MEMORANDUM

To: CIR Expert Panel Members and Liaisons
From: Director, CIR
Subject: 119th Meeting of the CIR Expert Panel — Monday and Tuesday, June 27-28, 2011
Date: May 27, 2011

Enclosed are the agenda and accompanying materials for the 119th CIR Expert Panel Meeting, to be held Monday and Tuesday, June 27-28, 2011 at the Madison Hotel, 1177 Fifteenth Street, NW, Washington, DC 20005. Phone: (202) 862-1600. Fax: (202) 785-1255.

The agenda includes consideration of 15 ingredient groups, along with an in-depth review of our aerosol boilerplate, a look at priorities, and review of one re-review summary from March.

Schedule and hotel accommodations

We will reserve rooms for the nights of Sunday, June 26th and Monday, June 27th at the Madison. If you have any problems, please contact me on my cell phone at 301-512-7846.

Team meetings - remember, we are back at the Madison and will have a breakfast buffet before the meeting starts. Check the agenda for times!

Re-review summary - buff book 1 - you’ll be able to review the re-review summary of Quaternium-15.

New re-reviews – 2 new 1996 safety assessments for consideration.

1. Glutaral - in 1996, the safety assessment of glutaral (aka glutaraldehyde) was published with the conclusion that this ingredient: (1) is “safe for use at concentrations up to 0.5% in rinse-off products; (2) there are insufficient data to determine the safety of glutaral in leave-on products; and (3) glutaral should not be used in aerosolized products.” Current uses in leave-on products and possibly one aerosolized product are reported. Is there a need to reopen this safety assessment? There do not appear to be any ingredients that could be added if this report is reopened.

2. HC Red No. 1 - in 1996, the safety assessment of HC Red NO. 1 was published with the conclusion that this ingredient was “safe as used in hair dye formulations at concentrations of ≤ 0.5%”. Is there a need to reopen this safety assessment? There do not appear to be any ingredients that could be added if this report is reopened.

Draft reports - there are 6 reports under green cover.

1. Benzoic Acid group – Originally Benzyl Alcohol, Benzoic Acid, and Sodium Benzoate, this safety assessment was reopened to amend the conclusion re inhalation toxicity and to add other simple salts of Benzoic Acid (in addition to Sodium Benzoate) such as Calcium Benzoate, Magnesium Benzoate, and Potassium Benzoate, and to add the Benzyl Benzoate ester. A new scientific literature review was prepared covering all of the listed ingredients and consideration of the draft report is the next step.

2. DEA Amides – at the last meeting, the Panel agreed to reopen the safety assessment of DEA separate from MEA and TEA. Because the Panel was uncomfortable including the DEA Amides with DEA as part of that effort, agreement was reached to separately pursue reopening Cocamide DEA to include the larger group of DEA Amides. This draft report is the result of that effort.

3. Decyl Glucosides – This is the first time the Panel is seeing this document. The Scientific Literature Review was issued on February 24, 2011. Consideration of this draft report is the next step. Are the data sufficient?
4. Pentaeathytriyl Tetraisostearates - This is the first time the Panel is seeing this document. A Scientific Literature Review was issued in February, 2011. Consideration of this draft report is the next step. Are the data sufficient?

5. Trisodium Sulfosuccinate and Alkyl PEG Sulfosuccinates - This is the first time the Panel is seeing this document. A Scientific Literature Review was issued in March, 2011. Consideration of this draft report is the next step. Are the data sufficient?

6. TEA – at the last meeting, the Panel agreed to reopen the safety assessment of DEA separate from MEA and TEA. Here is the draft report on the TEA group and the potential TEA-related ingredients for inclusion. Once the final list of ingredients to be included is determined, a draft tentative amended report will be prepared. This draft report step also gives the Panel the opportunity to suggest any additional data that may be needed.

Draft tentative reports – There are 2 reports under pink cover.

1. Acrylates Cross Polymers (officially, Crosslinked Alkyl Acrylates) – at the March meeting, the Panel issued an insufficient data announcement asking for impurity data, specifically referring to the amount of residual benzene present. These data have been received, and the amount of residual benzene that has been found is included in the report. The teams should consider if the data now are adequate and issue a tentative report. If the data still are insufficient, then that should be the conclusion of the tentative report.

2. Silylates – back in March an insufficient data announcement was issued. The data needs were: 1) physical and chemical properties of the co-condensed ingredients trimethylsiloxysilicate and trifluoropropyldimethyl/trimethylsiloxysilicate; 2) identities and levels of impurities of both of the co-condensed ingredients, 3) stability of trifluoropropyldimethyl/trimethylsiloxysilicate, and 4) the impurities and biological activity of Antifoam A. Data from industry (characterization and impurities of trimethylsiloxysilicate) have been incorporated into the report. The teams should consider if the data now are adequate and issue a tentative report. If the data still are insufficient, then that should be the conclusion of the tentative report.

Draft final reports - there are 3 reports under blue cover. After reviewing these drafts, especially the rationale in the discussion section, the Panel should issue them as final reports.

1. Caprylyl Glycol and other 1,2-glycols - technical comments from the Personal Care Products Council have been addressed. These 16 ingredients were found safe in the present practices of use and concentration.

2. DEA and its salts - technical comments from the Personal Care Products Council have been addressed. These 18 ingredients were found safe in the present practices of use and concentration. There is a question for the Panel to consider re the inclusion of DEA-lauraminodipropionate in this report.

3. Formaldehyde/Methylene Glycol - technical comments from the Personal Care Products Council have been addressed and significant input has been received from the Nail Manufacturers Council regarding uses in nail care products and from the Professional Keratin Smoothing Council regarding uses in hair smoothing products. While review of these data will represent a significant task for the Panel, receipt of such data was contemplated and, after review, the Panel can proceed to issue a final amended safety assessment.

New data – new data have been submitted for 2 safety assessments.

1. PEGs Cocamine - in 1999, the CIR Expert Panel concluded that the available data were insufficient to support the safety of PEGs Cocamine (PEG-2, -3, -5,-10, -15, and -20 Cocamine). Additional data needed were: (1) physical and chemical properties, including impurities (especially nitrosamines); (2) genotoxicity in a mammalian system; (3) 28-day dermal toxicity using PEG-2 Cocamine; and (4) dermal sensitization data on PEG-2 Cocamine. In addition to the fundamental question of reopening this safety assessment to amend the conclusion, the CIR SSC has identified 3 additional PEGs Cocamine that now are identified as cosmetic ingredients (PEG-4, -8, and -12 Cocamine) and has recommended that they be included if this is reopened. Also, the CIR SSC has asked the Panel to consider adding other PEG fatty acid amines which differ from PEGs Cocamine group only by length of alkyl chain and degree of saturation. These would include an additional 37 ingredients.

2. Sodium Lauriminodipropionate - in 1997, the CIR Expert Panel reviewed the safety of Sodium Lauraminodipropionate and Sodium Laurimniodipropionate and found that the available data were insufficient to support the safety for use of either ingredient in cosmetics. There was a long list of additional data that were needed. The Council’s CIR Science and Support Committee has submitted data (memo attached) relating to one of these ingredients, Sodium Lauraminodipropionate, and has asked that the Panel consider these data to determine if the available data now are sufficient, for this one ingredient.

Boilerplate language – as promised, CIR is reviewing the language we use repetitively in our safety assessments to address specific issues. For this meeting, we will focus on inhalation toxicity and the exposures that users would receive from cosmetic aerosols. The inhalation boilerplate has been updated and follows a tab with the same name. Please note that all boilerplate information will be available to the public on the CIR website, and that the boilerplate statements in the reports themselves are
Review priorities for 2012 - The CIR Procedures require that we prepare the Draft 2012 Priority List for public comment by June 1, 2011. The Draft 2012 Priority list has been prepared and was posted on the website for public comment. The list was based on frequency of use data (FOU) from FDA’s Voluntary Cosmetic Registration Program (VCRP), received from FDA in March, 2011. We are expecting to select about 15 ingredient groups for review in 2012. The list includes only the lead ingredient/s. The Panel will be provided with potential groupings before a final priority decision is made. We anticipate receiving comments from the industry and Public. The Expert Panel will also have the opportunity to review this list and any public comments at the September, 2011 meeting at which time a Final 2012 Priority List will need to be issued.

Full Panel Meeting - remember, breakfast buffet at 7:30 am and meeting starts at 8:00 am on day 2 (we anticipate a lengthy discussion on formaldehyde/methylene glycol, so we are starting early).

The Panel will consider the 3 reports to be issued as final safety assessments, followed by the 6 reports under green covers and the remaining items on the agenda.

It is likely that the full Panel session will conclude late in the morning on day 2, so plan your travel accordingly. Have a safe journey.

Future Planning - it appears that we will celebrate CIR’s 35th anniversary at the September 26-27, 2011 meeting of CIR Expert Panel. As for all CIR anniversary events, your spouses are invited to join you in traveling to Washington for the meeting and participating in the gala celebration the evening of September 26th planned at the upscale Sofitel Hotel here in Washington. CIR staff and their spouses also will participate.

In the longer term, I want to remind you that the 2012 meeting dates have been established. Yes, 2012 (next year)! They are March 5-6, 2012 (Mon-Tues); June 11-12, 2012 (Mon-Tues); September 10-11, 2012 (Mon-Tues); and December 10-11, 2012 (Mon-Tues).
### 119th Cosmetic Ingredient Review Expert Panel Meeting

**June 27-28, 2011**

**Madison Hotel**  
1177 Fifteenth Street, NW  
Washington, DC 20005  
Phone: (202) 862-1600  
Fax: (202) 785-1255  
http://www.loewshotels.com

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<tr>
<th>Time</th>
<th>Event</th>
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<td>8:00 am</td>
<td><strong>CONTINENTAL BREAKFAST</strong></td>
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<tr>
<td>8:30 am</td>
<td><strong>WELCOME TO THE 119th EXPERT PANEL TEAM MEETINGS</strong></td>
<td>Drs. Bergfeld/Andersen</td>
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<td>9:00 am</td>
<td><strong>HAIR DYE EPIDEMIOLOGY PRESENTATION</strong></td>
<td>Dr. Julie Skare</td>
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<td>9:30 am</td>
<td><strong>TEAM MEETINGS</strong></td>
<td>Drs. Marks/Belsito</td>
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<td>9:00 am - 5:00 pm</td>
<td><strong>Dr. Marks’ Team</strong></td>
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<td>Buff (CLB)</td>
<td>HC Red No. 1 - re-review</td>
<td>Blue (IB)</td>
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<td>Buff (CLB)</td>
<td>Glutaral - re-review</td>
<td>Blue (IB)</td>
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<td>Pink (MF)</td>
<td>Crosslinked Alkyl Acrylates group</td>
<td>Buff (FAA)</td>
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<td>Green (MF)</td>
<td>Decyl Glucosides group</td>
<td>Buff (FAA)</td>
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<td>Blue (MF)</td>
<td>DEA group</td>
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<td>Green (MF)</td>
<td>DEA Amides group</td>
<td>Buff (BAH)</td>
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<td>Green (MF)</td>
<td>TEA group</td>
<td>Buff (CLB)</td>
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<td>Silylates group</td>
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<td>Green (LB)</td>
<td>Pentaerythrityl Tetraisostearate group</td>
<td>Blue (WJ)</td>
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<td>Buff (IB)</td>
<td>Aerosol Precedent Review</td>
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<td>Buff (BAH)</td>
<td>Priority List</td>
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<td>Blue (WJ)</td>
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<td>Blue (IB)</td>
<td>Formaldehyde/Methylene Glycol</td>
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<td>Buff (FAA)</td>
<td>Sodium Lauriminodipropionate – new data</td>
<td>Green (MF)</td>
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<td>Buff (FAA)</td>
<td>PEGs Cocamine – new data</td>
<td>Pink 4 (LB)</td>
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<td>Buff (FAA)</td>
<td>Re-review Summary-Quaternium-15</td>
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<td>Noon</td>
<td><strong>Lunch</strong></td>
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<td>1:00 pm</td>
<td><strong>TEAM MEETINGS (continued as needed)</strong></td>
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<td>5:00 pm</td>
<td><strong>ADJOURN DAY 1 SESSION</strong></td>
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**NOTE:** The order of presentation and discussion of each topic will be maintained. However, the scheduled times may be accelerated or delayed depending upon the time required for the Expert Panel to complete its review of each subject.
Tuesday, June 28

7:30 am  CONTINENTAL BREAKFAST

8:00 am  WELCOME TO THE 119TH FULL CIR EXPERT PANEL MEETING

8:15 am  MINUTES OF THE March, 2011 EXPERT PANEL MEETING

Dr. Bergfeld

8:25 am  DIRECTOR’S REPORT

Dr. Andersen

8:45 am  REPORTS ADVANCING TO THE NEXT LEVEL, RE-REVIEWS, and NEW DATA

Final Reports
Blue (WJ)  Capryl Glycol - Dr. Belsito reports
Blue (MF)  DEA - Dr. Marks reports
Blue (IB)  Formaldehyde/Methylene Glycol - Dr. Belsito reports

Reports Advancing
Pink 4 (LB)  Silylates group - Dr. Marks reports
Green (LB)  Pentaerythrityl Tetraisostearate - Dr. Belsito reports
Green (WJ)  Benzoic Acid - Dr. Belsito reports

Pink (MF)  Crosslinked Alkyl Acrylates group - Dr. Marks reports
Green (MF)  Decyl Glucosides - Dr. Belsito reports
Green (MF)  DEA Amides - Dr. Marks reports
Green (MF)  TEA - Dr. Belsito reports

Re-Reviews
Buff (CLB)  HC Red No. 1 Dr. Marks reports
Buff (CLB)  Glutaral - Dr. Belsito reports

New Data
Buff (FAA)  Sodium Lauriminodipropionate - Dr. Marks reports
Buff (FAA)  PEGs Cocamine – Dr. Belsito reports

Other Discussion Items
Buff (IB)  Aerosol Precedent Review – Drs. Breslawec/Boyer
Buff (BAH)  Priority List – Drs. Breslawec/Heldreth
Buff 1 (FAA)  Re-review summary - Quaternium-15 - Dr. Andersen

ADJOURN - Next meeting Monday and Tuesday, September 26-27, 2011

NOTE: The order of presentation and discussion of each topic will be maintained. However, the scheduled times may be accelerated or delayed depending upon the time required for the Expert Panel to complete its review of each subject.
Cosmetic Ingredient Review

ONE HUNDRED EIGHTEENTH MEETING

OF THE

EXPERT PANEL

March 3-4, 2011

The Madison Hotel

Washington, D.C.

Expert Panel Members

Wilma F. Bergfeld, M.D., Chair
Donald V. Belsito, M.D.
Ronald A. Hill, Ph.D.
Curtis D. Klaassen, Ph.D.
Daniel C. Liebler, Ph.D.
James G. Marks, Jr., M.D.
Ronald C. Shank, Ph.D.
Thomas J. Slaga, Ph.D.
Paul W. Snyder, D.V.M., Ph.D.

Liaison Representatives

Consumer
Rachel Weintraub, Esq.

Industry
John Bailey, Ph.D.

Government
Linda Katz, MD., M.P.H.

Adopted (Date)

Wilma F. Bergfeld, M.D.
**Others Present at Meeting**

<table>
<thead>
<tr>
<th>Name</th>
<th>Organization</th>
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<tr>
<td>F. Alan Andersen</td>
<td>CIR</td>
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<td>David Andrews</td>
<td>EWG</td>
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<td>Jay Ansell</td>
<td>The Council</td>
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<td>Javier Avalos</td>
<td>Kao Brands</td>
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<td>Lillian Becker</td>
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<td>Ivan Boyer</td>
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<td>Halyna Breslawec</td>
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<td>Robert Bronaugh</td>
<td>FDA</td>
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<td>Christina Burnett</td>
<td>CIR</td>
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<td>Jon Busch</td>
<td>American Chemistry Council</td>
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<td>Rosemary Cook</td>
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<td>Kapal Dewa</td>
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<td>David Fisher</td>
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<td>Monice Fiume</td>
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<td>George A. Harelau</td>
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<td>Don Havery</td>
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<td>Bart Heldreth</td>
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<td>Myra Irizarry</td>
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<td>Wilbur Johnson, Jr.</td>
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<td>Akihiro Kinoshita</td>
<td>Shiseido</td>
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<td>Elizabeth Krell</td>
<td>J K Consultants</td>
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<td>Dennis Laba</td>
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<td>Stanley Milstein</td>
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<td>Lauren Nardella</td>
<td>The Rose Sheet</td>
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<td>Paul Pestano</td>
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<td>P. Kloepro Sans</td>
<td>P&amp;G</td>
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<td>Doug Schoon</td>
<td>NMC</td>
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<td>Noriko Shibuya</td>
<td>Shiseido</td>
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<td>Jeremy Wong</td>
<td>Estee Lauder</td>
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CHAIRMAN’S OPENING REMARKS

The 118th meeting of the CIR Expert Panel was called to order by Dr. Bergfeld at 8:30 a.m on Friday, March 4, 2011. She welcomed the attendees and noted that this year marks the 35th Anniversary of the Cosmetic Ingredient Review. The CIR program has been very productive, having reviewed the safety of 2,200 ingredients, and it is likely that an additional 352 ingredients will be added to this group today. Dr. Bergfeld complimented the CIR staff on the quality of the safety assessments that are being produced.

APPROVAL OF MINUTES

The minutes of the March 3-4, 2011 CIR Expert Panel meeting were unanimously approved.

DIRECTOR’S REPORT

♦ Dr. Andersen announced that the Council has approved the addition of another technical writer to the CIR staff.
♦ CIR analysts are now being provided with a Pre-production package (Pre-Pro Pack) prior to report development. This package includes the chemical structures of all ingredients included in a safety assessment, pertinent information referenced in the International Cosmetic Ingredient Dictionary and Handbook, and likely literature search approaches. Eventually, each Pre-Pro Pack will also contain a toxicology overview.
♦ At the invitation of the Council’s CIR Science and Support Committee, CIR staff met to discuss approaches to creating groups of chemicals for review. CIR has been as expansive as possible in identifying which chemicals could be included groups that may be reviewed in a safety assessment. As noted above, those groups, including sub-groups, are captured at the stage a pre-production package is prepared and represent CIR’s initial view of what should be included based on similar chemistry and/or toxicology. While agreeing that groups should be as large as possible, the CIR SSC urged that the flexibility subsequently to determine that one or more chemical sub-groups should be eliminated from a group if there are valid reasons.

The Panel discussed this latter point and reached a consensus that it was most useful to maximize the number of ingredients that could be considered in a particular group for initial review. At the initial review by the Panel, in agreement with the view expressed by the CIR SSC, a decision would be made to accept the group or to constrain the list by removing certain sub-groups that raised, for example, different toxicity issues.

APPROVAL OF FINAL REPORTS

Alkyl Benzoates

These 17 alkyl benzoate ingredients are esters of benzoic acid and a corresponding alcohol used in cosmetics mostly as skin conditioning agents, preservatives, solvents, and plasticizers. The Panel noted gaps in the available safety data for some of the alkyl benzoates in this safety assessment. The available data on many of the alkyl benzoates are sufficient, however, and similar structural activity relationships, biologic functions, and cosmetic product usage, suggests that the available data may be extrapolated to support the safety of the entire group.

The Expert Panel noted the sensitization potential of isostearyl alcohol, a metabolite of isostearyl benzoate, and encouraged sensitization testing of isostearyl benzoate-containing formulations with concentrations above 1%. 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 CIR Expert Panel concluded that the following alkyl benzoates are safe in the present practices of use and concentration described in this safety assessment (ingredients not in current use are identified with an *):

- methyl benzoate,
- ethyl benzoate,
- propyl benzoate*,
- butyl benzoate*,
- amyl benzoate*,
- lauril/myristyl benzoate*,
- C12-15 alkyl benzoate,
- C16-17 alkyl benzoate,
- stearyl benzoate,
- behenyl benzoate*,
Plant-derived Fatty Acid Oils

Plant-derived fatty acid oils are the glyceryl esters of fatty acid (triglycerides) normally found in plants, including those which have been hydrogenated to reduce or eliminate unsaturation and those that are unsaponifiable. These ingredients can be used in cosmetics for their skin conditioning, occlusive, emollient, and moisturizing properties. The CIR Expert Panel determined that these ingredients, based on their similar fatty acid profiles, also are similar in structural activity relationships, biologic functions, and cosmetic product usage. While the data on the fatty acid composition of Fragraria Vesca (Strawberry) Seed Oil and Fragraria Virginiana (Strawberry) Seed Oil were not available, these are minor species. Data were available for Fragraria Ananassa (Strawberry) Seed Oil and Fragraria Chiloensis (Strawberry) Seed Oil and the fatty acid compositions were similar to each other.

The Panel concluded that these 244 plant-derived fatty acid oils included in this review, listed below, are safe in the present practices of use and concentration described in this safety assessment. The Panel did note that while the fatty acid profiles of Oryza Sativa (Rice) Germ Oil and Sclerocarya Birrea Seed Oil state that arachidonic acid, an ingredient previously found by the Panel to have insufficient data for safety, is one of the components of these ingredients, the amount of arachidonic acid in the oil is low and the concentration of use of these ingredients was sufficiently low as to not warrant concern.

Were the ingredients 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 concentrations comparable to others in these groups. The ingredients found safe are:

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<th>Plant-derived Fatty Acid Oils</th>
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<td>Actinidia Chinensis (Kiwi) Seed Oil</td>
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<td>Adansonia Digitata Oil</td>
<td>Carthamus Tinctorius (Safflower) Seed Oil</td>
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<td>Adansonia Digitata Seed Oil*</td>
<td>Carya Illinoensis (Pecan) Seed Oil*</td>
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<td>Chenopodium Quinoa Seed Oil</td>
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<td>Citrullus Lanatus (Watermelon) Seed Oil</td>
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<td>Anacardium Occidentale (Cashew) Seed Oil</td>
<td>Citrus Aurantifolia (Lime) Seed Oil*</td>
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<td>Arachis Hypogaea (Peanut) Oil</td>
<td>Citrus Aurantifolia (Lime) Seed Oil Unsaponifiables*</td>
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<td>Corylus Avellana (Hazel) Seed Oil</td>
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<td>Brassica Oleracea Italica (Broccoli) Seed Oil</td>
<td>Cottonseed Acid*</td>
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<td>Butyrospermum Parkii (Shea) Butter</td>
<td>Crambe Abyssinica Seed Oil</td>
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<td>Butyrospermum Parkii (Shea) Butter Unsaponifiables</td>
<td>Cucumis Sativus (Cucumber) Seed Oil</td>
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<td>Butyrospermum Parkii (Shea) Oil</td>
<td>Cucurbita Pepo (Pumpkin) Seed Oil</td>
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<td>Elaeis (Palm) Oil</td>
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<td>Camellia Kissi Seed Oil</td>
<td>Elaeis Guineensis (Palm) Butter*</td>
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<td>Elaeis Guineensis (Palm) Kernel Oil</td>
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<td>Camellia Sinensis Seed Oil</td>
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<td>Fragaria Ananassa (Strawberry) Seed Oil*</td>
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<td>Fragaria Chiloensis (Strawberry Seed Oil*)</td>
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<td>Fragaria Vesca (Strawberry) Seed Oil*</td>
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<td>Fragaria Virginiana (Strawberry) Seed Oil*</td>
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<td>Helianthus Annuus (Sunflower) Seed Oil Unsaponifiables</td>
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<td>Hydrogenated Kukui Nut Oil*</td>
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<td>Irvingia Gabonensis Kernel Butter</td>
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<td>Juglans Regia (Walnut) Seed Oil</td>
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<td>Limnanthes Alba (Meadowfoam) Seed Oil</td>
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<td>Linseed Acid</td>
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<td>Linum Usitatissimum (Linseed) Seed Oil</td>
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<td>Luffa Cylindrica Seed Oil</td>
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<td>Lupinus Albus Oil Unsaponifiables*</td>
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<td>Lycium Barbarum Seed Oil</td>
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<td>Magnesium Cocoate</td>
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<td>Morinda Citrifolia Seed Oil*</td>
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<td>Oenothera Biennis (Evening Primrose) Oil</td>
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<td>Olea Europae (Olive) Husk Oil*</td>
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<td>Olea Europaea (Olive) Oil Unsaponifiables</td>
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<td>Perilla Ocymoides Seed Oil</td>
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<td>Persea Gratissima (Avocado) Butter</td>
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<td>Persea Gratissima (Avocado) Oil</td>
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<td>Persea Gratissima (Avocado) Oil Unsaponifiables</td>
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<td>Pistacia Vera Seed Oil</td>
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<td>Plukenetia Volubilis Seed Oil</td>
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<td>Potassium Babassuate*</td>
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<td>Potassium Cocoate</td>
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<td>Potassium Hydrogenated Cocoate*</td>
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<td>Potassium Olivate</td>
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<td>Potassium Peanutrate</td>
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<td>Potassium Rapeseedate*</td>
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<td>Potassium Soyate*</td>
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<td>Prunus Amygdalus Dulcis (Sweet Almond) Oil</td>
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<td>Prunus Amygdalus Dulcis (Sweet Almond) Oil Unsaponifiables*</td>
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<td>Prunus Armeniaca (Apricot) Kernel Oil</td>
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<tr>
<td>Prunus Armeniaca (Apricot) Kernel Oil Unsaponifiables*</td>
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Prunus Avium (Sweet Cherry) Seed Oil
Prunus Domestica Seed Oil
Prunus Persica (Peach) Kernel Oil
Punica Granatum Seed Oil
Pyrus Malus (Apple) Seed Oil
Rapeseed Acid*
Ribes Nigrum (Black Currant) Seed Oil
Ribes Rubrum (Currant) Seed Oil*
Rice Bran Acid*
Rosa Canina Fruit Oil
Rubus Chamaemorus Seed Oil
Rubus Idaeus (Raspberry) Seed Oil
Safflower Acid*
Schinziophyton Rautanenii Kernel Oil
Sclerocarya Birrea Seed Oil
Sesamum Indicum (Sesame) Oil Unsaponifiables
Sesamum Indicum (Sesame) Seed Butter*
Sibybum Marianum Seed Oil [Thistle]
Sodium Astrocaryum Murumuruate
Sodium Avocadoate
Sodium Babassuate
Sodium Cocoa Butterate*
Sodium Cocoate
Sodium Grapeseedate
Sodium Hydrogenated Cacaoate*
Sodium Hydrogenated Palmate*
Sodium MacadamiaSeedate*
Sodium MangoSeedate
Sodium Olive
Sodium Palm Kernelate
Sodium Palmate
Sodium Peanutate*
Sodium Rapeseedate*
Sodium Safflowerate*
Sodium Sesameseedate
Sodium Soyate*
Sodium Sweet Almondate
Sodium Theobroma Grandiflorum Seedate*
Solanum Lycopersicum (Tomato) Fruit Oil
Solanum Lycopersicum (Tomato) Seed Oil
Soy Acid*
Sunflower Seed Acid*
Theobroma Cacao (Cocoa) Seed Butter
Theobroma Grandiflorum Seed Butter
Torreya Nucifera Seed Oil*
Triticum Aestivum (Wheat) Germ Oil*
Triticum Vulgare (Wheat) Germ Oil
Triticum Vulgare (Wheat) Germ Oil Unsaponifiables*
Vaccinium Corymbosum (Blueberry) Seed Oil*
Vaccinium Macrocarpon ( Cranberry) Seed Oil
Vaccinium Myrtillus Seed Oil
Vaccinium Vitis-Idaea Seed Oil
Vegetable (Olus) Oil
Vitis Vinifera (Grape) Seed Oil
Wheat Germ Acid
Zea Mays (Corn) Germ Oil
Zea Mays (Corn) Oil
Zea Mays (Corn) Oil Unsaponifiables

TENTATIVE SAFETY ASSESSMENTS

Caprylyl Glycol and Other 1,2-Glycols

The 1,2-glycols function mostly as skin and hair conditioning agents and viscosity increasing agents in cosmetics; caprylyl glycol and pentylene glycol also function as preservatives. Concern was expressed that the lipophilicity of 1,2-glycols with greater than 12 carbons in the chain may alter the dermal penetration of these ingredients and that the available metabolic modeling may not be relevant. The Panel reached a consensus, however, that there were ample data demonstrating that the lower chain length 1,2-glycols penetrate the skin readily and that repeat dose systemic toxicity data demonstrating the safety of these ingredients are available. The available data on these are sufficient, and similar structural activity relationships, biologic functions, and cosmetic product usage suggest that the available data may be extrapolated to support the safety of the entire group.

Accordingly, the Panel reached the tentative conclusion that the 16 ingredients in the report are safe in the present practices of use and concentration. Were ingredients in this group not in current use (marked with an *) 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:

Caprylyl Glycol
Arachidyl Glycol*
Cetyl Glycol*
Hexacosyl Glycol*
Lauryl Glycol*
Myristyl Glycol*
Octacosanyl Glycol*
Stearyl Glycol*
Decylene Glycol*
Pentylene Glycol
1,2-Butanediol*
1,2-Hexanediol
C14-18 Glycol*
C15-18 Glycol
C18-30 Glycol*
C18-30 Glycol*
C20-30 Glycol*

Diethanolamine (DEA) and Its Salts

The CIR Expert Panel reached a tentative conclusion that DEA and related salts, including inorganic acid salts, organic acid salts, and organo-substituted inorganic acid salts are safe for use in cosmetics when formulated to be non-irritating. These 18 ingredients include:
Were the ingredients 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 this group.

The safety of DEA in cosmetics previously was affirmed. The Panel considered the available NTP carcinogenicity data in mice exposed to DEA and certain DEA fatty acid esters is likely related to exposure to DEA itself or DEA impurities in the DEA fatty acid esters. The mode of action appears to be via effects on choline metabolism in mice. This mode of action was not considered relevant to assessing the safety of DEA in humans.

While the Panel noted gaps in the available safety data for many of the ingredients included in this group, the Panel relied on the safety assessment of several previously reviewed several of these ingredients. The available data could be read-across to support the safety of additional ingredients due to similar structure activity relationships, biological function, and cosmetic product usage. For example, DEA itself, as discussed above, is considered safe as used and myristic acid has been found safe as used, so the Panel was able to extrapolate these data to support the safety of DEA-Myristate (i.e., the DEA salt of myristic acid).

The Expert Panel cautioned that products containing these ingredients should be formulated to avoid the formation of nitrosamines.

Formaldehyde and Methylene Glycol

The CIR Expert Panel emphasized that these two ingredients exist in an equilibrium in aqueous cosmetic formulations whenever either one is present. That is, the addition of methylene glycol to a cosmetic formulation will rapidly yield formaldehyde and water on a one to one basis until an equilibrium is reached. Addition of formaldehyde to an aqueous cosmetic formulation will, in combination with water, yield methylene glycol on a one to one basis until an equilibrium is reached. Further reactions to produce other forms such as paraformaldehyde also are possible.

The Panel noted that, as given in the International Cosmetic Ingredient Dictionary and Handbook, the cosmetic functions of formaldehyde are: cosmetic biocide, denaturant, and preservative; and that methylene glycol is reported to function as an artificial nail builder. None of these reported functions appears to address the use of formaldehyde/methylene glycol in hair smoothing products. In such products, it appears that formaldehyde/methylene glycol is applied to the hair, the hair is dried, and heated. In this process, the equilibrium described above shifts towards production of formaldehyde and the high temperatures may lead to the formation of formaldehyde and/or methylene glycol gas.

The Panel considered the available data on the safety of formaldehyde/methylene glycol, noting that formaldehyde is a dermal sensitizer and there is a paucity of data on methylene glycol. In many cases, however, published studies of formaldehyde, given the chemistry described above, actually determined the toxicity of both formaldehyde/methylene glycol. Additional data demonstrate that nasopharyngeal cancers are produced by formaldehyde gas and epidemiology studies have suggested an association between exposure to formaldehyde and leukemia.

The Panel was uncertain about the exposure levels for users of formaldehyde/methylene glycol in nail builder products and sought further information about the concentration of formaldehyde/methylene glycol in nail builder products that FDA has allowed to remain on the market. The Panel believes that these pieces of information will be made available.

Based on these considerations, the Panel issued a tentative report with the following conclusions:
Formaldehyde/methylene glycol are safe in cosmetic products when formulated to ensure use at the minimal effective concentration, but in no case should formaldehyde equivalents exceed 0.2%.*

It cannot be concluded that formaldehyde/methylene glycol is safe in cosmetic products intended to be aerosolized or in which formaldehyde/methylene glycol vapor or gas will be produced under conditions of use.

The available data are insufficient to determine the safety of formaldehyde/methylene glycol in nail care products, pending receipt of additional information: (a) clarifying the U.S. FDA position on allowed levels of these ingredients in nail care products and (b) nail salon exposure levels.

INSUFFICIENT DATA ANNOUNCEMENTS

Crosslinked Alkyl Acrylates

These crosslinked polymers are comprised of co-monomers of at least one of: acrylic acid, sodium acrylate, methacrylic acid, or alkyl acrylate and share chemical properties, including a general lack of chemical reactivity. The 23 ingredients included in this group are:

- Acrylates/C10-30 Alkyl Acrylate Crosspolymer
- Acrylates/C12-13 Alkyl Methacrylates/Methoxyethyl Acrylate Crosspolymer
- Acrylates Crosspolymer
- Acrylates/Ethylhexyl Acrylate Crosspolymer
- Acrylates/Ethylhexyl Acrylate/Glycidyl Methacrylate Crosspolymer
- Acrylates/PEG-4 Dimethacrylate Crosspolymer
- Acrylates/Steareth-20 Methacrylate Crosspolymer
- Acrylates/Vinyl Isodecanoate Crosspolymer
- Acrylates/Vinyl Neodecanoate Crosspolymer
- Allyl Methacrylate/Glycol Dimethacrylate Crosspolymer
- Allyl Methacrylates Crosspolymer
- Butyl Acrylate/Glycol Dimethacrylate Crosspolymer
- C8-22 Alkyl Acrylates/Methacrylic Acid Crosspolymer
- Glycol Dimethacrylate/Vinyl Alcohol Crosspolymer
- Lauryl Methacrylate/Glycol Dimethacrylate Crosspolymer
- Lauryl Methacrylate/Sodium Methacrylate Crosspolymer
- Methacrylic Acid/PEG-6 Methacrylate Crosspolymer
- PEG/PPG-5/2 Methacrylate/Methacrylic Acid Crosspolymer
- Potassium Acrylates/C10-30 Alkyl Acrylate Crosspolymer
- Sodium Acrylates Crosspolymer-2
- Sodium Acrylates/C10-30 Alkyl Acrylate Crosspolymer
- Sodium Acrylates/Vinyl Isodecanoate Crosspolymer, and
- Stearyl/Lauryl Methacrylate Crosspolymer

These ingredients function in cosmetics as absorbents, film formers, emulsion stabilizers, viscosity increasing agents, suspending agents, binders, or skin conditioning agents. While recognizing that these highly crosslinked polymers are stable, unreactive compounds, the CIR Expert Panel noted that benzene is an impurity in Acrylates/C10-30 Alkyl Acrylate Crosspolymer at maximum levels up to 0.5%. Benzene impurity levels may be lower in actual production. The Panel requested additional data on actual production levels of benzene impurities. If such data are not available, the Panel may establish a limit for benzene impurities.

The Panel issued an insufficient data announcement requesting available benzene impurity data for the crosslinked alkyl acrylates.

Silylates and Surface Modified Siloxysilicates

Silylates and Surface Modified Siloxysilicates are organo-silane hybrid materials, modified to have desired properties for their use in cosmetics. They include:
• silica silylate,
• silica dimethyl silylate,
• trimethylsiloxysilicate, and
• trifluoropropyldimethyl(trimethylsiloxysilicate).

These ingredients can function in cosmetics as antifoaming agents, anti-caking agents, bulking agents, binders, skin-conditioning agents-emollient, skin-conditioning agents-occlusive, slip modifiers, suspension agents-nonsurfactant, and viscosity increasing agents-nonaqueous. Silica, which is the core of silica silylate and silica dimethyl, has been reviewed by the CIR Expert Panel and was found to be “…safe as cosmetic ingredients in the practices of use and concentrations as described in this safety assessment”. These silica materials are amorphous (synthetic amorphous silica and silicates), not crystalline silica.

Data on silane, dichlorodimethyl-, reaction products with silica (CAS No. 68611-44-9) and treated fumed silica dust (as CAB-O-SIL TS-720) were also considered, since these chemicals are the same as silica dimethyl silylate. Data from 2 mixtures: siloxanes and silicones, di-Me (dimethyl silicones and siloxanes) 93% (CAS No. 63148-62-9) with dimethyl silicones and siloxanes, reaction product with silica 7% (as Antifoam A; CAS No. 67762-90-7) and siloxanes and silicones, di-me, hydroxyl-terminated (as Antifoam M) were also included because the data may also be relevant to the individual ingredients. One such study using rodents, monkeys, and human subjects given Antifoam A orally resulted in silica appearing in bile which raised a concern about how that would happen – one possibility considered was the presence of impurities in Antifoam A.

The Panel issued an insufficient data announcement for the safety assessment of silylates and surface modified siloxysilicates. Additional data needed include:

1) physical and chemical properties of the co-condensed ingredients trimethylsiloxysilicate and trifluoropropyldimethyl(trimethylsiloxysilicate);
2) identities and levels of impurities of both of the co-condensed ingredients,
3) stability of trifluoropropyldimethyl(trimethylsiloxysilicate), and
4) identification of any impurities of Antifoam A that could be metabolized (or not) and be found in the bile as silica.

RE-REVIEWS

Disperse Blue 1

In 1995, the CIR Expert Panel concluded that Disperse Blue 1 was safe for use in hair dyes at concentrations up to 1%. The Panel focused on and further discussed the existing carcinogenicity data on Disperse Blue 1 and considered risk assessment input from FDA and industry. Based on these inputs, CIR developed an overall risk assessment which demonstrated a margin of safety were Disperse Blue 1 to be used as a hair dye at a concentration of 1%. The Panel noted that disperse blue 1 is not in current use. The CIR Expert Panel determined to not reopen the safety assessment of Disperse Blue 1. Technical comments on the summary basis were received and incorporated into the final version.

Quaternium-15

The Expert Panel reviewed new data on quaternium-15 with regard to evidence of the release of formaldehyde. The previous publication (Becker 2010) stated in the conclusion that quaternium-15 is not a formaldehyde releaser. Due to improved detection methodology and published reports, it is now clear that quaternium-15 is a formaldehyde releaser.

Because the use of quaternium-15 was restricted to 0.2% in cosmetic products by the Expert Panel, the amount of formaldehyde that could be released from a formulation with this amount of quaternium-15 would be 0.003% to 0.005% (300 and 500 ppm, respectively), which is well below the amount of formaldehyde currently allowed in a cosmetic formulation (0.2%).

The Expert Panel noted the use of quaternium-15 in aerosolized products, such as hairspray, in conjunction with the potential release of formaldehyde. However, at the current limit of quaternium-15 used in cosmetic formulation, the amount of formaldehyde which could be released in an aerosol is sufficiently low as to not present a safety concern.

The Expert Panel, while acknowledging the release of formaldehyde by quaternium-15, determined to not re-open the safety assessment since the conclusion of “…safe as a cosmetic ingredient in the practices of use in this safety assessment at concentrations not to exceed 0.2%” would not change.
The CIR Expert Panel reviewed a compilation of issues previously discussed by the CIR Expert Panel, along with language
developed to articulate the Panel’s thinking. Consistent with the approach taken to report preparation in general, these so-called
boilerplates have been streamlined as well and the current version was reviewed by the Panel in the context of the previous version
to provide historical context. Many of the specific boilerplates were discussed during discussion of reports on the agenda at this
meeting. Individual Panel member comments on these and any others will be incorporated and a revised document prepared for
public review.
COSMETIC INGREDIENT REVIEW

CIR Precedents

Aerosols

Draft Revision

6/2011

This document is a compilation of issues discussed by the CIR Expert Panel along with boilerplate language used in CIR Reports to articulate the Panel’s views. Standard formats for Tables used in Panel Reports are also provided. This is intended to provide background on issues and serve as a reference to the reasoning behind previous Panel decisions.
Sprays/aerosols – particle size

Draft Update 6/2011

Boilerplate language for specific report sections:

**Cosmetic Use Section**

[INGREDIENT] is used in [LIST TYPE OF COSMETIC INGREDIENT, e.g., hair spray], and could be inhaled. The average particle size of aerosols from aerosol hair sprays is around 38 μm, with particle sizes > 60 μm and >80 μm reported for aerosol and pump hair sprays, respectively. These particle sizes are considerably larger than the sizes of respirable particles (≤10 μm). Thus, most aerosol particles inhaled during hair spray use are deposited in the nasopharyngeal region, and do not enter the deeper, absorptive surfaces of the lungs.

**Discussion**

Some product use types are aerosols, and the potential for inhalation of [ingredient(s)] exists. However, the particle sizes produced by cosmetic aerosols are typically not respirable. [If inhalation toxicity data are available, they should be mentioned].

**Re-review summaries**

The CIR Expert panel noted the absence of inhalation toxicity data. However, the Panel determined that [INGREDIENT] can be used safely in hair sprays, because aerosols from these products are generally not respirable. The Panel reasoned that the particle sizes typical of aerosol hair sprays and pump hair sprays are large compared to respirable particle sizes (≤10 μm).

**BACKGROUND**

Inhalation safety is an important consideration for ingredients of cosmetic sprays. The safety of an inhaled aerosol (liquid droplets or solid particles) depends on several key factors, including the chemical and physical properties of the aerosol, its concentration in inhaled air, the duration of inhalation exposure, and the deposition and clearance of the aerosol in the respiratory tract.1

The three major regions of the respiratory tract are the (1) nasopharyngeal, (2) tracheobronchial, and (3) pulmonary regions. In the nasopharyngeal region, the nares and nasal cavities warm and humidify the air, and mucus-secreting and ciliated cells form a protective mucociliary blanket that carries deposited particles to the throat to be swallowed.2 In the tracheobronchial region, mucociliary action carries deposited particles away from the lungs and toward the throat. In the pulmonary region, a very thin coating of water, containing pulmonary surfactant, and extremely thin membranes facilitate the absorption of substances from the air and into the bloodstream.3,4

Aerodynamic size is the primary factor determining the depth to which inhaled aerosol particles enter the respiratory tract, and the fraction of the particles deposited within specific regions.1,5 The parameter most closely associated with the deposition pattern of an aerosol is the aerodynamic equivalent diameter (d_{ae}). The d_{ae} is defined as the diameter of a hypothetical sphere of unit density (1 g/cm³) having the same terminal settling velocity in calm air as the particle in question, regardless of the particle’s actual size, shape and density.1,2,5 The d_{ae} of a hygroscopic particle may increase in the warm, water-saturated air in the respiratory tract, before it is deposited.2,6

The distribution of particle sizes in an aerosol can usually be adequately described as log-normal.2,4 By convention, the particles in an aerosol are defined by their median size (e.g., mass median aerodynamic diameter; MMAD) and a measure of size variability (e.g., geometric standard deviation; GSD). The particles of an aerosol can be divided into three mass fractions, which differ in the depth to which the particles will
enter the respiratory tract. These fractions include the inhalable fraction, which can enter the
nasopharyngeal region, the thoracic fraction, which can pass through the larynx to enter the
tracheobronchial region, and the respirable fraction, which can enter the pulmonary region.\(^7\)

In general, less than 30-50% of aerosols with particle MMADs >30-80 µm are inhalable through the
nose or mouth.\(^4,6,8\) Most particles with MMADs ≤ 0.01 µm (i.e., ultrafine particles) or >10 µm are deposited in
the nasopharyngeal region by diffusion (MMADs ≤ 0.01 µm) or impaction and sedimentation (MMADs >10
µm).\(^4,5\) Typically, about 50% of particles with an MMAD = 11.64 µm (GSD = 1.5 µm) are deposited in the
tracheobronchial region, and 50% of particles with an MMAD = 4.25 µm (GSD = 1.5 µm) are deposited in the
pulmonary region.\(^7\) Particles with MMADs >10 µm will not enter the pulmonary region to any appreciable
extent and, thus, are not considered to be respirable.\(^5,9,10\)

Particle diameters of 60-80 µm and ≥80 µm have been reported for anhydrous hair sprays and pump
hairsprays, respectively.\(^11\) The mean particle diameter in a typical aerosol spray has been reported to be ~38
µm.\(^12\) In practice, aerosols will have at least 99% of their particle diameters in the 10 - 110 µm range.\(^12\)
Thus, most aerosol particles inhaled during hair spray use are deposited in the nasopharyngeal region,
where they are trapped and rapidly cleared from the respiratory tract through mucociliary action, and do not
enter the deeper, absorptive surfaces of the pulmonary region.

The Panel has discussed this issue extensively, and has adopted the general stance that, in the
absence of primary assessment of inhalation toxicity data on a specific ingredient, they will consider the
aerosol particle size in determining the inhalation safety of an ingredient.

REFERENCES

References

Measurement: Principals, Techniques, and Applications. New York: John Wiley & Sons; 1993:537-
559.


the of a Symposium held at Pacific Northwest Laboratory, Richland, WA, November 9-10, 1993.
1995. Pacific Northwest Laboratory, Richland, WA.


5. Oberdorster, G., Oberdorster, E., and Oberdorster, J. Nanotoxicology: an emerging discipline evolving from

Annexe D. Deposition of Inhaled Particles. Smith, H.In: Human Respiratory Tract Model for
Radiological Protection. Didcot, Oxfordshire, England: International Commission on Radiological
Protection (ICRP); 1994:231-299.

Distribution, Fibre Length and Diameter Distribution of Chemical Substances. Luxembourg, Office


Date: June 1, 2011

From: Halyna Breslawec, Ph.D., Deputy Director, CIR
      Bart Heldreth, Ph.D., Chemist CIR

To: CIR Expert Panel Members and Liaisons

Re: Draft 2012 Priority List

The CIR Procedures require that we prepare the Draft 2012 Priority List for public comment by June 1, 2011. The list was based on frequency of use data (FOU) from FDA’s Voluntary Cosmetic Registration Program (VCRP), received from FDA in March, 2011.

On April 29, 2011, we sent out a draft 2012 Priority List for public review. (Attachment 1). We received comments from the Council, which are in Attachment 2. We have reviewed these comments and made some changes to the Draft 2012 Priority list (below).

At this meeting, we would like your thoughts on the lead ingredients on this list. The Panel will be provided with potential groupings before a final priority at the September, 2011 meeting, at which time the Panel will need to issue a Final 2012 Priority List.

Draft CIR 2012 Priority List (6/1/11)

<table>
<thead>
<tr>
<th>LEAD INGREDIENT</th>
<th>FOU (2011)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TALC</td>
<td>3150</td>
</tr>
<tr>
<td>MATRICARIA CHAMOMILLA FLOWER EXTRACT</td>
<td>737</td>
</tr>
<tr>
<td>ANTHEMIS NOBILIS FLOWER EXTRACT</td>
<td>498</td>
</tr>
<tr>
<td>CHAMOMILLA RECUTITA (MATRICARIA) FLOWER/LEAF EXTRACT</td>
<td>368</td>
</tr>
<tr>
<td>LAUROYL LYSINE (and related ingredients)</td>
<td>675</td>
</tr>
<tr>
<td>ARGinine (and related ingredients)</td>
<td>442</td>
</tr>
<tr>
<td>HYDROLYZED SOY PROTEIN</td>
<td>613</td>
</tr>
<tr>
<td>HYDROLYZED SILK</td>
<td>535</td>
</tr>
<tr>
<td>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER</td>
<td>441</td>
</tr>
<tr>
<td>DIMETHICONE CROSSPOLYMER</td>
<td>389</td>
</tr>
<tr>
<td>BORON NITRATE</td>
<td>523</td>
</tr>
<tr>
<td>VITIS VINIFERA (GRAPE) SEED EXTRACT</td>
<td>508</td>
</tr>
<tr>
<td>NITROCELLULOSE</td>
<td>498</td>
</tr>
<tr>
<td>POLYETHYLENE TEREPTHALATE</td>
<td>496</td>
</tr>
<tr>
<td>TROMETHAMINE</td>
<td>479</td>
</tr>
</tbody>
</table>
2012 Re-reviews

While there is no requirement for CIR to publish an annual list of scheduled re-reviews, below is the list of the re-reviews planned for 2012. This list is based on those safety assessments completed in 1997 and not re-reviewed.

<table>
<thead>
<tr>
<th>2012 RE-REVIEWS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formic Acid</td>
</tr>
<tr>
<td>PEG-30 Castor Oil, PEG-33 Castor Oil, PEG-35 Castor Oil, PEG-36 Castor Oil, PEG-40 Castor Oil, PEG-30 Hydrogenated Castor Oil, PEG-40 Hydrogenated Castor Oil (include PEG-60 Hydrogenated Castor Oil (361)?)</td>
</tr>
<tr>
<td>PPG-5 Lanolin Wax, PPG-5 Lanolin Wax Glyceride</td>
</tr>
<tr>
<td>2-Amino-6-Chloro-4-Nitrophenol</td>
</tr>
<tr>
<td>Benzoxiquine</td>
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<tr>
<td>Cetyl Esters</td>
</tr>
<tr>
<td>m-Phenylenediamine m-Phenylenediamine Sulfate</td>
</tr>
<tr>
<td>Pyrocatechol</td>
</tr>
<tr>
<td>Cetrimonium/Steartrimonium                        RR 2010</td>
</tr>
<tr>
<td>p-Chloro-m-Cresol                                 RR 2006</td>
</tr>
</tbody>
</table>

ND-New Data submitted
RR Re-review
# Draft CIR 2012 Priority List (6/11)

## LEAD INGREDIENT

<table>
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</tr>
<tr>
<td>TROMETHAMINE</td>
<td>479</td>
</tr>
<tr>
<td>PALMITOYL OLIGOPEPTIDE</td>
<td>462</td>
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<tr>
<td>STEARAMIDOPROPYL DIMETHYLAMINE</td>
<td>431</td>
</tr>
<tr>
<td>PEG-120 METHYL GLUCOSE DIOLEATE</td>
<td>402</td>
</tr>
<tr>
<td>6-HYDROXYINDOLE (HAIR DYE)</td>
<td>104</td>
</tr>
</tbody>
</table>

## 2012 RE-REVIEWS

- **Formic Acid**
- **PEG-30 Castor Oil, PEG-33 Castor Oil, PEG-35 Castor Oil, PEG-36 Castor Oil, PEG-40 Castor Oil, PEG-30 Hydrogenated Castor Oil, PEG-40 Hydrogenated Castor Oil** (include PEG-60 Hydrogenated Castor Oil (361)?)
- **PPG-5 Lanolin Wax, PPG-5 Lanolin Wax Glyceride**
- **2-Amino-6-Chloro-4-Nitrophenol**
- **Benzoxiquine**
- **Cetyl Esters**
- **m-Phenylenediamine m-Phenylenediamine Sulfate**
- **Pyrocatechol**
- **Cetrimonium/Steartrimonium**
- **p-Chloro-m-Cresol**

*ND-New Data submitted*
*RR RR Re-review*
TO: F. Alan Andersen, Ph.D.
Director - COSMETIC INGREDIENT REVIEW (CIR)

FROM: CIR Science and Support Committee of the Personal Care Products Council

DATE: May 9, 2011

SUBJECT: CIR Science and Support Committee Recommendations for Ingredients to be Included on the 2012 CIR Priority List

The CIR Science and Support Committee (CIR SSC) reviewed information from the FDA Voluntary Registration Program (VCRP) to develop the attached list of ingredients to be considered for the current 2011 priority list and the 2012 priority list. Ingredients on the 2011 priority list for which a concentration of use survey has not yet been completed are indicated in all capital letters.

The CIR SSC recommends that the following ingredients be included in the 2012 priority list.

Talc
Amino acids (completion of a review of amino acids would provide a base of information useful for review of amino acid containing ingredients, such as Lauroyl Lysine [675 uses], and mixtures of amino acids, such as Silk Amino Acids [338 uses]; Arginine is the single amino acid that currently has the highest number of uses [442])

Hydrolyzed Soy Protein
Hydrolyzed Silk
Boron Nitride
Vitis Vinifera (Grape) Seed Extract
Nitrocellulose
Polyethylene Terephthalate
<table>
<thead>
<tr>
<th>INCI Name</th>
<th>FOU 2011/2010</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Talc</td>
<td>3150/3054</td>
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</tr>
<tr>
<td>XANTHAN GUM</td>
<td>3047/2785</td>
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</tr>
<tr>
<td>Benzyl Salicylate</td>
<td>1968/1926</td>
<td>fragrance ingredient; published RIFM review 2007</td>
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<tr>
<td>CHLORPHENESIN</td>
<td>1184/1068</td>
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<tr>
<td>NYLON-12</td>
<td>1096/1159</td>
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<tr>
<td>HYDROLYZED WHEAT PROTEIN</td>
<td>989/1015</td>
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<tr>
<td>TIN OXIDE</td>
<td>978/860</td>
<td></td>
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<tr>
<td>CALCIUM SODIUM BOROSILICATE</td>
<td>853/759</td>
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<tr>
<td>GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE</td>
<td>824/751</td>
<td></td>
</tr>
<tr>
<td>Algae Extract</td>
<td>844/850</td>
<td>not specific</td>
</tr>
<tr>
<td>SYNTHETIC FLUOROPHLOGOPITE</td>
<td>687/586</td>
<td></td>
</tr>
<tr>
<td>Lauroyl Lysine</td>
<td>675/646</td>
<td>should be reviewed after amino acids</td>
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<tr>
<td>DISTEARDIMONIUM HECTORITE</td>
<td>627/636</td>
<td></td>
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<tr>
<td>Hydrolyzed Soy Protein</td>
<td>613/607</td>
<td></td>
</tr>
<tr>
<td>Honey</td>
<td>568/515</td>
<td></td>
</tr>
<tr>
<td>CUCUMIS SATIVUS (CUCUMBER) FRUIT EXTRACT</td>
<td>552/546</td>
<td></td>
</tr>
<tr>
<td>Alumina</td>
<td>542/488</td>
<td>dried aluminum hydroxide, drug color; aluminum hydroxide also in the Dictionary, OTC/GRAS (658 VCRP uses)</td>
</tr>
<tr>
<td>BIS-DIGLYCERYL POLYACYLADIPATE-2</td>
<td>542/529</td>
<td></td>
</tr>
<tr>
<td>Hydrolyzed Silk</td>
<td>535/508</td>
<td></td>
</tr>
<tr>
<td>Boron Nitride</td>
<td>523/477</td>
<td></td>
</tr>
<tr>
<td>Vitis Vinifera (Grape) Seed Extract</td>
<td>508/447</td>
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</tr>
<tr>
<td>Nitrocellulose</td>
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<tr>
<td>Ingredient</td>
<td>Code</td>
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<tr>
<td>Polyethylene Terephthalate</td>
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<tr>
<td>POLYQUATERNIUM-22</td>
<td>485/524</td>
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<tr>
<td>Tromethamine</td>
<td>479/463</td>
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<tr>
<td>Yeast Extract</td>
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<td>Sodium Methylparaben</td>
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<td>Panax Quinquefolius Root Extract</td>
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<tr>
<td>Palmitoyl Oligopeptide</td>
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<tr>
<td>Arginine (GRAS)</td>
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<tr>
<td>Betaine</td>
<td>441/343</td>
<td></td>
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<tr>
<td>Dimethicone/Vinyl Dimethicone Crosspolymer</td>
<td>441/419</td>
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<tr>
<td>Phospholipids</td>
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<tr>
<td>Sea Salt</td>
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<tr>
<td>Steamidopropyl Dimethylamine</td>
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<td>PEG-120 Methyl Glucose Dioleate</td>
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<tr>
<td>Dimethicone Crosspolymer</td>
<td>389/378</td>
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<td>PPG-5-Ceteth-20</td>
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<tr>
<td>Avena Sativa (Oat) Kernel Extract</td>
<td>376/346</td>
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<tr>
<td>Sodium Benzetriaolyl Butylphenol Sulfonate</td>
<td>374/356</td>
<td></td>
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<tr>
<td>Pyrus Malus (Apple) Fruit Extract</td>
<td>367/343</td>
<td></td>
</tr>
<tr>
<td>Hydrolyzed Keratin</td>
<td>363/331</td>
<td></td>
</tr>
<tr>
<td>Centella Asiatica Extract</td>
<td>361/311</td>
<td></td>
</tr>
<tr>
<td>PEG-60 Hydrogenated Castor Oil</td>
<td>361/318</td>
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<tr>
<td>Trehalose</td>
<td>361/308</td>
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<tr>
<td>Methyl Gluceth-20</td>
<td>359/336</td>
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<tr>
<td>Pentae:rythrityl Tetra-di-t-butyl Hydroxyhydrocinnamate</td>
<td>342/277</td>
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<tr>
<td>Tocotrienols</td>
<td>341/292</td>
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<tr>
<td>Hydrogenated Polydecene</td>
<td>339/316</td>
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<tr>
<td>Helianthus Annuus (Sunflower) Seed Extract</td>
<td>338/378</td>
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<tr>
<td>Silk Amino Acids</td>
<td>338/347</td>
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<tr>
<td>Substance</td>
<td>FOU</td>
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<tr>
<td>Tributyl Citrate</td>
<td>336/309</td>
<td></td>
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<tr>
<td>PANAX GINSENG ROOT EXTRACT</td>
<td>52/506</td>
<td></td>
</tr>
</tbody>
</table>

FOU = frequency of use from 2011 VCRP/2010 VCRP
2011 FOU in green indicates it is greater than 2010 value; 2011 FOU in red indicates that it is less than 2010 value
Memorandum

TO: F. Alan Andersen, Ph.D.
    Director - COSMETIC INGREDIENT REVIEW (CIR)

FROM: Hair Coloring Technical Committee (HCTC) of the Personal Care Products Council

DATE: May 3, 2011

SUBJECT: Hair Dye Ingredient Recommended for Inclusion in the 2012 CIR Priority List of Ingredients

The Hair Coloring Technical Committee (HCTC) recommends that the hair dye ingredient, 6-Hydroxyindole, with 104 uses reported in the 2011 FDA Voluntary Cosmetic Registration Program (VCRP) data be included as the hair dye ingredient in the 2012 priority list of ingredients for review by CIR. This hair dye ingredient has been reviewed by the European Scientific Committee for Consumer Products (SCCP) (opinion found at http://ec.europa.eu/health/archive/ph_risk/committees/04_sccp/docs/sccp_o_046.pdf). Additional details about the studies reviewed by the SCCP will be provided by industry when the review of this ingredient has started.
Memorandum

TO: F. Alan Andersen, Ph.D.
   Director - COSMETIC INGREDIENT REVIEW (CIR)

FROM: CIR Science and Support Committee of the Personal Care Products Council

DATE: May 9, 2011

SUBJECT: Comments on the CIR Draft 2012 Priority List (Memo from Drs. Breslawec and Heldreth dated April 29, 2011)

The CIR Science and Support Committee (CIR SSC) of the Personal Care Products Council supports CIR in using the FDA’s Voluntary Cosmetic Registration Program (VCRP) frequency of use (FOU) information as the primary determinant of prioritizing ingredients for review by the CIR Expert Panel. The CIR SSC is pleased to see that two amino acids (Lysine and Arginine) have been included in the draft 2012 priority list and encourages CIR staff to explore ways to group amino acids so that a larger number of amino acids can be reviewed in an expeditious manner. Perhaps the review of amino acids for flavoring use by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) (WHO Food Additive Series: 54, 2006, pp. 435-486; found at http://whqlibdoc.who.int/publications/2006/9241660546_eng.pdf) would be helpful.

Based on FOU values greater than some ingredients included on the draft 2012 priority list, the CIR SSC suggests that Boron Nitride (523 uses) and Vitis Vinifera (Grape) Seed Extract (508 uses) also be considered for the 2012 priority list.

As Citrus Limon (Lemon) Peel Oil and Citrus Limon (Lemon) Fruit Extract are primarily used as fragrance ingredients, the CIR SSC believes that it is appropriate to defer the review of these ingredients (and their main components) to the Research Institute for Fragrance Materials, Inc. (RIFM). (Please note that Citrus limon rather than Citrus medica limonum is the genus species name currently used for cosmetic labeling names for lemon-derived ingredients). Lemon oil was the subject of a RIFM monograph published in 1974 in Food and Cosmetics Toxicology (volume 12, p.725).

Although not approved for cosmetic use, Alumina is an FDA approved drug color additive. In addition, Aluminum Hydroxide (also called hydrated alumina) is an FDA approved OTC skin protectant. Based on the CIR procedures which excludes CIR from reviewing color additives and allows CIR to defer review of OTC ingredients, the CIR SSC recommends that Alumina not be reviewed by CIR.
The Expert Panel reviewed new data on quaternium-15 with regard to evidence of the release of formaldehyde. The previous publication stated in the conclusion that quaternium-15 is not a formaldehyde releaser.\textsuperscript{1} Due to improved detection methodology and published reports, it is now clear that quaternium-15 is a formaldehyde releaser.\textsuperscript{2-10}

Because the use of quaternium-15 was restricted to 0.2\% in cosmetic products by the Expert Panel, the amount of formaldehyde that could be released from a formulation with this amount of quaternium-15 would be 0.003\% to 0.005\% (300 and 500 ppm, respectively), which is well below the amount of formaldehyde currently allowed in a cosmetic formulation (0.2\%).

The Expert Panel noted the use of quaternium-15 in aerosolized products, such as hairspray, in conjunction with the potential release of formaldehyde. However, at the current limit of quaternium-15 used in cosmetic formulation, the amount of formaldehyde which could be released in an aerosol is sufficiently low as to not present a safety concern.

The Expert Panel, while acknowledging the release of formaldehyde by quaternium-15, determined to not re-open the safety assessment since the conclusion of “...safe as a cosmetic ingredient in the practices of use in this safety assessment at concentrations not to exceed 0.2\%” would not change.


