Announcement

Cosmetic Ingredient Review Expert Panel
122nd Meeting (March 5-6) - Findings

March 9, 2012

- **Final Safety Assessments and Amended Safety Assessments**
  - **Alkyl PEG sulfosuccinates – 18 ingredients**
  - **Ammonium hectorites – 4 ingredients**
  - **Citric acid group – 33 ingredients**
  - **Ethanolamine and ethanolamine salts – 13 ingredients**
  - **Ethanolamides – 28 ingredients**
  - **Galactomannans – 16 ingredients**

- **Tentative Safety Assessment**
  - **Cucumis sativus (cucumber) derived ingredients – 6 ingredients**

- **Insufficient Data Announcements**
  - **α-Amino acids – 34 ingredients**
  - **Bis-diglyceryl polyacyladipates – 2 ingredients**

- **Re-Reviews**
  - **Alkyl esters – reopened – 253 ingredients**
  - **PEGylated oils – reopened – 130 ingredients**
  - **Polyether lanolins – reopened – 39 ingredients**
  - **Re-review summaries for methyldibromo glutaronitrile and polyvinyl acetate approved**

- **122nd Meeting Notes**
  - **CIR Expert Panel Chair, Dr. Wilma Bergfeld, receives award**
  - **Director's Report**
  - **SAR Workshop**
  - **Cosmetics Aerosols**
  - **Parabens**
  - **Scientific Literature Reviews**
    - **previously posted on the CIR website (www.cir-safety.org) - comment period closed - will be considered for the next CIR Expert Panel meeting**
      - Borosilicates
      - Chlorophenesin
      - Microbial Polysaccharides
      - Nylon Polymers
    - **for ingredients that may be considered at the next Panel meeting)**
      - Dimethicone Crosspolymers
      - Fatty Acid Amidopropyl Dimethylamines
      - Tin and Tin Oxide
      - Vitis Vinifera (Grape) ingredients
    - **under development**
      - Hydrolyzed Proteins
      - Source Amino Acids
      - Methyl Glucose Polyethers and Esters
      - Modified Terephthalate Polymers
      - Talc
  - **Next CIR Expert Panel Meeting – Monday and Tuesday, June 11-12, 2012**

Final Safety Assessments

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/further amend the safety assessment. Unpublished data cited as references in CIR safety assessments are posted on the CIR website and available for review at the CIR office. Final safety assessments and final amended safety assessments will be posted on the CIR website at www.cir-safety.org.

Alkyl PEG Sulfosuccinates

Disodium laureth sulfosuccinate and the other 17 alkyl PEG sulfosuccinate salts and esters listed below are safe in the present practices of use and concentration when formulated to be non-irritating.

Disodium Laureth Sulfosuccinate
Disodium Laureth-6 Sulfosuccinate
Disodium Laureth-9 Sulfosuccinate*
Disodium Laureth-12 Sulfosuccinate*
Disodium Deceth-5 Sulfosuccinate*
Disodium Deceth-6 Sulfosuccinate
Magnesium Laureth-3 Sulfosuccinate*
Disodium C12-14 Pareth-1 Sulfosuccinate*
Disodium C12-14 Pareth-2 Sulfosuccinate
Disodium C12-15 Pareth Sulfosuccinate*
Disodium Coceth-3 Sulfosuccinate*
Disodium Laneth-5 Sulfosuccinate*
Disodium C12-14 Sec-Pareth-3 Sulfosuccinate*
Disodium C12-14 Sec-Pareth-5 Sulfosuccinate*
Disodium C12-14 Sec-Pareth-7 Sulfosuccinate*
Disodium C12-14 Sec-Pareth-9 Sulfosuccinate*
Disodium C12-14 Sec-Pareth-12 Sulfosuccinate*
Disodium Oleth-3 Sulfosuccinate*

Were ingredients in this group not in current use (as indicated by *) to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in the group and that they would be formulated to be non-irritating.

These ingredients share a sulfo-substituted succinic acid core and function mostly as surfactants – cleansing agents in cosmetics. The data available for disodium laureth sulfosuccinate include single-dose and repeated-dose toxicity, genotoxicity and carcinogenicity, and dermal irritation and sensitization. Reproductive and developmental toxicity data were available for laureths. Because of the similarities in chemical structure and in usage in cosmetics, these data can be extended to address the safety of all alkyl PEG sulfosuccinates.

The Panel acknowledged receipt of a material safety data sheet (MSDS) on disodium laureth sulfosuccinate indicating that this ingredient contains 1,4-dioxane at a maximum level of 0.001% and formaldehyde at a maximum level of 0.056%. The cosmetics industry should continue to use the necessary procedures to remove the 1,4-dioxane impurity from the alkyl PEG sulfosuccinates before blending them into cosmetic formulations. While formaldehyde was reported at a maximum of 0.056% as an impurity, the use of disodium laureth sulfosuccinate at concentrations up to 10% in rinse-off products and at concentrations up to 2% in leave-on products would result in formaldehyde levels well below the threshold for any toxicity concerns.

Ammonium Hectorites

Disteardimonium hectorite and the other 3 ammonium hectorite ingredients listed below are safe in the present practices of use and concentration in cosmetic products.

Dihydrogenated Tallow Benzylmonium Hectorite* Stearalkonium Hectorite Quaternium-18 Hectorite

Were dihydrogenated tallow benzylmonium hectorite, which is not in current use (as indicated by*), to be used in the future, the expectation is that it would be used in product categories and at concentrations comparable to others in the group.

These clay-based ingredients function as suspending agents in cosmetic products and may be used as viscosity increasing agents (i.e., they thicken the formulation). The CIR Expert Panel reviewed the available single-dose and repeated-dose toxicity data, along with specific studies addressing dermal irritation and sensitization, and determined that the data support the safety of these ingredients in cosmetics. While no data were available on dermal penetration, the Panel viewed these large sheets of octahedral magnesium/lithium silicate, to which are adhered cationic surfactants (e.g., stearalkonium), as unlikely to pass the stratum corneum. Components, such as lithium, in these ingredients are tightly bound and have no chance of leaching from these compounds.

Citric Acid Group

Citric acid, its 12 inorganic salts, and its 20 alkyl esters listed below (total of 33 ingredients) are safe in the present practices of use and concentration.

Inorganic Salts
Aluminum Citrate
Calcium Citrate*
Copper Citrate*
Diammonium Citrate
Disodium Cupric Citrate*
Ferric Citrate
Magnesium Citrate
Manganese Citrate*
Monosodium Citrate
Potassium Citrate
Sodium Citrate
Zinc Citrate

Alkyl Mono-, Di-, and Triesters
Dilauryl Citrate
Distearyl Citrate*
Ethyl Citrates
Isodecyl Citrate
Isopropyl Citrate*
Stearyl Citrate
Tributyl Citrate
Tri-C 12-13 Alkyl Citrate
Tri-C14-15 Alkyl Citrate
Tricaprylyl Citrate
Triethyl Citrate
Triethylhexyl Citrate
Trihexyldecyl Citrate*
Triisocetyl Citrate
Triisopropyl Citrate*
Triisostearyl Citrate
Trilauryl Citrate*
Trioctyldodecyl Citrate
Trioleyl Citrate*
Tristearyl Citrate*

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

The focus of this safety assessment was on the dermal exposure to these 10 GRAS direct food additives that are also cosmetic ingredients. The available repeated insult patch test data at the highest leave-on concentration of 4% citric acid demonstrated an absence of both dermal irritation and sensitization, suggesting that these ingredients would not be irritants in formulation. Similarities in chemical structures, physicochemical properties, and functions and concentrations in cosmetics were cited as support for including all 33 ingredients in this safety assessment, and for extending the available toxicological data to support the safety of the entire group.

Ethanolamine and Ethanolamine Salts

Ethanolamine and the 12 ethanolamine salts listed below are safe in the current practices of use (rinse-off products only) and concentration when formulated to be non-irritating. The Expert Panel cautioned that these ingredients should not be used in cosmetic products in which N-nitroso compounds may be formed.

Ethanolamine
Ethanolamine HCl*
MEA-Benzoate*
MEA-Cocoate
MEA-Laureth Sulfate
MEA-Laureth-6 Carboxylate*
MEA-Lauryl Sulfate
MEA-PPG-6-Laureth-7 Carboxylate*
MEA-PPG-8-Steareth-7 Carboxylate*
MEA-Salicylate*
MEA-Sulfite*
MEA-Tallowate
MEA-Undecylenate*

Were ingredients in this group not in current use (as indicated by *) to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in the group, that they would be formulated to be non-irritating, and that they would not be used in cosmetic products in which N-nitroso compounds may be formed.

The CIR Expert Panel noted that the salts dissociate freely in water and relied on the information available for ethanolamine in conjunction with previous safety assessments of the components of these ingredients. The Panel extrapolated those data to support the safety of the ethanolamine salts in this amended safety assessment.

Because small amounts of diethanolamine could be present in ethanolamine, the Panel was concerned about the levels of free diethanolamine that could be present as an impurity; it is for this reason that the Panel included the N-nitroso caveat in its conclusion. Also, because diethanolamine might be present as an impurity, the Panel reiterated its discussion regarding the positive findings of a dermal carcinogenicity study of diethanolamine, noting that the carcinogenic effects of diethanolamine reported in mice were not thought to be relevant to human exposure from the use of personal care products.

Ethanolamides

The 28 ethanolamides listed below are safe in the current practices of use and concentration when formulated to be non-irritating. The Expert Panel cautioned that these ingredients should not be used in cosmetic products in which N-nitroso compounds may be formed.

Acetamide MEA
Azelamide MEA*
Babassuamide MEA*
Behenamide MEA*
C16-22 Acid Amide MEA*
Cocamide MEA
Cocamide Methyl MEA
Cocamidopropyl Betainamide MEA Chloride
Hydroxystearamide MEA*
Isostearamide MEA*
Lactamide MEA
Lauramide MEA
Linoleamide MEA*
Myristamide MEA
Oatamide MEA*
Oleamide MEA*
Oliveamide MEA*
Palm Kernelamide MEA*
Palmamide MEA*
Palmitamide MEA*
Pantothenamide MEA*
Peanutamide MEA
Ricinoleamide MEA
Stearamide MEA
Sunfloweramide MEA*
Tallowamide MEA*
Trideceth-2 Carboxamide MEA
Undecylenamide MEA

Were ingredients in this group not in current use (as indicated by *) to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in the group, that they would be formulated to be non-irritating, and that they would not be used in cosmetic products in which N-nitroso compounds may be formed.

Because ethanolamides consist of covalent, secondary amides, the Panel was concerned that secondary amides tend to react with nitrosating agents to form nitrosamides; it is for this reason that the Panel included the N-nitroso caveat in its conclusion. The Panel noted that if diethanolamine is present as an impurity, the levels of free diethanolamine must not exceed those considered safe by the Panel in the current CIR safety assessment of diethanolamine. Additionally, the Panel reiterated its discussion regarding the positive findings of a dermal carcinogenicity study of diethanolamine, noting that the carcinogenic effects of diethanolamine reported in mice were not thought to be relevant to human exposure from the use of personal care products.

Similarities in chemical structures and cosmetic functions and expected similarities in structure/activity relationships were cited as support for including all 28 ethanolamides in this safety assessment, and for extending the available toxicological data to support the safety of these ethanolamides. The Panel acknowledged the lack of reproductive and developmental toxicity data, but relied on the totality of the data set to demonstrate safety. Supporting this reasoning is the expectation that only very small amounts of the compounds will be bioavailable.

Galactomannans

Guar hydroxypropyltrimonium chloride and the other 15 galactomannans listed below are safe in the present practices of use and concentration.

Caesalpinia Spinosa Gum
Caesalpinia Spinosa Hydroxypropyltrimonium Chloride*
Carboxymethyl Hydroxypropyl Guar*
Cassia Gum*
Cassia Hydroxypropyltrimonium Chloride
Ceratonia Siliqua Gum
Cyamopsis Tetragonoloba (Guar) Gum
Hydrolyzed Ceratonia Siliqua Gum Extract*
Hydrolyzed Caesalpinia Spinosa Gum
Hydrolyzed Guar
C18-22 Hydroxyalkyl Hydroxypropyl Guar*
Hydroxypropyl Guar
Hydroxypropyl Guar Hydroxypropyltrimonium Chloride
Locust Bean Hydroxypropyltrimonium Chloride
Trigonella Foenum-Graecum Hydroxypropyltrimonium Chloride*

Were ingredients in this group not in current use (as indicated by *) to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in the group

These ingredients are legume polysaccharides that function mostly as hair/skin conditioning agents and viscosity increasing agents in cosmetic products. The Panel deleted a case report relating to ingestion of curry because the flavor ingredient made from Trigonella foenum-graecum that is used in curry is not a galactomannan and, therefore, was not relevant. The Panel also noted that the ash resulting from the heating of guar hydroxypropyltrimonium chloride at high temperatures signifies the presence of inorganic salts as impurities.

Tentative Safety Assessment

For tentative safety assessments, 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, posted on the CIR website, and are available at the CIR office for review by any interested party. ***Please submit data and/or comments to CIR by May 16, 2012, or sooner if possible.*** *This report may be scheduled for review by the CIR Expert Panel at its* ***June 11-12, 2012 meeting.*** *This tentative safety assessment will be posted on the CIR website at www.cir-safety.org.*

Cucumis Sativus (Cucumber) Ingredients

The CIR Expert Panel issued a tentative safety assessment for public comment with the conclusion that 6 Cucumis sativus (cucumber)-derived ingredients were safe in the present practices of use and concentration in cosmetics.

The ingredients included:

Cucumis Sativus (Cucumber) Fruit Extract,
Cucumis Sativus (Cucumber) Extract,
Cucumis Sativus (Cucumber) Fruit,
Cucumis Sativus (Cucumber) Fruit Water,
Cucumis Sativus (Cucumber) Juice, and
Cucumis Sativus (Cucumber) Seed Extract.

Cucumis Sativus (Cucumber) Seed, an ingredient that was included in the initial Scientific Literature Review, was deleted from this safety assessment because its reported function (exfoliant) is different from that of all the other ingredients (skin conditioning agent). Information on the method of manufacture of Cucumis Sativus (Cucumber) Seed Extract was lacking in the report. Such information (if available) would improve the data set included in this assessment.

In that cucumber is a commonly consumed food and generally recognized as safe, the focus of this safety assessment was on the dermal exposure to these ingredients. Skin sensitization and phototoxicity testing of a formulation containing 5% Cucumis Sativus (Cucumber) Fruit Extract (which is greater than the highest reported use concentration of 1%) demonstrated an absence of sensitization, and phototoxicity potential. An irritant response was observed, in some subjects, to the formulation containing 5% Cucumis Sativus (Cucumber) Fruit Extract, but no irritation was observed with cosmetic formulations containing up to 2.5% ethanol extract of Cucumis sativus prepared as an oil-in-water emulsion based cream or with a formulation containing 1% Cucumis Sativus (Cucumber) Fruit Extract. Cucumis sativus, and therefore derived extracts, contains a variety of phytochemicals, all present at relatively low concentrations. Whereas certain components of these extracts could exert significant biological effects (e.g., isoflavones), the low levels preclude significant effects. Also, although no dermal absorption data were available, in the Panel's experience, phytosterols and phytosterol esters are not significantly absorbed and do not result in systemic exposure. Data on phytosterols and phytosterol esters from the CIR safety assessment of soy sterols will be added.

The Panel discussed a published tumor promotion study reporting a high level of mortality in mice after a dose of 5.0 mg cucumber extract in 0.2 ml acetone was applied to skin, noting that the high mortality was also observed with other so-called nutraceuticals that were tested. The Panel stated that this study had sufficient methodological flaws to render the results not relevant to assessing the safety of cucumber extract in cosmetics.

Insufficient Data Announcements

For 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, posted on the CIR website, and are available at the CIR office for review by any interested party. ***Please submit data and/or comments to CIR by May 8, 2012, or sooner if possible.*** *These ingredient reports may be scheduled for review by the CIR Expert Panel at its* ***June 11-12, 2012*** *meeting.*

α-Amino Acids

The CIR Expert Panel made a request for additional data for the α-amino acids group listed below. The data needs include (1) method of manufacture and (2) impurities.

This was the Panel's first review of this ingredient group. α-Amino acids that have L- stereochemistry are generally recognized as safe (GRAS) direct food additives. Since these ingredients have been shown to be safe for ingestion, the report focused on the dermal exposure of these ingredients. The amino acids and their salts included in this safety assessment are:

Alanine
Arginine
Arginine HCl
Asparagine
Aspartic Acid
Sodium Aspartate
Potassium Aspartate
Dipotassium Aspartate
Calcium Aspartate
Magnesium Aspartate
Cysteine
Cysteine HCl
Cystine
Glutamic Acid
Sodium Glutamate
Glutamine
Glycine
Sodium Glycinate
Calcium Glycinate
Magnesium Glycinate
Histidine
Histidine HCl
Isoleucine
Leucine
Lysine
Lysine HCl
Methionine
Phenylalanine
Proline
Serine
Threonine
Tryptophan
Tyrosine
Valine

Bis-Diglyceryl Polyacyladipate-2 and Bis-Diglyceryl Polyacyladipate-1

The CIR Expert Panel made a request for additional data on bis-diglyceryl polyacyladipate-2 and bis-diglyceryl polyacyladipate-1. The additional data needed included (1) representative structures, (2) method of manufacture, and (3) impurities data.

This was the Panel's first review of this ingredient group. The Panel noted that the large size of these molecules likely would preclude significant dermal penetration, but data were not available. Dermal penetration and toxicokinetics data (if available) would improve the data set included in this assessment.

Re-Reviews

Cetyl Esters – reopened

The Panel reopened this report to create a new grouping of 253 ingredients, which will be titled **alkyl esters**. The CIR Expert Panel reviewed data newly available since its original safety assessment of Cetyl Esters. While the conclusion reached for the original single ingredient was reaffirmed, the Panel considered that the available data could be used to support the safety of 252 additional alkyl esters.

Supporting the creation of this larger group was the Panel's consistent findings for 58 previously reviewed/re-reviewed alkyl esters. These data will be extended to support the safety of the alkyl esters that have not been reviewed.

The Panel considered an additional 6 ingredients that might have been included, but determined that it was not appropriate. The ingredients that will not be included (for the following reasons)are: decyl hempseedate (hempseedate has not been reviewed); hexyldecyl ester of hydrolyzed collagen (lack of chemical similarity); lauryl Carpotroche brasiliensis seedate; lauryl Theobroma grandiflorum seedate; myristyl Carpotroche brasiliensis seedate; and myristyl Theobroma grandiflorum seedate (these four ingredients have reported function as skin bleaching agents).

A concern was expressed regarding the lack of data on biotransformation of branched fatty acids and branched alcohols in the skin. Submission of such data, if available, was encouraged.

The new alkyl esters report will include:

Arachidyl Behenate
Arachidyl Erucate
Arachidyl Propionate
Batyl Isostearate
Batyl Stearate
Behenyl Beeswax
Behenyl Behenate
Behenyl Erucate
Behenyl Isostearate
Behenyl Olivate
Behenyl/Isostearyl Beeswax
Butyl Avocadate
Butyl Babassuate
Butyl Isostearate
Butyl Myristate
Butyl Oleate
Butyl Stearate
Butyloctyl Beeswax
Butyloctyl Behenate
Butyloctyl Candelillate
Butyloctyl Cetearate
Butyloctyl Oleate
Butyloctyl Palmitate
C10-40 Isoalkyl Acid Octyldodecanol Esters
C12-13 Alkyl Ethylhexanoate
C12-15 Alkyl Ethylhexanoate
C14-18 Alkyl Ethylhexanoate
C14-30 Alkyl Beeswax
C16-36 Alkyl Stearate
C18-38 Alkyl Beeswax
C18-38 Alkyl C24-54 Acid Ester
C20-40 Alkyl Behenate
C20-40 Alkyl Stearate
C30-50 Alkyl Beeswax
C30-50 Alkyl Stearate
C32-36 Isoalkyl Stearate
C40-60 Alkyl Stearate
C4-5 Isoalkyl Cocoate
Caprylyl Butyrate
Caprylyl Caprylate
Caprylyl Eicosenoate
Cetearyl Behenate
Cetearyl Candelillate
Cetearyl Ethylhexanoate
Cetearyl Isononanoate
Cetearyl Nonanoate
Cetearyl Olivate
Cetearyl Palmate
Cetearyl Palmitate
Cetearyl Rice Branate
Cetearyl Stearate
Cetyl Babassuate
Cetyl Behenate
Cetyl Caprate
Cetyl Caprylate
Cetyl Dimethyloctanoate
Cetyl Esters

Cetyl Ethylhexanoate
Cetyl Isononanoate
Cetyl Laurate
Cetyl Myristate
Cetyl Oleate
Cetyl Palmitate
Cetyl Ricinoleate
Cetyl Stearate
Cetyl Tallowate
Chimyl Isostearate
Chimyl Stearate
Coco-Caprylate
Coco-Caprylate/Caprate
Coco-Rapeseedate
Decyl Castorate
Decyl Cocoate
Decyl Isostearate
Decyl Jojobate
Decyl Laurate
Decyl Myristate
Decyl Oleate
Decyl Olivate
Decyl Palmitate
Decyltetradecyl Cetearate
Decyltetradecyl Ethylhexanoate
Erucyl Arachidate
Erucyl Erucate
Erucyl Oleate
Ethylhexyl Adipate/Palmitate/Stearate
Ethylhexyl C10-40 Isoalkyl Acidate
Ethylhexyl Cocoate
Ethylhexyl Ethylhexanoate
Ethylhexyl Hydroxystearate
Ethylhexyl Isononanoate
Ethylhexyl Isopalmitate
Ethylhexyl Isostearate
Ethylhexyl Laurate
Ethylhexyl Myristate
Ethylhexyl Neopentanoate
Ethylhexyl Oleate
Ethylhexyl Olivate
Ethylhexyl Palmitate
Ethylhexyl Pelargonate
Ethylhexyl Stearate
Heptyl Undecylenate
Heptylundecyl Hydroxystearate
Hexyl Isostearate
Hexyl Laurate
Hexyldecyl Ethylhexanoate
Hexyldecyl Hexyldecanoate
Hexyldecyl Isostearate
Hexyldecyl Laurate
Hexyldecyl Oleate
Hexyldecyl Palmitate
Hexyldecyl Stearate
Hexyldodecyl/Octyldecyl Hydroxystearate
Hydrogenated Castor Oil Behenyl Esters
Hydrogenated Castor Oil Cetyl Esters
Hydrogenated Castor Oil Stearyl Esters
Hydrogenated Ethylhexyl Olivate
Hydrogenated Ethylhexyl Sesamate
Hydrogenated Isocetyl Olivate
Hydrogenated Isopropyl Jojobate
Hydroxycetyl Isostearate
Hydroxyoctacosanyl Hydroxystearate
Isoamyl Laurate
Isobutyl Myristate
Isobutyl Palmitate
Isobutyl Perlargonate
Isobutyl Stearate
Isobutyl Tallowate
Isocetyl Behenate
Isocetyl Ethylhexanoate
Isocetyl Isodecanoate
Isocetyl Isostearate
Isocetyl Laurate
Isocetyl Myristate
Isocetyl Palmitate
Isocetyl Stearate
Isodecyl Cocoate
Isodecyl Ethylhexanoate
Isodecyl Hydroxystearate
Isodecyl Isononanoate
Isodecyl Laurate
Isodecyl Myristate
Isodecyl Neopentanoate
Isodecyl Oleate
Isodecyl Palmitate
Isodecyl Stearate
Isohexyl Caprate
Isohexyl Laurate
Isohexyl Neopentanoate
Isohexyl Palmitate
Isolauryl Behenate
Isononyl Isononanoate
Isooctyl Caprylate/Caprate
Isooctyl Tallate
Isopropyl Isostearate
Isopropyl Arachidate
Isopropyl Avocadate
Isopropyl Babassuate
Isopropyl Behenate
Isopropyl Hydroxystearate
Isopropyl Jojobate
Isopropyl Laurate
Isopropyl Linoleate
Isopropyl Myristate
Isopropyl Oleate
Isopropyl Palmitate
Isopropyl Ricinoleate
Isopropyl Sorbate
Isopropyl Stearate
Isopropyl Tallowate
Isostearyl Avocadate
Isostearyl Behenate
Isostearyl Erucate
Isostearyl Ethylhexanoate
Isostearyl Hydroxystearate
Isostearyl Isononanoate
Isostearyl Isostearate
Isostearyl Laurate
Isostearyl Linoleate
Isostearyl Myristate
Isostearyl Neopentanoate
Isostearyl Palmitate
Isotridecyl Isononanoate
Isotridecyl Laurate
Isotridecyl Myristate
Isotridecyl Stearate
Lauryl Behenate
Lauryl Cocoate
Lauryl Ethylhexanoate
Lauryl Isostearate
Lauryl Laurate
Lauryl Myristate
Lauryl Oleate
Lauryl Palmitate
Lauryl Stearate
Lignoceryl Erucate
Myristyl Ethylhexanoate
Myristyl Isostearate
Myristyl Laurate
Myristyl Myristate
Myristyl Neopentanoate
Myristyl Stearate
Octyldecyl Oleate
Octyldodecyl Avocadoate
Octyldodecyl Beeswax
Octyldodecyl Behenate
Octyldodecyl Cocoate
Octyldodecyl Erucate
Octyldodecyl Ethylhexanoate
Octyldodecyl Hydroxystearate
Octyldodecyl Isostearate
Octyldodecyl Meadowfoamate
Octyldodecyl Myristate
Octyldodecyl Neodecanoate
Octyldodecyl Neopentanoate
Octyldodecyl Octyldodecanoate
Octyldodecyl Oleate
Octyldodecyl Olivate
Octyldodecyl Ricinoleate
Octyldodecyl Safflowerate
Octyldodecyl Stearate
Oleyl Arachidate
Oleyl Erucate
Oleyl Linoleate
Oleyl Myristate
Oleyl Oleate
Oleyl Stearate
Propylheptyl Caprylate
Stearyl Beeswax
Stearyl Behenate
Stearyl Caprylate
Stearyl Erucate
Stearyl Ethylhexanoate
Stearyl Heptanoate
Stearyl Linoleate
Stearyl Olivate
Stearyl Palmitate
Stearyl Stearate
Tetradecyleicosyl Stearate
Tetradecyloctadecyl Behenate
Tetradecyloctadecyl Hexyldecanoate
Tetradecyloctadecyl Myristate
Tetradecyloctadecyl Stearate
Tetradecylpropionates
Tridecyl Behenate
Tridecyl Cocoate
Tridecyl Erucate
Tridecyl Ethylhexanoate
Tridecyl Isononanoate
Tridecyl Laurate
Tridecyl Myristate
Tridecyl Neopentanoate
Tridecyl Stearate

PEGs castor oil and PEGs hydrogenated castor oil – reopened

The Panel reopened this report to create a new grouping of 130 ingredients, which will be titled **PEGylated oils**. The CIR Expert Panel reviewed data newly available since its original safety assessment of PEG-30, -33, -35, -36, and-40 castor oil and PEG-30 and -40 hydrogenated castor oil. While the conclusion reached for the original 7 ingredients was reaffirmed, the Panel considered that the available data could be used to support the safety of 123 additional PEGylated oils.

Supporting the creation of this larger group were the recently completed review of PEGs and the review of vegetable oils. The Panel determined to not include PEGylated oils for which the oil moiety had not previously been reviewed.

The ingredients included in the new PEGylated oils group include:

PEG-2 Castor Oil
PEG-3 Castor Oil
PEG-4 Castor Oil
PEG-5 Castor Oil
PEG-8 Castor Oil
PEG-9 Castor Oil
PEG-10 Castor Oil
PEG-11 Castor Oil
PEG-15 Castor Oil
PEG-16 Castor Oil
PEG-20 Castor Oil
PEG-25 Castor Oil
PEG-26 Castor Oil
PEG-29 Castor Oil
PEG-30 Castor Oil
PEG-33 Castor Oil
PEG-35 Castor Oil
PEG-36 Castor Oil
PEG-40 Castor Oil
PEG-44 Castor Oil
PEG-50 Castor Oil
PEG-54 Castor Oil
PEG-55 Castor Oil
PEG-60 Castor Oil
PEG-75 Castor Oil
PEG-80 Castor Oil
PEG-100 Castor Oil
PEG-200 Castor Oil
PEG-18 Castor Oil Dioleate
PEG-60 Castor Oil Isostearate 25
PEG-2 Hydrogenated Castor Oil
PEG-5 Hydrogenated Castor Oil
PEG-6 Hydrogenated Castor Oil
PEG-7 Hydrogenated Castor Oil
PEG-8 Hydrogenated Castor Oil
Hydrogenated Castor Oil PEG-8 Esters
PEG-10 Hydrogenated Castor Oil
PEG-16 Hydrogenated Castor Oil
PEG-20 Hydrogenated Castor Oil
PEG-25 Hydrogenated Castor Oil
PEG-30 Hydrogenated Castor Oil
PEG-35 Hydrogenated Castor Oil
PEG-40 Hydrogenated Castor Oil
PEG-45 Hydrogenated Castor Oil
PEG-50 Hydrogenated Castor Oil
PEG-54 Hydrogenated Castor Oil
PEG-55 Hydrogenated Castor Oil
PEG-60 Hydrogenated Castor Oil
PEG-65 Hydrogenated Castor Oil
PEG-80 Hydrogenated Castor Oil
PEG-100 Hydrogenated Castor Oil
PEG-200 Hydrogenated Castor Oil
PEG-5 Hydrogenated Castor Oil Isostearate
PEG-10 Hydrogenated Castor Oil Isostearate
PEG-15 Hydrogenated Castor Oil Isostearate
PEG-20 Hydrogenated Castor Oil Isostearate
PEG-30 Hydrogenated Castor Oil Isostearate 25
PEG-40 Hydrogenated Castor Oil Isostearate
PEG-50 Hydrogenated Castor Oil Isostearate
PEG-58 Hydrogenated Castor Oil Isostearate
PEG-20 Hydrogenated Castor Oil Laurate
PEG-30 Hydrogenated Castor Oil Laurate
PEG-40 Hydrogenated Castor Oil Laurate
PEG-50 Hydrogenated Castor Oil Laurate
PEG-60 Hydrogenated Castor Oil Laurate
PEG-20 Hydrogenated Castor Oil PCA Isostearate
PEG-30 Hydrogenated Castor Oil PCA Isostearate
PEG-40 Hydrogenated Castor Oil PCA Isostearate
PEG-60 Hydrogenated Castor Oil PCA Isostearate
PEG-50 Hydrogenated Castor Oil Succinate
Potassium PEG-50 Hydrogenated Castor Oil Succinate
Sodium PEG-50 Hydrogenated Castor Oil Succinate
PEG-5 Hydrogenated Castor Oil Triisostearate
PEG-10 Hydrogenated Castor Oil Triisostearate
PEG-15 Hydrogenated Castor Oil Triisostearate
PEG-20 Hydrogenated Castor Oil Triisostearate
PEG-30 Hydrogenated Castor Oil Triisostearate
PEG-40 Hydrogenated Castor Oil Triisostearate
PEG-50 Hydrogenated Castor Oil Triisostearate
PEG-60 Hydrogenated Castor Oil Triisostearate
Adansonia Digitata Seed Oil PEG-8 Esters
Almond Oil PEG-6 Esters 25
Almond Oil PEG-8 Esters
Apricot Kernel Oil PEG-6 Esters
Apricot Kernel Oil PEG-8 Esters
Apricot Kernel Oil PEG-40 Esters
Argan Oil PEG-8 Esters
Avocado Oil PEG-8 Esters
Avocado Oil PEG-11 Esters
Bertholletia Excelsa Seed Oil PEG-8 Esters
Borage Seed Oil PEG-8 Esters
Coconut Oil PEG-10 Esters
Corn Oil PEG-6 Esters
Corn Oil PEG-8 Esters
Grape Seed Oil PEG-8 Esters
Hazel Seed Oil PEG-8 Esters
Hydrogenated Palm/Palm Kernel Oil PEG-6 Esters
Jojoba Oil PEG-8 Esters
Jojoba Oil PEG-150 Esters
Linseed Oil PEG-8 Esters
Macadamia Ternifolia Seed Oil PEG-8 Esters
Mango Seed Oil PEG-70 Esters
Mink Oil PEG-13 Esters
Olive Oil PEG-6 Esters
Olive Oil PEG-7 Esters
Olive Oil PEG-8 Esters
Olive Oil PEG-10 Esters 25
Orbignya Oleifera Seed Oil PEG-8 Esters
Palm Oil PEG-8 Esters
Passiflora Edulis/Passiflora Incarnata Seed Oils PEG-8 Esters
Peanut Oil PEG-6 Esters
PEG-75 Crambe Abyssinica Seed Oil
PEG-75 Meadowfoam Oil
Pumpkin Seed Oil PEG-8 Esters
Rapeseed Oil PEG-3 Esters
Rapeseed Oil PEG-20 Esters
Raspberry Seed Oil PEG-8 Esters
Safflower Seed Oil PEG-8 Esters

Schinziophyton Rautanenii Kernel Oil PEG-8 Esters
Sclerocarya Birrea Seed Oil PEG-8 Esters
Sesame Seed Oil PEG-8 Esters
Soybean Oil PEG-8 Esters
Soybean Oil PEG-20 Esters
Soybean Oil PEG-36 Esters
Sunflower Seed Oil PEG-8 Esters
Sunflower Seed Oil PEG-32 Esters
Sweet Almond Oil PEG-8 Esters
Watermelon Seed Oil PEG-8 Esters
Wheat Germ Oil PEG-40 Butyloctanol Esters
Wheat Germ Oil PEG-8 Esters 23

The Panel noted that the limitations on the PEGs castor oil in the original conclusion were due to supporting safety data in which the ingredients was tested at concentrations up to 50%. If industry uses these ingredients at concentrations greater than 50%, the Panel expects that safety test data will be supplied that can support the use of ingredients at higher use concentrations. PEGs hydrogentated castor oil had been tested neat.

PPG-5 lanolin wax and PPG-5 lanolin wax glyceride – reopened

The Panel reopened this report to create a new grouping of 39 ingredients, which will be titled **polyether lanolins**. The CIR Expert Panel reviewed data newly available since its original safety assessment of the 2 PPG lanolin wax ingredients. While the conclusion reached for these original 2 ingredients was reaffirmed, the Panel considered that the available data could be used to support the safety 37 additional polyether lanolins.

Supporting the creation of this larger group was the Panel's consistent findings in reviewing PEG lanolin and PEG hydrogenated lanolin ingredients, as well as the review of PEGs, the review of dipropylene glycol, the review of PPGs, and the review of lanolin ingredients. These data, coupled with the data for the PPG lanolin wax ingredients, will be extended to support the safety of 12 polyether lanolins that have not been reviewed.

The new polyether lanolin report will include:

PPG-5 Lanolin Wax,
PPG-5 Lanolin Wax Glyceride,
PEG-75 Lanolin Wax,
PEG-5 Hydrogenated Lanolin,
PEG-10 Hydrogenated Lanolin,
PEG-15 Hydrogenated Lanolin,
PEG-20 Hydrogenated Lanolin,
PEG-24 Hydrogenated Lanolin,
PEG-30 Hydrogenated Lanolin,
PEG-40 Hydrogenated Lanolin,
PEG-70 Hydrogenated Lanolin,
PEG-5 Lanolin,
PEG-10 Lanolin,
PEG-20 Lanolin,
PEG 24 Lanolin,
PEG-25 Lanolin,
PEG-27 Lanolin,
PEG-30 Lanolin,
PEG-35 Lanolin,
PEG-40 Lanolin,
PEG-50 Lanolin,
PEG-55 Lanolin,
PEG-60 Lanolin,
PEG-70 Lanolin,
PEG-75 Lanolin,
PEG-85 Lanolin,
PEG-100 Lanolin,
PEG-150 Lanolin,
PEG-75 Lanolin Oil,
Polyglyceryl-2 Lanolin Alcohol Ether,
PPG-2 Lanolin Alcohol Ether,
PPG-5 Lanolin Alcohol Ether,
PPG-10 Lanolin Alcohol Ether,
PPG-20 Lanolin Alcohol Ether,
PPG-30 Lanolin Alcohol Ether,
PPG-20-PEG-20 Hydrogenated Lanolin,
PPG-12-PEG-50 Lanolin,
PPG-12-PEG-65 Lanolin Oil, and
PPG-40-PEG-60 Lanolin Oil

Re-review summaries - The CIR Expert Panel approved the re-review summaries for methyldibromo glutaronitrile and polyvinyl acetate. The safety of these ingredients in cosmetics had been reaffirmed at the December 2011 meeting.

122nd Meeting Notes

CIR Expert Panel Chair, Dr. WIlma F. Bergfeld, Receives Master Dermatologist Award

Dr. Wilma F. Bergfeld, MD, FACP, has received the Master Dermatologist Award from the American Academy of Dermatology (AAD). She will be formally recognized at the 70th Annual AAD Meeting in San Diego.

The Master Dermatologist Award recognizes an AAD member who has made significant contributions to dermatology and the AAD over his or her career, according to information on the AAD website.

"I'm the first woman to receive this award, which is nice — I was the first woman president of the American Academy of Dermatology and now I'm the first woman to receive the dermatologist's Master Award," explains Dr. Bergfeld. "I cannot express how thrilled I am to be recognized in this manner."

The recipient of the Master Dermatologist Award is nominated by the History Committee and approved by the Board of Directors, according to the AAD website. Dr. Bergfeld found out about the award when the AAD President, Ronald Moy, MD, called her to share the news.

"I was absolutely thrilled," Dr. Bergfeld says. "To have peer recognition at this time in my life is fantastic. To be recognized for the work over your career is fantastic, because not everybody gets that recognition, and I just feel very privileged."

Director's Report

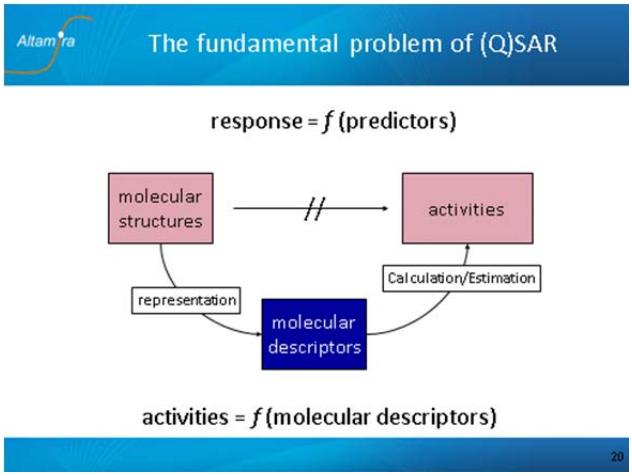
Dr. Andersen reported that the new CIR website continues to be adjusted to improve functionality. He also noted the first-time use of graphics in the CIR summary minutes approved by the Panel for the December 2011 meeting. CIR expects to continue to include graphics, especially those from the SAR workshop held on day 1 of this meeting. He congratulated the Panel on reaching a total of 2547 individual cosmetic ingredients reviewed through the end of 2011.

SAR Workshop

In June of 2011, the CIR Expert Panel had asked for a workshop that would address the use of structure activity relationships (SAR) in toxicological evaluations. Four speakers, representing diverse areas of responsibility, each addressed the current status of the use of SAR.

Chihae Yang, Ph.D., is the Chief Scientific Officer of Altamira LLC, which is a knowledge development company collaborating with the U.S. FDA to develop publicly available toxicity databases, and serves as a work package leader for the European COSMOS project. She reviewed the history, development, and prospects of computational toxicology methods and tools, and discussed the current challenges of using these approaches to predict toxicity and support chemical risk assessments.

Dr. Yang explained that computational methods can be used effectively to derive knowledge from theory and the results of past experiments. She emphasized that inherent problems and limitations of methods currently being developed must be recognized and addressed before such methods can be widely accepted by the regulatory community and broadly used to support the risk assessment of ingredients in cosmetics or other consumer products. She illustrated the fundamental problem of quantitative structure activity relationship (Q)SAR analysis, in particular, using the figure below.



The central problem is that (Q)SAR technologies cannot predict biological activities directly from molecular structures. Rather, they are used to predict biological activity indirectly, based on molecular descriptors (i.e., electronic and steric/size effects and hydrophobicity) that represent the molecular structures. Further, applying these technologies produces results that need additional transformation and translation to enable using them effectively in risk assessments, which adds more complexity to an already very complex paradigm.

One of the more specific problems to be addressed in the development of these methods is the need for a formal, quantitative, weight-of-evidence approach to synthesizing and presenting the results of structural alert, SAR and read-across analyses. Solving this problem would substantially facilitate the use of these methods to support risk assessments and risk management decisions.

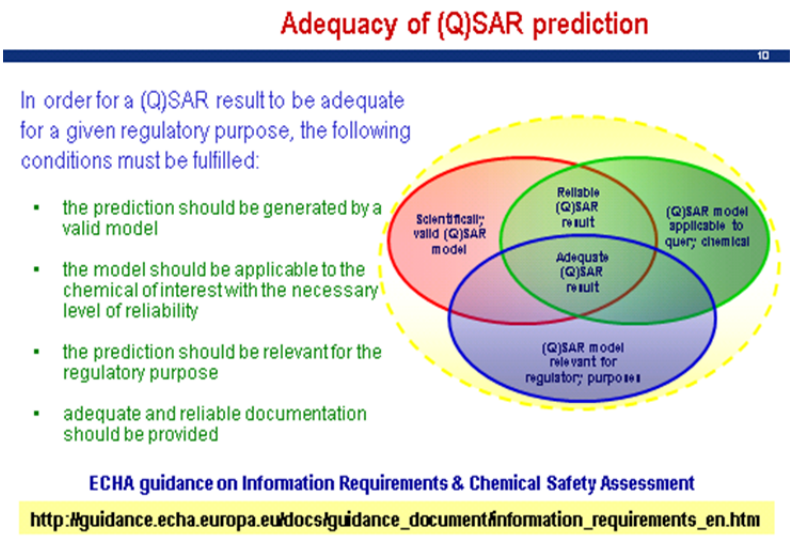
Dr. Yang emphasized that defining mode-of-action (MoA) categories of chemicals will enable the incorporation of mechanistic descriptors, as well as biological assay descriptors, which can significantly improve the interpretability and biological relevance of the results of (Q)SAR analyses. Such (Q)SAR results for chemicals with sufficient data can serve as the basis for developing chemical and biological space profiles. These profiles could, in turn, be used to support reliable read-across for evaluating chemicals for which suitable analogs can be identified, and facilitate the application of knowledge about metabolic pathways, structural alerts, and structure activity relationships to predict toxicological endpoints and potencies for chemicals without adequate data or suitable analogs.

Andrew Worth, Ph.D., is the leader of the Computational Toxicology group at the European Union (EU) Joint Research Centre (JRC) in Ispra, Italy. This group develops and evaluates computational methods for the regulatory assessment of chemicals. Dr. Worth reviewed the EU cosmetic legislation that is largely driving current efforts to develop alternatives to the whole animal testing of cosmetic ingredients, and he discussed the computational tools and approaches that the JRC has developed to help meet that challenge.

Dr. Worth noted that the SEURAT-1 Cluster is a European Commission (EC) research initiative aimed at developing knowledge and technology building blocks required for the ultimate replacement of *in vivo* repeated dose systemic toxicity testing in animals. The objective is to replace such testing with alternative predictive toxicology tools developed based on a complete understanding of how chemicals can cause adverse effects in humans. Within the SEURAT-1 Cluster, the COSMOS project has the goal of developing integrated *in silico* models for predicting the toxicity and supporting the safety assessment of cosmetic ingredients.

He explained that, while (Q)SAR analyses can replace whole animal testing in principle, it is much more likely that these analyses will be used as a key element of many in integrated toxicology testing strategies.

One of the principle barriers to the acceptance of (Q)SAR methods is the lack of practical guidance on how to use them to support regulatory decisions. Dr. Worth used the diagram below to outline three key information elements needed to support the adequacy of (Q)SAR predictions for regulatory purposes.



and safety assessment of cosmetic ingredients.

In addition, petitioners need to explain and document the adequacy of a tool within the appropriate regulatory context if they want to use the tool for this purpose. Standardized templates have been developed for reporting the validity of (Q)SAR models and the adequacy of predictions.

Dr. Worth indicated that acceptable alternatives to whole animal tests should be achievable in the short-term for toxicological endpoints for which the chemistry is well understood, such as skin irritation, sensitization and penetration, as well as genotoxicity. However, full replacement of whole animal skin sensitization tests is not likely for at least another 7 years, and no timelines have been estimated for more challenging areas, such as toxicokinetics, repeated dose toxicity, carcinogenicity and reproductive toxicity.

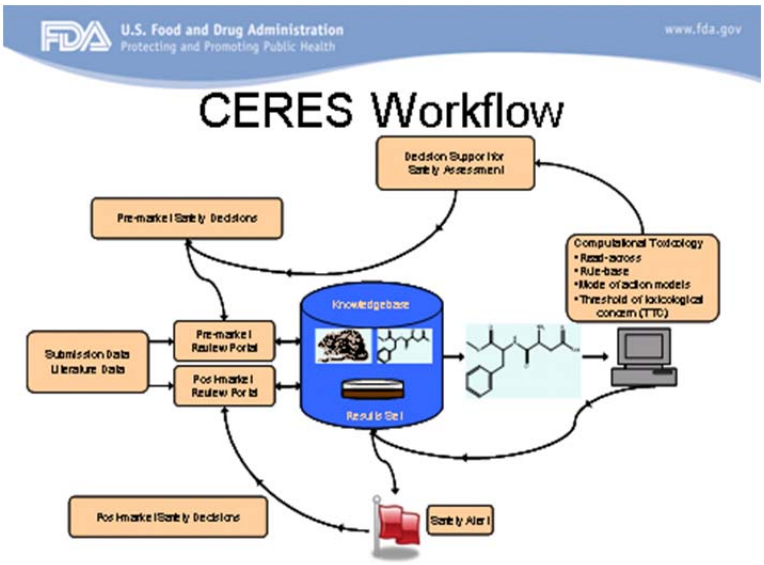
He noted that very limited use of *in vitro*, (Q)SAR, and read-across methods have been made under the European REACH regulation to date, probably because the focus has been on evaluating the more dangerous chemicals for which there is much data. Efforts to address lower tonnage chemicals with less information will likely involve the increasing use of (Q)SAR methods, especially grouping and read-across approaches, in accordance with SCCS guidance for the testing

Kirk Arvidson, Ph.D., is a review chemist and leader of the Structure Activity Relationship (SAR) Team in the U.S. FDA Office for Food Additive Safety (OFAS). This team performs computational toxicology modeling and research and knowledgebase development to support the safety assessment of food additives. Dr. Arvidson discussed how the OFAS uses (Q)SAR in their assessments and reviewed the ongoing development of the Chemical Evaluation and Risk Estimation System (CERES) knowledgebase.

Dr. Arvidson explained that (Q)SAR tools are used by his group and by U.S. FDA toxicologists primarily to identify toxicity data gaps and provide specific toxicity testing recommendations during premarket notification consultations.

He noted that FDA staff use multiple (Q)SAR tools and databases, in concert, to maximize the chemical space (i.e., the domain of applicability) of this approach. In addition, they employ a weight-of-evidence, consensus approach to develop predictions and recommendations for the food contact notification review process. Emphasis is placed on fully evaluating and understanding how to run the models before using them. Further, the U.S. FDA takes a conservative approach to interpreting and making decisions based on the output of these models. For example, one positive result among multiple (Q)SAR predictions may trigger a recommendation to evaluate additional structural analogs or conduct additional toxicity testing.

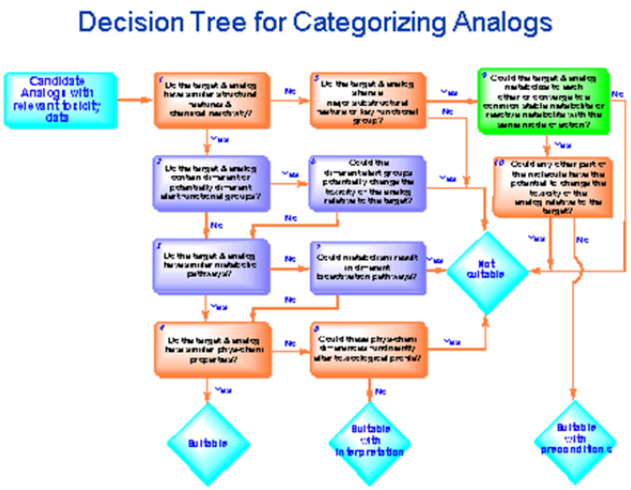
Dr. Arvidson depicted the CERES workflow in the figure to the right.



The CERES system is a food additive knowledgebase developed to improve pre- and post-marketing reviews and promote more robust safety assessments. CERES captures institutional knowledge and consolidates information on chemical structures (including substructures), physical properties, toxicities, mode of action, metabolism, and exposures, as well as specific regulatory decisions and actions for chemicals of interest. CERES can be used to facilitate the identification of suitable analogs for (Q)SAR analysis and read-across, and to discover useful relationships between new and existing data.

Dr. Arvidson noted that Procter and Gamble (P&G) has donated approximately 40,000 high quality chemical structures to the CERES project. Eventually the U.S. FDA will share CERES with the COSMOS group. The CERES system will be available online when the JRC begins to host the system on their Website.

Karen Blackburn, Ph.D., is a Research Fellow at P&G, Central Product Safety, where she provides technical oversight and collaborates with expert groups to develop risk assessment methods. She outlined a framework for using structural, metabolic, and other properties of chemicals to identify and evaluate the suitability of analogs for use in SAR read-across assessments. The framework was recently published by Dr. Shengde Wu, Dr. Blackburn, and their colleagues at P&G.



Dr. Blackburn presented the decision tree shown below to describe this integral element in their overall approach to SAR assessments.

She explained that the process for characterizing the suitability of candidate analogs involves a chemistry evaluation, a metabolism evaluation, a toxicity review, and a rating of the uncertainty associated with each candidate.

Dr. Blackburn noted that their published case studies demonstrate that the framework can be applied successfully for read-across, and consistently provides reasonable, conservative estimates of no effect levels for substances of interest (SOIs). She stated that her experience developing and testing the framework suggests that, in some cases, more confidence could be placed in the conservative assessments developed based on high quality analogs identified using the framework than to assessments based on the results of a single animal study on an SOI, given the variability typically associated with such studies.

Dr. Blackburn also presented a PEG-Cocamine case study to illustrate the potential application of the framework for performing read-across to support the safety assessment of a relatively large and complex cosmetic ingredient group. She explained that her group was able to identify analogs that could adequately cover the chemical space represented by all of the ingredients in the group.

The Panel indicated that the Workshop provided good background material in preparation for submittals that they will likely see in the future. They noted that future discussions addressing the definition of the relevant chemical space in a systematic way would be most important to the Panel. The Panel suggested periodic updates on the current state-of-the-art in this field.

Cosmetics aerosols

The Panel directed that the revised cosmetic aerosols precedents document should be posted on the CIR website to provide interested parties with easy access to the background information, the location of which would be included in relevant ingredient safety assessments.

The Panel reaffirmed the view that the particles produced from the use of cosmetics sprays and aerosols are predominantly non-respirable, and, given the small actual exposure in the breathing zone, are not usually a significant route of exposure. The Panel stated, explicitly, that inhaled chemicals deposited in the nasopharyngeal and tracheobronchial regions of the respiratory tract may cause toxic effects in these regions, depending on their chemical and other properties, and that the potential for toxic effects is not limited to respirable particles deposited in the lungs. The Panel did note that reference to toxicity would not be made in any CIR report cosmetic use section.

Parabens

The Panel reaffirmed the safety of parabens as preservatives in the present practices of use and concentration in cosmetics.

At the request of the Personal Care Products Council, the Panel re-examined its 2008 published safety assessment of parabens. The Council cited new opinions from the European Commission's Scientific Committee on Consumer Safety (SCCS) regarding (1) safe levels of parabens in cosmetics and (2) parabens in products intended for children under 3 years of age.

The SCCS updated opinion on parabens confirmed that methyl- and ethylparaben are safe up to 0.4% for one and a total of 0.8% for any mixture, but lowered the level in cosmetics considered safe for propyl- and butylparaben to 0.19% for any one or any mixture. This lowering appeared to be based on a re-evaluation of existing dermal penetration/metabolism data, not on new data. The Panel reiterated its very conservative value of 50% dermal penetration and the robust toxicity study it used as a benchmark to evaluate a margin of safety, i.e. how far below the exposure levels known to produce no damage in the toxicity study are the levels found in cosmetics. The Panel stated that its published margins of safety are still valid and continue to offer ample assurance that parabens are safe in the present practices of use and concentration.

The second recent SCCS opinion addressed the Danish decision to ban parabens in products intended for children under 3 years of age. The SCCS opinion appeared to say that there is no real basis for the Danish ban, and the Panel agreed with that position. The SCCS opinion did note that additional data would be useful for children <6 mo of age.

The Panel agreed that infants are a sensitive subpopulation for risk assessment and has consistently considered the higher skin surface area to body mass ratio in infants when performing cosmetic ingredient safety assessments. The Panel believes that more data regarding dermal penetration through infant skin and potential metabolism in infant skin are available and should be brought to bear on this question. The Panel directed CIR staff to begin the process of pulling that information together in an overview report, with the intent of providing the information to the public, as was done for aerosols as discussed above.

Scientific Literature Reviews

- previously posted on the CIR website - comment period closed - will be considered for the next Panel meeting
  - Borosilicates
  - Chlorophenesin
  - Microbial Polysaccharides
  - Nylon Polymers
- recently posted on the CIR website - may be considered at the next Panel meeting
  - Dimethicone Crosspolymers
  - Fatty Acid Amidopropyl Dimethylamines
  - Tin and Tin Oxide
  - Vitis Vinifera (Grape) ingredients
- under development
  - Hydrolyzed Proteins
  - Source Amino Acids
  - Methyl Glucose Polyethers and Esters
  - Modified Terephthalate Polymers
  - Talc

Next CIR Expert Panel Meeting - Monday and Tuesday, June 11-12, 2012 at the Madison Hotel, 1177 Fifteenth Street, NW, Washington, DC 20005 --- Please contact Carla Jackson (jacksonc@cir-safety.org) at CIR before the meeting if you plan to attend.

►►IMPORTANT CHANGE◄◄

CIR no longer includes an order form listing CIR safety assessments available for sale. Because all CIR documents will be posted on the web site, they will be freely available for comment (scientific literature reviews and tentative reports) or for downloading and retention (final reports).