on this ingredient, given the available composition data on Euterpe Oleracea Fruit Extract and Euterpe oleracea fruit. Additionally, the Panel concluded that the available data are insufficient to make a determination that Euterpe Oleracea Palm Heart Extract is safe under the intended conditions of use in cosmetic formulations. The data needs to determine the safety of this ingredient are:

- Composition data
  - If the composition of this ingredient is found to be significantly different from the other ingredients in this report, dermal irritation and sensitization data would be needed.

- Euterpe edulis
  - Euterpe oleracea
Pomegranate

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

- Punica Granatum Fruit Extract
- Punica Granatum Juice Extract
- Punica Granatum Seed Extract
- Punica Granatum Fruit Juice
- Punica Granatum Pernicarp Extract
- Punica Granatum Seed
- Punica Granatum Seed Extract
- Punica Granatum Seed Powder

The Panel noted that the available data indicate the potential for extracts of *Punica granatum* plant parts to cause skin lightening effects. Skin lightening is considered to be a drug effect and should not occur during the use of cosmetic products. Based on the concentration of use of these extracts in cosmetic products, the known mechanism of action, the results of an in vitro study, and clinical experience, however, the Panel was not concerned that these ingredients would have these effects in cosmetic products under the present practices of use and concentration described in the safety assessment. Nevertheless, cosmetic formulators should only use *Punica granatum* extracts in products in a manner that does not cause skin depigmentation.

However, the Panel also concluded that the data were insufficient to make a determination of safety for the following 10 ingredients:

- Punica Granatum Extract
- Punica Granatum Bark Extract
- Punica Granatum Bark/Fruit Extract
- Punica Granatum Callus Culture Extract
- Punica Granatum Flower Extract
- Punica Granatum Fruit/Root/Stem Powder
- Punica Granatum Fruit/Sucrose Ferment Filtrate
- Punica Granatum Leaf Cell Extract
- Punica Granatum Peel Extract
- Punica Granatum Seed Cell Culture Lysate

* Ingredient has been deleted from the Dictionary, but uses are currently reported.

* 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 additional data needed for these cosmetic ingredients are:

- Method of manufacture, especially with regard to solvent used for the extracts
- Composition and impurities data
- Systemic toxicity data
- Dermal irritation and sensitization data

Soy

The Panel issued a Tentative Report for public comment with the conclusion that the following 24 soy-derived ingredients are safe in the present practices of use and concentration described in the safety assessment:

- Glycine Max (Soybean) Fiber
- Glycine Max (Soybean) Flower/Leaf/Stem Juice
- Glycine Max (Soybean) Leaf Cell Extract
- Glycine Max (Soybean) Leaf Extract
- Glycine Max (Soybean) Phytoplacenta Extract
- Glycine Max (Soybean) Pulp
- Glycine Max (Soybean) Seed Extract
- Glycine Max (Soybean) Seedcake Extract
- Glycine Max (Soybean) Seedcoat Extract
- Glycine Max (Soybean) Seed Powder
- Glycine Soja (Soybean) Fiber
- Glycine Soja (Soybean) Flour
- Glycine Soja (Soybean) Germ Extract
- Glycine Soja (Soybean) Hull
- Glycine Soja (Soybean) Lipids
- Glycine Soja (Soybean) Phytoplacenta Extract
- Glycine Soja (Soybean) Seed
- Glycine Soja (Soybean) Seedcake Extract
- Glycine Soja (Soybean) Seed Extract
- Glycine Soja (Soybean) Seed Water
- Glycine Soja (Soybean) 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.

However, the Panel determined that there were insufficient data to determine the safety of the following 4 ingredients:

- Glycine Max (Soybean) Callus Culture
- Glycine Max (Soybean) Callus Culture Extract
- Glycine Max (Soybean) Phytoplacenta Conditioned Media

None of these 4 ingredients is reported to be in use. The data needs to determine safety of these ingredients comprise:

- Composition
- Impurities
- Method of manufacture
- 28-day dermal toxicity
- Dermal sensitization/irritation data

According to 2019 VCRP data, Glycine Max (Soybean) Seed Extract and Glycine max (soybean) flour (synonymous with Glycine Soja (Soybean) Flour) are reported to be used in 395 and 66 formulations, respectively. Results of the 2016 concentration of use survey conducted by Council indicate that Glycine Soja (Soybean) Seed Extract has the highest concentration of use; it is used at up to 2% in face and neck products.

Vanilla

The Panel issued a Tentative Report for public comment with the conclusion that the following 7 vanilla-derived ingredients are safe in the present practices of use and concentration described in the safety assessment when formulated to be non-sensitizing:

- Vanilla Planifolia Fruit Extract
- Vanilla Planifolia Seed
- Vanilla Tahitensis Seed
- Vanilla Planifolia Fruit Oil
- Vanilla Planifolia Seed Powder
- Vanilla Tahitensis Fruit Extract
- Vanilla Tahitensis Fruit Extract
While the available human skin sensitization data on Vanilla Planifolia Fruit Extract, Vanilla Tahitensis Fruit Extract, and vanilla extract are negative, final product formulations may contain multiple botanicals, each possibly containing the same constituents of concern. Thus, formulators are advised to be aware of these constituents and to avoid reaching levels that may be hazardous to consumers. Therefore, when formulating products, manufacturers should avoid reaching levels of plant constituents that may cause sensitization or other adverse health effects.

However, the Panel also concluded that the available data are insufficient to make a determination that the following 2 ingredients are safe under the intended conditions of use in cosmetic formulations:

- Vanilla Planifolia Flower Extract
- Vanilla Planifolia Leaf Cell Extract

The data needed to determine the safety of these two ingredients comprise:

- Method of manufacture and impurities
- Composition
- Concentration of use
- 28-day dermal toxicity

Depending on the results, other toxicological endpoints may be needed (e.g., genotoxicity and DART)

The Panel was not concerned about the positive (+) photopatch test reactions to vanilla extract in a photodermatitis patient, because the strength of the reactions at photoirradiated and non-irradiated sites were the same. Therefore, it was agreed that the observed test results were not due to a photosensitization reaction.

### 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 CIR Expert 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 February 18, 2020, for full consideration. These reports may be scheduled for review by the CIR Expert Panel as soon as the March 16-17, 2020 meeting.

#### Amino Acid Diacetates

The Panel issued an Insufficient Data Announcement (IDA) for Beta-Alanine Diacetic Acid and Tetrasodium Glutamate Diacetate. The additional data needed to determine safety for these cosmetic ingredients are:

- Method of manufacturing, composition, and impurities data
- Clarification on the status of isomerization of Tetrasodium Glutamate Diacetate

#### Cocos nucifera (Coconut)-Derived Ingredients

The Panel issued an IDA for the following 9 ingredients:

- Cocos Nucifera (Coconut) Flower Extract
- Cocos Nucifera (Coconut) Fruit Extract
- Cocos Nucifera (Coconut) Fruit Juice
- Cocos Nucifera (Coconut) Fruit Powder
- Cocos Nucifera (Coconut) Fruit/Fruit Juice Extract
- Cocos Nucifera (Coconut) Liquid Endosperm
- Cocos Nucifera (Coconut) Shell Powder
- Cocos Nucifera (Coconut) Shell Powder, and Cocos Nucifera (Coconut) Tree Powder
- Cocos Nucifera (Coconut) Tree Powder

The additional data needed for these cosmetic ingredients are:

- Method of manufacturing data for Cocos Nucifera (Coconut) Fruit Powder
- Composition and impurities data for Cocos Nucifera (Coconut) Flower Extract, Cocos Nucifera (Coconut) Fruit Powder, Cocos Nucifera (Coconut) Shell Powder, and Cocos Nucifera (Coconut) Fruit Extract or another Cocos nucifera (coconut) fruit-derived ingredient.
- Data on Cocos Nucifera (Coconut) Flower Extract and Cocos Nucifera (Coconut) Shell Powder on the following endpoints:
  - 28-day dermal toxicity, and if positive, DART may be needed
  - Genotoxicity
  - Dermal irritation and sensitization
- Clarification as to whether the data on the trade name mixture containing 20% Cocos Nucifera (Coconut) Fruit Extract and 80% Lactobacillus are actually for a Lactobacillus ferment of coconut fruit extract, or for a mixture of the fruit extract and Lactobacillus.

#### Glycerin Ethoxylates

The Panel reviewed the safety of these 8 glycerin ethoxylate ingredients for the second time and issued a new IDA:

- Glycereth-3
- Glycereth-7
- Glycereth-8
- Glycereth-12
- Glycereth-18
- Glycereth-20
- Glycereth-26
- Glycereth-31

The Panel deemed that their previous data insufficiency requests were satisfied because the described method of manufacture addressed the family of ingredients, the received Glycereth-26 certificate of analysis confirmed minimal levels for impurities of concern, and the revised Glycereth-3 inhalation toxicity study reassured the respiratory safety of these ingredients. However, the Panel found the available HRIPT summaries to provide insufficient information. Thus, the Panel has requested full experimental details for each of these summaries, or, newly completed HRIPT experimental data at or above maximum concentrations of use, with n ≥ 100 participants. The Panel was especially interested in receiving complete experimental data for an HRIPT done with the maximum reported concentration of use for the ingredient with the highest reported use, namely, 6% Glycereth-26.

#### Polysilicone-11

The Panel issued an IDA for Polysilicone-11. The insufficiencies include data regarding impurities, such as residual monomers and other reactants (e.g., polymerization initiators, chain propagators, terminators, and solvents), molecular weight distribution, composition, 28-day dermal toxicity, mammalian genotoxicity, and sensitization/irritation at the current maximum use concentration of 35%.
Tabled Assessment

Caprylhydroxamic Acid
The Panel was informed that the requested HRIPT is underway, but not yet available for review by the Panel. Therefore, discussion of the draft Tentative Report on Caprylhydroxamic Acid was tabled until the March 2020 meeting.

Re-Review

Methicones
The Panel first published a review of the safety of these 20 ingredients in 2003. The Panel considered it unlikely for any of these polymers to be absorbed into the skin due to their large molecular weights and low concentrations of use; hence, the Panel concluded that these ingredients are safe as used in cosmetic products. Because it has been at least 15 years since the report was published, in accordance with CIR Procedures, the Panel considered whether the safety assessment of Methicones should be re-opened.

Upon review of the updated frequency and concentration of use data, the Panel determined to re-open this safety assessment. Although Amodimethicone Hydroxystearate, Hydroxypropyltrimethicone, and Stearamidopropyl Dimethicone are not reported to be in use, the overall frequency of use for this group of ingredients has increased significantly. The reported frequency of use of Dimethicone has increased from 1659 uses in 1998 to 12,934 uses in 2019, while the reported frequency of use of Methicone increased from 0 in 1998 to 600 in 2019. The reported maximum concentration of use of Dimethicone also increased, from 80% to 85%, with the maximum concentration notably increased for sprays. This dramatic increase, across various product categories and routes of exposure, led to the Panel’s concern for potential inhalation toxicity. The Panel noted limited acute inhalation toxicity data in the original report, and acknowledged the need for toxicity data describing ingredient concentration and particle size distribution, especially as it pertains to inhalation toxicity.

153rd Meeting Notes

Director’s Report
Dr. Heldreth expressed gratitude for the Panel’s and other stakeholders’ continued support of the Cosmetic Ingredient Review program. He also reported on 2 new faces participating in these safety assessments. Dr. Lisa Peterson joined the Marks teams at this meeting, filling the vacancy for a chemist. Dr. Peterson is Professor of Environmental Health Sciences and a Co-Leader of Carcinogenesis and the Chemoprevention Program, at the University of Minnesota School of Public Health and Masonic Cancer Center. CIR is thrilled to have this expert join the Panel. This meeting is also the first meeting wherein CIR’s newest analyst, Ms. Preethi Raj, participated in the deliberations. Dr. Heldreth noted on what a great addition Preethi has been to the CIR staff.

CIR was invited by the Latin American Cosmetics, Toiletry and Perfumery Association (CASIC) to speak at their international safety symposium in Buenos Aires last month. The symposium was to provide the audience in South America with tools for proper management of cosmetic safety. CIR’s Senior Director, Monice Fiume, presented on “Evaluating the Safety of Cosmetics in the US,” and was very well received. Her presentation served to inform the audience about the CIR – especially in regard to its mission, this Expert Panel, the CIR process, and conclusions reached thus far. She also clarified some similarities and differences between CIR assessments as compared to our counterparts in Europe.

Also since this Panel’s last meeting, 2 commentaries were published, each disparaging the notion that “natural means safe.” Each commentary pointed to the importance of scientifically sound safety assessments, regardless of raw material source (e.g., synthetic or botanical). Moreover, in both of the opinions, offered by Dr. Bruce Brod in JAMA Dermatology and by Dr. Mary Beth Genter in the International Journal of Toxicology, this Expert Panel is lauded as the eminent, scientifically-backed, source of cosmetic safety information.

Strategy Document

Silicates, Clays, and Zeolites
The Panel considered the proposed groupings of the 38 ingredients that had been previously removed from the Amended Safety Assessment on Silica and Hydrated Silica and a larger re-review package of silicate ingredients. The Panel accepted the groupings proposed by CIR Staff, which will be presented in 3 separate reports at future Panel meetings. The Panel also accepted the proposed addition of the ingredient, Clay, to the reviews. The groups are as follows:

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**Read-Across Resource Document**

At this meeting, a newly prepared draft of a Read-Across Resource Document was presented for Panel review. The Panel consensus was to table this document until further efforts were completed within the Panel processes related to read-across. These further efforts are to include a special working group of the Panel to evaluate grouping/clustering of ingredients and to propose read-across sources where necessary.

**Re-Review Summaries**

**Sodium Naphthalenesulfonate and Sodium Polynaphthalenesulfonate**

The Panel approved the re-review summary of Sodium Naphthalenesulfonate and Sodium Polynaphthalenesulfonate, reaffirming that these ingredients are “safe as used in cosmetic formulations intended to be applied to the skin. The available data, however, are insufficient to support the safety for use in cosmetic products which may contact mucous membranes or be ingested.” This conclusion was originally published by CIR in 2003. Limited new data that were identified in the published literature, as well as updated information regarding frequencies of use, provided by the FDA, and maximum use concentrations of use, provided by the Council, were reviewed by the Panel.

**Isopropyl Lanolate**

The Panel approved the re-review summary of Isopropyl Lanolate, reaffirming that this ingredient is “safe as currently used in cosmetic products.” This conclusion was originally published by CIR in 1980, and again in 2001. Limited new data identified in the published literature that have become available since the original report was published, as well as updated information regarding frequencies of use (provided by the FDA) and maximum use concentrations of use (provided by the Council), were reviewed by the Panel.

**Scientific Literature Reviews**

*The following Scientific Literature Reviews 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 two meetings.*

- Acetylhexapeptide-8 and Acetyl Hexapeptide-8 Amide
- Acrylate/Acrylamide Copolymers
- Ascorbyl Glucoside
- Basic Brown 17
- Carica papaya (Papaya)-Derived Ingredients
- Diacetone Alcohol
- Hordeum vulgare-Derived Ingredients
- Levulinic Acid & Sodium Levulinate
- Melaleuca alternifolia (Tea Tree)-Derived Ingredients
- Saccharide Humectants
- Tris(Tetramethylhydroxypiperidinol) Citrate

Of note, a rereview of MI is also in preparation.

**Next CIR Expert Panel Meeting**

Monday and Tuesday, March 16-17, 2020 at the Carnegie Endowment for International Peace, Washington, DC.

Please contact Carla Jackson ([jacksonc@cir-safety.org](mailto:jacksonc@cir-safety.org)) before the meeting if you plan to attend.