Announcement

Cosmetic Ingredient Review Expert Panel
132nd Meeting (September 8-9, 2014) - Findings

September 15, 2014

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  - **PCA and Its Salts – 5 ingredients**
  - **PEGylated Alkyl Glycerides – 60 ingredients**
  - **Polyoxyalkylene Siloxane Copolymers, Alkyl-Polyoxyalkylene Siloxane Copolymers, and Related Ingredients – 111 ingredients**
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Final Safety Assessments

Final safety assessments and final amended 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 Unpublished data cited as references in CIR safety assessments are available for review.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 believes that a final safety assessment or final amended safety assessment is incorrect may petition the CIR Expert Panel to amend the safety assessment.

Alkyl Phosphates

The Panel issued a final safety assessment with the conclusion that the following 28 alkyl phosphates are safe as used in cosmetics when formulated to be non-irritating:

potassium cetyl phosphate
potassium C9-15 alkyl phosphate
potassium C11-15 alkyl phosphate*
potassium C12-13 alkyl phosphate
C8-10 alkyl ethyl phosphate*
C9-15 alkyl phosphate
C20-22 alkyl phosphate
potassium C12-14 alkyl phosphate*
potassium lauryl phosphate

castor oil phosphate
cetearyl phosphate*
cetyl phosphate
disodium lauryl phosphate*
disodium oleyl phosphate*
lauryl phosphate
myristyl phosphate*
octyldecyl phosphate*
oleyl ethyl phosphate*
oleyl phosphate*
sodium lauryl phosphate*
stearyl phosphate
dicetyl phosphate
dimyristyl phosphate*
dioleyl phosphate
tricetyl phosphate*
trilauryl phosphate*
trioleyl phosphate
tristearyl phosphate*

*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 ingredients in the alkyl phosphate family share a common phosphate core structure, and vary by the identity of the attached alkyl chains.

The Panel discussed the potential for ocular and/or dermal irritation with the use of products formulated using alkyl phosphates. The Panel reviewed studies showing that some of the alkyl phosphates were irritating to the skin of test animals, and found that these studies were conducted with concentrations much greater than the concentrations reported to be used in cosmetics

2-Amino-3-Hydroxypyridine

The Panel issued a final safety assessment with the conclusion that 2-amino-3-hydroxypyridine is safe in the present practices of use and concentration in oxidative hair dye formulations.

Considering hair dye epidemiology data, the Panel noted that the available epidemiology studies are insufficient to conclude that there is a causal relationship between hair dye use and cancer or other toxicological endpoints, based on the lack of strength of the associations and the inconsistency of the findings of such studies.

The Panel revisited their previous discussion that hair dyes containing 2-amino-3-hydroxypyridine should be formulated to avoid the formation of *N*-nitrosopyridinium compounds because the nitrogen atom of the pyridine core can be susceptible to nitrosation. The Panel found that the formation of *N*-nitrosopyridinium compounds from this ingredient would be likely to occur only under anhydrous conditions that would not be physiologically relevant or applicable to hair dye product formulations.

***Camellia sinensis*-Derived Ingredients**

The Panel issued a final safety assessment with the conclusion that the following 7 *Camellia sinensis* leaf-derived ingredients are safe in cosmetic products when formulated to be non-sensitizing:

camellia sinensis leaf
camellia sinensis leaf extract
camellia sinensis leaf oil
camellia sinensis leaf powder
camellia sinensis leaf water
camellia sinensis catechins *
hydrolyzed camellia sinensis leaf *

The Panel also concluded that the available data are insufficient to assess the safety of the following 7 camellia sinensis ingredients:

camellia sinensis flower extract
camellia sinensis flower/leaf/stem juice
camellia sinensis root extract
camellia sinensis seedcoat powder
camellia sinensis seed extract
camellia sinensis seed powder
hydrolyzed camellia sinensis seed extract

* Not reported to be in current use. Were the 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 are (1) methods of manufacturing; (2) chemical characterization of the constituents of these ingredients; (3) human sensitization data; and (4) concentrations of use in cosmetics.

These ingredients have several reported functions in cosmetics, including antioxidant and skin-conditioning agent. The *C. sinensis*-derived ingredients in this safety assessment are from plants that are present extensively in the human diet. The Panel agreed that exposures to these ingredients in beverages result in much larger systemic exposures than exposures from cosmetic uses, and they noted the absence of reports of incidents of sensitization in the literature. The potential toxicity from oral exposures was not a primary concern for these ingredients. Reproductive toxicity, genotoxicity, and carcinogenicity data are presented in the safety assessment; but the primary focus of the safety assessment was on evaluating the potential for these ingredients to cause irritation and sensitization.

Citrus-Derived Peel Oils

The Panel issued a final safety assessment with the conclusion that the 14 citrus-derived peel oils listed below are safe for use in cosmetic products when finished products, excluding rinse-off products, do not contain more than 0.0015% (15 ppm) 5-methoxypsoralen (5-MOP), and when formulated to be non-sensitizing and non-irritating.

citrus aurantifolia (lime) peel oil*
citrus aurantium amara (bitter orange) peel oil
citrus aurantium currassuviensis peel oil*
citrus aurantium dulcis (orange) peel oil
citrus clementina peel oil*
citrus grandis (grapefruit) peel oil
citrus iyo peel oil*
citrus junos peel oil
citrus limon (lemon) peel oil
citrus medica vulgaris peel oil*
citrus nobilis (mandarin orange) peel oil
citrus reticulata (tangerine) peel oil*
citrus tachibana/reticulata peel oil*
citrus tangerina (tangerine) peel oil

*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.

Multiple botanical ingredients may each contribute to the final concentration of a single constituent. When formulating products containing citrus-derived peel oils, manufacturers should avoid reaching levels of plant constituents that may cause sensitization or other adverse effects. The Panel clarified that ingredients reviewed in this assessment are safe for use in rinse-off products and safe for use in leave on products that are applied to the skin, hair and nails when 5-MOP is less than or equal to 15 ppm.

Industry commented that the only known function for citrus aurantifolia (lime) peel oil is as a fragrance, and suggested removing this ingredient from the assessment. However, the Panel decided to keep citrus aurantifolia (lime) peel oil in the safety assessment, because it is not clear whether the ingredient reviewed by RIFM was oil from the peel or from the entire fruit.

Methylisothiazolinone

The Panel issued a final safety assessment with the conclusion that methylisothiazolinone (MI) is safe for use in rinse-off cosmetic products at concentrations up to 100 ppm, and safe for use in leave-on cosmetic products when formulated to be non-sensitizing, which may be determined based on a quantitative risk assessment (QRA).

The results of QRAs performed by Cosmetics Europe and the CIR Science and Support Committee supported the safety of the use of MI in rinse-off product categories at concentrations up to 100 ppm. However, the QRAs indicated that MI use in many leave-on product categories would be safe only at lower concentrations. Leave-on products should be formulated to contain MI concentrations that are below 100 ppm and are formulated to be non-sensitizing, as demonstrated, for example, by QRA estimates of safe exposures for the relevant cosmetic product categories. The Panel emphasized that the concentrations of MI should never exceed 100 ppm in any hair product, leave-on product, or rinse-off product.

The Panel's recommendations for MI in rinse-off and leave-on cosmetic products are intended to prevent the induction of sensitization to MI. The Panel cautioned that following these recommendations may not necessarily prevent the elicitation of allergic reactions in individuals who are already allergic to MI. Individuals sensitized to MI should avoid products that contain MI.

Styrene and Vinyl-type Styrene Copolymers

The Panel issued a final safety assessment for public comment with the conclusion that the following 35 ingredients are safe in the present practices of use and concentration in cosmetics.

ethylene/propylene/styrene copolymer
butylene/ethylene/styrene copolymer
acrylates/ethylhexyl acrylate/styrene copolymer*
butyl acrylate/styrene copolymer
C4-6 olefin/styrene copolymer*
C5-6 olefin/styrene copolymer*
hydrogenated butadiene/isoprene/styrene copolymer*
hydrogenated butylene/ethylene/styrene copolymer
hydrogenated ethylene/ propylene/styrene copolymer
hydrogenated styrene/butadiene copolymer
hydrogenated styrene/isoprene copolymer
isobutylene/styrene copolymer
methacrylic acid/styrene/vp copolymer*
methylstyrene/vinyltoluene copolymer
polystyrene
polystyrene/hydrogenated polyisopentene copolymer
sodium methacrylate/styrene copolymer*
sodium styrene/acrylates copolymer
sodium styrene/acrylates/ethylhexyl acrylate/lauryl acrylate copolymer*
styrene/acrylates copolymer
styrene/acrylates/ethylhexyl acrylate/lauryl acrylate copolymer*
styrene/butadiene copolymer
styrene/isoprene copolymer*
styrene/methylstyrene copolymer*
styrene/stearyl methacrylate crosspolymer*
styrene/va copolymer*
styrene/vp copolymer
polyacrylate-2*
polyacrylate-5
polyacrylate-12*
polyacrylate-15
polyacrylate-16
polyacrylate-18*
polyacrylate-21
polyacrylate-30*

*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.

These ingredients function mostly as viscosity increasing agents, opacifying agents, and film formers in cosmetic products. The highest maximum use concentrations for rinse-off and leave-on products have been reported to be 36.5% (polystyrene) and 35% (styrene/acrylates copolymer), respectively.

The Panel agreed that percutaneous absorption of these ingredients is not expected, because of the chemical structures and large sizes of these molecules.

Styrene monomer, a component of all of the copolymers reviewed in this safety assessment, and 1,3-butadiene monomer are classified as carcinogens in animals and in humans. Data provided by industry suggest that the residual monomer concentrations of styrene in styrene and vinyl-type styrene copolymer trade name materials are <-100 ppm. The Panel stated that residual styrene or 1,3-butadiene in cosmetic products would be substantially below levels of concern, because of the low level of residual monomers and the low use concentrations of these ingredients.

The Panel discussed the potential for incidental inhalation exposures to these ingredients in products that are sprayed or are in powder form. They agreed that incidental inhalation would not lead to local respiratory or systemic effects, based on likely airborne particle-size distributions and concentrations in the breathing zone, ingredient use concentrations, and the negative results of toxicity tests.

Tentative Safety Assessments

Tentative safety assessments will be posted on the CIR website at www.cir-safety.org on or before ***September 19, 2014****. Interested persons are given 60 days 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 by* ***November 18, 2014, or sooner if possible.*** *These reports may be scheduled for review by the CIR Expert Panel at its* ***December 8-9, 2014*** *meeting.*

Avena Sativa–Derived Ingredients

The Expert Panel issued a tentative report for public comment with the conclusion of safe as used when formulated to be nonsensitizing for 20 of the 21 *Avena sativa*-derived ingredients. These ingredients are:

avena sativa (oat) bran
avena sativa (oat) bran extract
avena sativa (oat) flower/leaf/stem juice*
avena sativa (oat) kernel extract
avena sativa (oat) kernel flour
avena sativa (oat) kernel meal
avena sativa (oat) kernel protein
avena sativa (oat) leaf extract
avena sativa (oat) leaf/stalk extract*
avena sativa (oat) leaf/stem extract*
avena sativa (oat) meal extract
avena sativa (oat) peptide
avena sativa (oat) protein extract
avena sativa (oat) seed extract*
avena sativa (oat) seed water*
avena sativa (oat) sprout oil*
avena sativa (oat) straw extract
hydrolyzed oat protein
hydrolyzed oat flour
hydrolyzed oats

*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 concluded that there is insufficient data to come to a conclusion on the safety of avena sativa (oat) meristem cell extract. The additional data needed are (1) composition, and (2) concentration of use.

These ingredients function mostly as abrasives, antioxidants, skin-conditioning agents, absorbents, and bulking agents. Avena sativa (oat) kernel extract has the most reported uses; 499 in cosmetic products. The highest reported use concentration was 25% in face and neck products.

A. sativa grains are used extensively in both animal feed and human food, and the plant parts are used in animal feed, yielding in much larger oral exposures than would result from cosmetic uses. Therefore, the primary focus of this safety assessment was on evaluating the potential for these ingredients to cause irritation and sensitization.

Glycerin

The Panel issued a tentative report for public comment with the conclusion that glycerin is safe as used in the present practices of use and concentration in cosmetics.

Glycerin (also known as glycerol in the literature) had the third highest number of reported uses (15,654), after water and fragrance, based on data obtained from the Voluntary Cosmetic Registration Program (VCRP). Glycerin is reported to function as a denaturant; fragrance ingredient; hair conditioning agent; humectant; oral care agent; oral health care drug; skin protectant; skin-conditioning agent - humectant; and viscosity decreasing agent.

Glycerin is naturally occurring in all animal and plant matter, largely as glycerides in fats and oils and in intracellular spaces as the backbone of lipids. Glycerin is considered generally recognized as safe (GRAS) by the FDA as an indirect additive in food packaging materials and as a multiple purpose food substance. In addition to dermal protectant and ophthalmic drug products, Glycerin is approved for use in anorectal drug products, laxatives and oral health care products.

Hydroquinone

The Panel issued a revised tentative amended safety assessment of hydroquinone for public comment with the conclusion that hydroquinone is safe at concentrations ≤ 1% in cosmetic formulations designed for discontinuous, brief use followed by rinsing from the skin and hair. Hydroquinone is safe for use in nail adhesives and as a polymerization inhibitor in artificial nail coatings that are cured by LED (light emitting diode) light. Hydroquinone is unsafe for use in other leave-on cosmetic products.

The Panel remained concerned about the potential risk of squamous cell carcinoma in individuals whose hands are exposed to UVA fluorescent light sources used to cure artificial nail coatings that contain this ingredient. In addition, the UV bulbs used in nail lamps that emit UVA light (320-400 nm) can be easily replaced with UVB and UVC bulbs, which can potentially cause ocular and/or dermal damage. The Panel concluded that only nail lamp devices that use LED bulbs, and not fluorescent bulbs, are safe for use with artificial nail coatings that require curing by light, in both professional and home settings. The Panel cautioned that, if UV-light sources with fluorescent bulbs are used, photo-protective materials for the skin (e.g., gloves, sunscreen) should also be used.

p-Hydroxyanisole

The Panel issued a revised tentative amended safety assessment of *p*-hydroxyanisole for public comment with the conclusion that *p*-hydroxyanisole is safe for use in nail adhesives and as a polymerization inhibitor in artificial nail coatings that are cured by LED (light emitting diode) light. *p*-Hydroxyanisole is unsafe for use in all other cosmetic products because of the potential for dermal depigmentation.

The Panel remained concerned about the potential risk of squamous cell carcinoma in individuals whose hands are exposed to UVA fluorescent light sources used to cure artificial nail coatings that contain this ingredient. In addition, the UV bulbs used in nail lamps that emit UVA light (320-400 nm) can be easily replaced with UVB and UVC bulbs, which can potentially cause ocular and/or dermal damage. The Panel concluded that only nail lamp devices that use LED bulbs, and not fluorescent bulbs, are safe for use with artificial nail coatings that require curing by light in both professional and home settings. The Panel cautioned that if UV-light sources with fluorescent bulbs are used, photo-protective materials for the skin (e.g., gloves, sunscreen) should also be used.

PCA (2-pyrrolidone-5-carboxylic acid) and Its Salts

The Panel issued a tentative amended report for public comment with the conclusion that PCA and its salts (listed below) are safe as used in cosmetics, and these ingredients should not be used in cosmetic products in which *N*-nitroso compounds can be formed.

PCA
Sodium PCA
Calcium PCA
Magnesium PCA
Potassium PCA

In 1999, the Panel concluded that PCA and sodium PCA were safe as used in cosmetics, and that these ingredients should not be used in cosmetic products in which *N*-nitroso compounds can be formed. The Panel acknowledged the increase in the maximum concentration of use of PCA and sodium PCA from 2.5% in moisturizer formulations to 3% sodium PCA in skin cleansing preparations. However, the Panel noted that this increase did not present safety concerns.

New reproductive and developmental toxicity, genotoxicity, and irritation and sensitization data (summary) from the European Chemicals Agency (ECHA) website were available and presented to the Panel for review. The Panel determined that the information contained in the 1999 safety assessment and the new ECHA summary data support the safety of these ingredients, and reopened the safety assessment to add the salts (calcium, magnesium, and potassium PCA). However, the Panel requested clarification of the stereochemistry of PCA, particularly the identity of the stereoisomer that was evaluated in the studies described in the original report.

PEGylated Alkyl Glycerides

The Panel issued a tentative report for public comment with the conclusion that the following 60 PEGylated alkyl glycerides are safe as used in cosmetics when formulated to be non-irritating:

PEG-6 almond glycerides*
PEG-20 almond glycerides
PEG-35 almond glycerides*
PEG-60 almond glycerides
PEG-192 apricot kernel glycerides
PEG-11 avocado glycerides*
PEG-14 avocado glycerides*
PEG-11 babassu glycerides*
PEG-42 babassu glycerides*
PEG-4 caprylic/capric glycerides*
PEG-6 caprylic/capric glycerides
PEG-7 caprylic/capric glycerides
PEG-8 caprylic/capric glycerides
PEG-11 cocoa butter glycerides*
PEG-75 cocoa butter glycerides
PEG-7 cocoglycerides*
PEG-9 cocoglycerides*
PEG-20 corn glycerides*
PEG-60 corn glycerides*
PEG-20 evening primrose glycerides*
PEG-60 evening primrose glycerides*
PEG-3 glyceryl cocoate
PEG-7 glyceryl cocoate
PEG-30 glyceryl cocoate
PEG-40 glyceryl cocoate
PEG-78 glyceryl cocoate*
PEG-80 glyceryl cocoate
PEG-5 hydrogenated corn glycerides*
PEG-8 hydrogenated fish glycerides*
PEG-20 hydrogenated palm glycerides
PEG-6 hydrogenated palm/palm kernel glyceride*
PEG-16 macadamia glycerides
PEG-70 mango glycerides
PEG-13 mink glycerides*
PEG-25 moringa glycerides*
PEG-42 mushroom glycerides*
PEG-2 olive glycerides*
PEG-6 olive glycerides*
PEG-7 olive glycerides*
PEG-10 olive glycerides
PEG-40 olive glycerides*
PEG-18 palm glycerides*
PEG-12 palm kernel glycerides*
PEG-45 palm kernel glycerides

PEG-60 passiflora edulis seed glycerides*
PEG-60 passiflora incarnata seed glycerides*
PEG-45 safflower glycerides*
PEG-60 shea butter glycerides
PEG-75 shea butter glycerides
PEG-75 shorea butter glycerides*
PEG-35 soy glycerides
PEG-75 soy glycerides*
PEG-2 sunflower glycerides*
PEG-7 sunflower glycerides*
PEG-10 sunflower glycerides
PEG-13 sunflower glycerides
PEG-5 tsubakiate glycerides*
PEG-10 tsubakiate glycerides*
PEG-20 tsubakiate glycerides*
PEG-60 tsubakiate glycerides*

*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 decided to incorporate five previously reviewed PEG glyceryl cocoates, including PEG-7 glyceryl cocoate, PEG-30 glyceryl cocoate, PEG-40 glyceryl cocoate, PEG-78 glyceryl cocoate, and PEG-80 glyceryl cocoate, into this assessment. In 1999, the Panel concluded that these five ingredients were safe as used in rinse-off products and safe at up to 10% in leave-on products; the conclusion stated above supersedes this conclusion.

The Panel noted the lack of repeated dose and reproductive and developmental toxicity data, but determined that these ingredients are not expected to be absorbed systemically. Although there were no carcinogenicity data available, the negative mutagenicity studies and expected low dermal penetration of these ingredients led the Panel to conclude that carcinogenicity would not be a concern for cosmetic use. The Panel noted some reports of skin irritation in animal studies;, however the dermal tests were conducted at concentrations that were greater than the maximum reported use concentration of 11.3% PEG-7 glyceryl cocoate.

Because these ingredients are obtained from plant sources, the Panel expressed concern about pesticide residues and heavy metals that may be present in botanical ingredients. The Panel emphasized that the cosmetics industry should continue to use current good manufacturing practices to limit these impurities in the ingredient before blending into cosmetic formulation.

Polyoxyalkylene Siloxane Copolymers, Alkyl-Polyoxyalkylene Siloxane Copolymers, and Related Ingredients

The Expert Panel issued a tentative report for public comment with the conclusion that the following 111 polyoxalkylene siloxane copolymers, alkyl-polyoxyalkylene siloxane copolymers, and related ingredients are safe as used in cosmetics:

behenoxy dimethicone
behenoxy PEG-10 dimethicone*
bis-cetyl/PEG-8 cetyl PEG-8 dimethicone*
bis-hydroxyethoxypropyl dimethicone
bis-isobutyl PEG/PPG-10/7/dimethicone copolymer*
bis-isobutyl PEG-13/dimethicone copolymer*
bis-isobutyl PEG-24/PPG-7/dimethicone copolymer*
bis-PEG-1 dimethicone*
bis-PEG-4 dimethicone
bis-PEG-8 dimethicone*
bis-PEG-10 dimethicone*
bis-PEG-12 dimethicone
bis-PEG-12 dimethicone beeswax
bis-PEG-12 dimethicone candelillate
bis-PEG-15 methyl ether dimethicone
bis-PEG-20 dimethicone*
bis-PEG-8 PEG-8 dimethicone*
bis-PEG/PPG-14/14 dimethicone
bis-PEG/PPG-15/5 dimethicone*
bis-PEG/PPG-16/16 PEG/PPG-16/16 dimethicone
bis-PEG/PPG-18/6 dimethicone*
bis-PEG/PPG-20/20 dimethicone
bis-PEG/PPG-20/5 PEG/PPG-20/5 dimethicone*
bis-stearoxy dimethicone*
bis-stearoxyethyl dimethicone*
cetyl PEG/PPG-10/1 dimethicone
cetyl PEG/PPG-15/15 butyl ether dimethicone*
cetyl PEG/PPG-7/3 dimethicone*
cetyl PEG-8 dimethicone*
lauryl isopentyl-PEG/PPG-18/18 methicone*
lauryl PEG/PPG-18/18 methicone
lauryl PEG-10 methyl ether dimethicone*
lauryl PEG-10 tris(trimethylsiloxy)silylethyl dimethicone*
lauryl PEG-8 dimethicone
lauryl PEG-8 PPG-8 dimethicone*
lauryl PEG-9 polydimethylsiloxyethyl dimethicone
lauryl polyglyceryl-3 polydimethylsiloxyethyl dimethicone*
methoxy PEG-11 methoxy PPG-24 dimethicone*
methoxy PEG/PPG-25/4 dimethicone
methoxy PEG-13 ethyl polysilsesquioxane*
PEG/PPG-10/2 dimethicone*
PEG/PPG-10/3 oleyl ether dimethicone*
PEG/PPG-12/16 dimethicone*
PEG/PPG-12/18 dimethicone*
PEG/PPG-14/4 dimethicone
PEG/PPG-15/15 dimethicone
PEG/PPG-15/5 dimethicone*
PEG/PPG-16/2 dimethicone*
PEG/PPG-16/8 dimethicone*
PEG/PPG-17/18 dimethicone
PEG/PPG-18/12 dimethicone*
PEG/PPG-18/18 dimethicone
PEG/PPG-18/6 dimethicone*
PEG/PPG-19/19 dimethicone
PEG/PPG-20/15 dimethicone
PEG/PPG-20/20 dimethicone
PEG/PPG-20/22 butyl ether dimethicone*
PEG/PPG-20/22 methyl ether dimethicone*
PEG/PPG-20/23 dimethicone
PEG/PPG-20/29 dimethicone*
PEG/PPG-20/6 dimethicone
PEG/PPG-22/22 butyl ether dimethicone*
PEG/PPG-22/23 dimethicone
PEG/PPG-22/24 dimethicone
PEG/PPG-23/23 butyl ether dimethicone*
PEG/PPG-23/6 dimethicone*
PEG/PPG-24/18 butyl ether dimethicone*
PEG/PPG-25/25 dimethicone
PEG/PPG-27/27 dimethicone*
PEG/PPG-27/9 butyl ether dimethicone*
PEG/PPG-3/10 dimethicone*
PEG/PPG-30/10 dimethicone
PEG/PPG-4/12 dimethicone
PEG/PPG-6/4 dimethicone*
PEG/PPG-6/11 dimethicone*
PEG/PPG-8/14 dimethicone
PEG/PPG-8/26 dimethicone*
PEG-10 dimethicone
PEG-10 methyl ether dimethicone
PEG-10 polydimethylsiloxyethyl dimethicone/bis-vinyl dimethicone crosspolymer*
PEG-11 methyl ether dimethicone
PEG-12 dimethicone 0
PEG-14 dimethicone 0

PEG-17 dimethicone 0
PEG-3 dimethicone 0
PEG-32 methyl ether dimethicone 0
PEG-4 PEG-12 dimethicone*
PEG-6 dimethicone*
PEG-6 methyl ether dimethicone
PEG-7 dimethicone
PEG-7 methyl ether dimethicone*
PEG-8 cetyl dimethicone
PEG-8 dimethicone
PEG-8 dimethicone dimer dilinoleate*
PEG-8 dimethicone/dimer dilinoleic acid copolymer
PEG-8 methicone
PEG-8 methyl ether dimethicone*
PEG-8 PEG-4 dimethicone*
PEG-8 PPG-8 dimethicone*
PEG-9 dimethicone
PEG-9 methyl ether dimethicone*
PPG-25 dimethicone*
PPG-27 dimethicone*
PPG-4 oleth-10 dimethicone*
PEG-9 polydimethylsiloxyethyl dimethicone
polysilicone-13
PPG-12 butyl ether dimethicone*
PPG-12 dimethicone
PPG-2 dimethicone
stearoxy dimethicone
stearoxymethicone/dimethicone 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

These ingredients function as hair conditioning agents, viscosity increasing agents, emulsion stabilizers, and film formers. The highest frequencies of use were reported in lipsticks and products used around the eyes. The highest maximum concentrations of use were reported for stearoxy dimethicone (22% in hair conditioners), cetyl PEG/PPG010/1 dimethicone (15% in eyebrow pencils), PEG/PPG-17/18 dimethicone (14% in perfumes and 13% in hair products), cetyl PEG/PPG-10/1 dimethicone (13.6% in eye shadow), and bis-hydroxyethyoxypropyl dimethicone (12% in blushers).

The Panel discussed their initial concern about the presence of up to 30% residual allyl alcohol ethoxylates as impurities. At the meeting, industry representatives clarified that the manufacturing process of these co-polymers involves the silylation of preformed polyethers (i.e., not allyl alcohol ethers) with dimethicone, which yields products containing up to 30% of the polyether starting material. The Panel requested that this explanation be submitted to them in writing, along with complete manufacturing details and resultant impurities. Accordingly, the Panel determined that residual allyl alcohol ethers do not represent a valid concern for these ingredients.

Propylene Glycol Esters – 31 ingredients

The CIR Expert Panel issued a tentative amended report for propylene glycol esters affirming the conclusion that these ingredients are safe as used. The Panel reviewed newly provided data and determined to reopen this safety assessment to combine 16 previously reviewed propylene glycol esters and add 15 ingredients, bringing the total number of ingredients in this report to 31. These ingredients are:

propylene glycol behenate*
propylene glycol caprylate*
propylene glycol cocoate*
propylene glycol dicaprate
propylene glycol dicaproate
propylene glycol dicaprylate
propylene glycol dicaprylate/dicaprate
propylene glycol dicocoate*
propylene glycol diethylhexanoate
propylene glycol diisononanoate*
propylene glycol diisostearate*
propylene glycol dilaurate*
propylene glycol stearate
propylene glycol stearate SE
soybean oil propylene glycol esters*
almond oil propylene glycol esters*
propylene glycol dioleate
propylene glycol dipelargonate
propylene glycol distearate*
propylene glycol diundecanoate*
propylene glycol heptanoate*
propylene glycol linoleate*
propylene glycol linolenate*
propylene glycol isostearate
propylene glycol laurate
propylene glycol myristate
propylene glycol oleate
propylene glycol oleate SE (self-emulsifying)*
apricot kernel oil propylene glycol esters*
avocado oil propylene glycol esters*
olive oil propylene glycol esters*

*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.

These 31 propylene glycol esters mostly function as skin-conditioning agents – emollient and as surfactants – emulsifying agent.

The frequency of use of propylene glycol dicaprylate/dicaprate increased from 202 in 1995 to 525 in 2014. The use frequency of propylene glycol dicaprylate increased from 1 in 1995 to 102 in 2014. The use frequencies of the other previously reviewed ingredients in this safety assessment have decreased.

The Panel noted that most of the data for these ingredients are on propylene glycol and associated acids. Although the Panel agreed that the existing data on propylene glycol and its associated acids were acceptable for determining the safety of all the ingredients of this safety assessment, they encouraged industry to provide additional data on any one or more of these ingredients.

Sorbitan Esters – 21 ingredients

The Panel issued a tentative amended report for public comment with the conclusion that the following 21 sorbitan esters are safe as used in cosmetics:

sorbitan caprylate
sorbitan cocoate*

sorbitan diisostearate*
sorbitan dioleate*
sorbitan distearate*
sorbitan isostearate
sorbitan laurate
sorbitan oleate
sorbitan olivate
sorbitan palmate
sorbitan palmitate
sorbitan sesquicaprylate*
sorbitan sesquiisostearate
sorbitan sesquioleate
sorbitan sesquistearate*
sorbitan stearate
sorbitan theobroma grandiflorum seedate*
sorbitan triisostearate
sorbitan trioleate
sorbitan tristearate
sorbitan undecylenate*

*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.

In 1985, the Panel determined that seven sorbitan esters were safe as used in cosmetic ingredients. In 2002, the Panel reviewed the safety of 10 additional sorbitan esters and issued an addendum to the 1985 report, concluding that the sorbitan fatty acid esters were safe as used in cosmetic ingredients. The frequency of use of the sorbitan esters has increased, but the concentration of use has not.

The Panel reaffirmed the safe as used conclusions of the 1985 and 2002 safety assessments. The Panel also determined that the data from those safety assessments together with the new data presented on the sorbitan esters support the safety of four additional esters that had not yet been reviewed, i.e., sorbitan palmate, sorbitan sesquicaprylate, sorbitan theobroma grandiflorum seedate, and sorbitan undecylenate. Thus, the Panel reopened the safety assessment to add these esters.

The Panel noted that a reported function of sorbitan theobroma grandiflorum seedate is skin bleaching agent. Since this is not a cosmetic use in the United States, the Panel emphasized that this review would not include the safety of any of these ingredients for use as skin bleaching agents.

Insufficient Data Announcement

For this insufficient data announcement, 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 by ***November 18, 2014 or sooner if possible****. This report is scheduled for review by the CIR Expert Panel at its* ***December 8-9, 2014*** *meeting.*

Polysaccharide Gums

The Panel issued an insufficient data announcement, requesting method of manufacture and impurities data on each of the ingredients, as categorized below, including the hydrolyzed polysaccharide gums and other modified polysaccharide gums reviewed in this safety assessment. In response to an industry request, the Panel recommended explaining the rationale for grouping the numerous polysaccharide gums addressed in this safety assessment, based on the sources (plant or algal) of the polysaccharide gums and the following 4 chemical-structure categories:

- Linear
- Branched
- Cyclic
- Structure unknown

Accordingly, the Panel agreed that the polysaccharide gums of the safety assessment should be organized to reflect the 4 structure categories enumerated above. The Panel emphasized that similar polysaccharides can be obtained from different sources, but the chemical structure, not the chemical source, generally determines toxicity.

These ingredients, organized based on the 4 chemical-structure categories are listed as follows:

Linear-Modified

dextrin
hydrolyzed furcellaran
hydrolyzed pectin
maltodextrin
sodium algin sulfate

Branched-Modified

calcium starch isododecenylsuccinate
calcium starch octenylsuccinate
corn starch modified
dextrin behenate
dextrin isostearate
dextrin laurate
dextrin myristate
dextrin palmitate
dextrin palmitate/ethylhexanoate
dextrin stearate
glyceryl alginate
glyceryl dimaltodextrin
glyceryl starch
hydroxypropyltrimonium hydrolyzed corn starch
hydroxypropyltrimonium hydrolyzed wheat starch
hydroxypropyl oxidized starch
hydroxypropyl starch
hydroxypropyltrimonium maltodextrin crosspolymer
laurdimonium hydroxypropyl hydrolyzed wheat starch
palmitoyl inulin

potassium dextrin octenylsuccinate
potassium undecylenoyl alginate
potato starch modified
propylene glycol alginate
sodium dextrin octenylsuccinate
sodium hydroxypropyl oxidized starch succinate
sodium oxidized starch acetate/succinate
sodium starch octenylsuccinate
sodium/tea-undecylenoyl alginate
starch diethylaminoethyl ether
starch hydroxypropyltrimonium chloride
starch laurate
starch tallowate
stearoyl inulin
tapioca starch crosspolymer
tea-dextrin octenylsuccinate
undecylenoyl inulin

Cyclic-Modified

hydroxyethyl cyclodextrin
hydroxypropyl cyclodextrin
cyclodextrin hydroxypropyltrimonium chloride
cyclodextrin laurate
methyl cyclodextrin

Unknown Structural Configuration - Modified

hydrogenated potato starch
hydrogenated starch hydrolysate
hydrolyzed corn starch hydroxyethyl ether
hydrolyzed corn starch octenylsuccinate
hydrolyzed soy starch
hydrolyzed starch
hydrolyzed triticum spelta starch
hydrolyzed wheat starch
hydrolyzed carrageenan
potassium undecylenoyl carrageenan
sodium/tea-undecylenoyl carrageenan

The Panel requested chemical-characterization data on modified polysaccharide gums, because reports in the published literature indicate elevated incidence of colorectal tumors in rats fed degraded carrageenan (a modified polysaccharide gum) in the diet. A representative from industry noted at the Panel meeting that degraded carrageenan, produced by the acid hydrolysis of seaweed, is not commercially available and is different from the carrageenan that is used in cosmetic products. Industry agreed to provide characterization data for degraded carrageenan to differentiate it from the native carrageenan used in cosmetic products. The Panel noted that chemical characterization data received for modified polysaccharide gums would be used to help evaluate any potentially toxic constituents that may be present.

The Panel reviewed reports of granulomatous reactions in subjects injected intradermally with alginate, but agreed that this mode of administration would not be relevant to cosmetic use. Additionally, Industry noted the potential toxicity of mannan, because exposures to glucomannan (a.k.a. konjac flour), a similar polysaccharide, has been associated with pulmonary sensitization. Industry agreed to provide CIR with a copy of the report of the pertinent study.

The Panel also agreed that the following 3 ingredients should be deleted from this safety assessment, because it would be more appropriate to review each of them in a separate safety assessment: croscarmellose (with cellulose gum and related ingredients), acacia seyal gum (with acacia Senegal gum and related ingredients), and natto gum (with ingredient group that would include fermentation products of soy protein).

Re-review Summaries - none

132nd Meeting Notes

Director's Report

Dr. Beth Lange, the new Executive Vice President and Chief Scientist of the Personal Care Products Council, was officially welcomed as the Industry Liaison to the CIR Expert Panel.

Dr. Gill discussed the increase in administrative issues that CIR has presented to the Panel to consider over the past few meetings, related to implementing some of CIR's 2014 strategic objectives. Beginning with the June 2014 meeting, the Panel reviewed 6 of the 15 boilerplate and guidance language documents, and a presentation focused on infant-skin-related issues enabled revising the infant skin resource document and drafting boilerplate language for review at this (September 2014) meeting. Also at this meeting, CIR proposed approaches to grouping ingredients in safety assessments for the apple and algae families of ingredients, and requested Panel input on strategies for re-reviewing 11 ingredient groups that are scheduled for review in 2015.

Dr. Gill was encouraged by the positive response from the Panel and the Industry to CIR's proposed approaches to ensuring the scientific credibility and defensibility of CIR safety assessments, increasing the efficiency of developing safety assessment reports, and improving communication throughout the safety-assessment process. She emphasized that she is committed to providing more opportunities for proactive discussions at future Panel meetings.

Reports tabled – none

Scientific Literature Reviews

- **These literature reviews are currently posted on the CIR website at http://www.cir-safety.org/ingredients/glossary/all**

  Centella asiatica-derived Ingredients
  Lecithin and Other Phosphoglycerides
  Sodium Benzotriazolyl Butylphenol Sulfonate

  Draft reports for these ingredient families, along with any unpublished data submitted by interested parties, may be presented to the Panel at its meeting on December 8-9, 2014.

- **These literature reviews are currently under development**

  Inorganic Hydroxides
  Polyene group
  Polymerized Tetramethylcyclotetrasiloxane
  Pyrus malus (apple)-derived ingredients
  Trialkyl Trimellitates

- **Re-reviews for the next Panel meeting**

  Bisabolol
  Hydroxystearic Acid
  Isostearamidopropyl Morpholine Lactate
  PEG Diesters
  Polysorbates

Next CIR Expert Panel Meeting

Monday and Tuesday, December 8-9, 2014, at the Washington Court Hotel, 525 New Jersey Avenue, NW, Washington, DC 20001 --- Please contact Carla Jackson (jacksonc@cir-safety.org) at CIR before the meeting if you plan to attend.