

ADMIN

Priorities

EXPERT PANEL MEETING

March 7-8, 2022



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Memorandum

Date: February 11th, 2022

From: Bart Heldreth, Ph.D., Executive Director, Cosmetic Ingredient Review

To: All Stakeholders

Re: 2023 Draft Priority List

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

While this list includes only the lead ingredients, groupings of ingredients, drafted by CIR Staff, can be found on the following pages. There are 15 reports proposed, covering 60 ingredients, on the 2023 Draft Priorities List (2 of the ingredients on this list are proposed to be grouped together in 1 report). Once a proposal of a hair dye for assessment has been received from the PCPC Hair Color Technical Committee, 16 new reports in total will be proposed for the 2023 docket. Reports previously prioritized and on the CIR docket at the end of 2022, as well as an extensive number of re-reviews of previous assessments, will supplement the total number of reports to be assessed in 2023. Additionally, if the prostaglandin analogs are considered to be within the Panel's purview, those will constitute at least 1 additional assessment.

Interested parties are encouraged to submit pertinent data to the CIR, as soon as possible, for use in the development of the Scientific Literature Reviews for these ingredients. Although the specific data needs vary for each safety assessment, the following are typical data that the Panel reviews for each safety assessment.

- Chemistry, impurities, and method of manufacture
- Toxicokinetics data, specifically dermal absorption and/or penetration
- Repeated-dose toxicity data
- Inhalation toxicity data, if the ingredient is used in a product that can be incidentally inhaled
- Reproductive/developmental toxicity data

- Genotoxicity data; if positive, carcinogenicity data may be needed
- Dermal irritation and sensitization data at maximum concentration of use

For the review of botanical ingredients, the additional data needed include: species, plant part, extraction method, solvent, and data on component chemical characterization. It is important that these data are specific for the ingredient(s) as used in cosmetics.

2023 Draft Priorities List

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

2023 Draft Priorities Groupings for New Reports

Proposed 2023 Report – per cause

To be determined – per PCPC Hair Color Technical Committee(HCTC) FOU = ___

Reported Function: Hair Colorant

Notes: Since FOU might not be a very accurate surrogate for exposure, with regard to hair dyes, the PCPC HCTC proposes one hair dye ingredient annually for CIR review. The HCTC typically submits a proposed hair dye ingredient between the 1st and 2nd meetings of the year.

Grouping proposal: None

Prostaglandins analogs – Alert from Dr. Belsito about SCCS activity

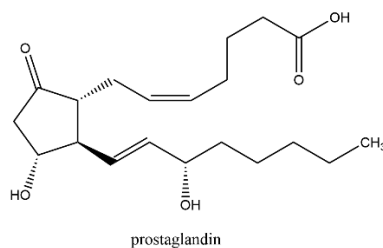
→ Isopropyl Cloprostenate

FOU = 3

→ Dehydrolatanoprost

→ Ethyl Tafluprostamide

→ Ethyl Travoprostamide



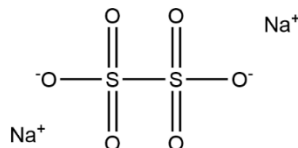
Reported Functions: Hair Conditioning Agents; Eyelash Conditioning Agents; Nail Conditioning Agents; Antimicrobial Agents; Antioxidants; Skin-Conditioning Agents - Miscellaneous

Notes: These are prostaglandin analogs that might be in use as cosmetic ingredients, despite more common usage as drugs. SCCS opinion:

https://ec.europa.eu/health/sites/default/files/scientific_committees/consumer_safety/docs/sccs_o_258.pdf

Proposed 2022 Reports – per FOU**Sodium Hydrosulfite**

FOU = 246

Definition: Sodium Hydrosulfite is the inorganic salt that conforms to the formula Na₂S₂O₄.**Reported Function:** Reducing Agents**Grouping proposal:** None**Pelargonium Graveolens Flower Oil**

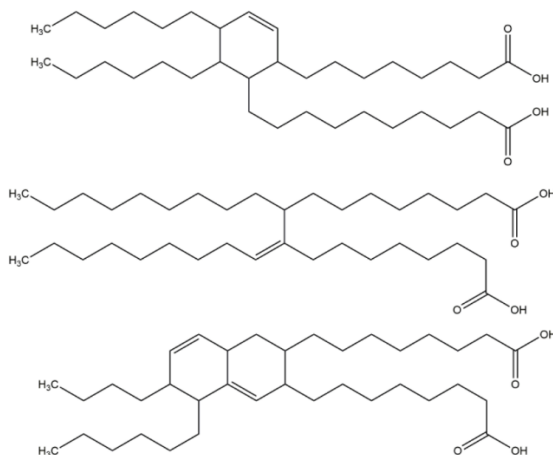
FOU = 236

Definition: Pelargonium Graveolens Flower Oil is the volatile oil obtained from the flowers of *Pelargonium graveolens*.**Reported Functions:** Fragrance Ingredients; Skin-Conditioning Agents - Miscellaneous**Notes:** (CAS Nos. 90082-51-2 (generic) and 8000-46-2) Pelargonium Graveolens Oil (FOU 179), Pelargonium Graveolens Leaf Oil (FOU 13), and Pelargonium Graveolens Flower/Leaf/Stem Water (FOU 9) are fragrance only ingredients.

CIR draft grouping/clustering: (5 ingredients proposed with a total FOU = 294)	FOU
<i>Pelargonium Graveolens Flower Oil</i>	236
<i>Pelargonium Graveolens Extract</i>	49
<i>Pelargonium Graveolens Flower Water</i>	4
<i>Pelargonium Graveolens Flower Extract</i>	3
<i>Pelargonium Graveolens Leaf Extract (VCRP name only)</i>	2

Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl**FOU = 234****Dimer Dilinoleate**

Definition: Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate is the ester of Dilinoleic Acid with a mixture of Phytosterols, Isostearyl Alcohol, Cetyl Alcohol, Stearyl Alcohol, and Behenyl Alcohol.



wherein the carboxylic acid functional groups are esterified with Phytosteryl, Isostearyl, Cetyl, Stearyl, and/or Behenyl chains.

Reported Functions: Hair Conditioning Agents; Skin-Conditioning Agents - Occlusive; Viscosity Increasing Agents – Nonaqueous

Notes: Final Amended Safety Assessment of Dialkyl Dimer Dilinoleates as Used in Cosmetics finalized in 2018 with a safe as used conclusion for all 8 ingredients therein. Final assessment on Diisostearyl Polyglyceryl-3 Dimer Dilinoleate finalized in 2016 with a safe when formulated to be non-irritating conclusion.

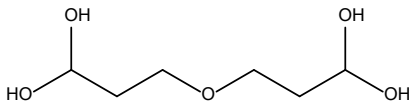
CIR draft grouping: (7 ingredients proposed with a total FOU = 398)	FOU
Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate	234
Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleate	82
Stearyl/PPG-3 Myristyl Ether Dimer Dilinoleate	33
Dimer Dilinoleyl Dimer Dilinoleate	23
Bis-Behenyl/Phytosteryl Dimer Dilinoleate	19
Phytosteryl Isostearyl Dimer Dilinoleate	6
Octyldodecyl/PPG-3 Myristyl Ether Dimer Dilinoleate	1

Diglycerin & Polyglycerin-3

FOU = 211

FOU = 208

Definition: Diglycerin is a dimer of Glycerin. Dimerization (and resultant connectivity) can occur at any of the alcohol groups (although less substituted alcohols are energetically favored (i.e., primary > secondary >> tertiary).



Reported Functions: Humectants; Skin-Conditioning Agents - Humectant

Notes: (CAS No. 59113-36-9) Polyglycerin-3 is essentially "triglycerin."

CIR draft grouping: (4 ingredients proposed with a total FOU = 451) **FOU**

Diglycerin 211

Polyglycerin-3 208

Polyglycerin-10 29

Polyglycerin-6 3

Sigesbeckia Orientalis Extract

FOU = 202

Definition: Sigesbeckia Orientalis Extract is the extract of *Sigesbeckia orientalis*.



Reported Functions: Skin-Conditioning Agents - Miscellaneous

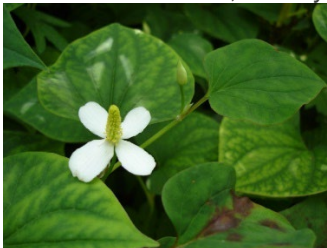
Notes: VCRP name is "*Sigesbeckia Orientalis* (Eastern St. Paul's Wort) Extract"

CIR draft grouping: None

Houttuynia Cordata Extract

FOU = 201

Definition: Houttuynia Cordata Extract is the extract of the herb, *Houttuynia cordata*.



Reported Functions: Skin-Conditioning Agents - Miscellaneous

Notes: (CAS No. 164288-50-0)

CIR draft grouping: (2 ingredients proposed with a total FOU = 203)

	<u>FOU</u>
<i>Houttuynia Cordata Extract</i>	201
<i>Houttuynia Cordata Powder</i>	2

Malva Sylvestris (Mallow) Extract

FOU = 198

Definition: Malva Sylvestris (Mallow) Extract is the extract of the whole plant, *Malva sylvestris*.



Reported Functions: Skin-Conditioning Agents - Miscellaneous

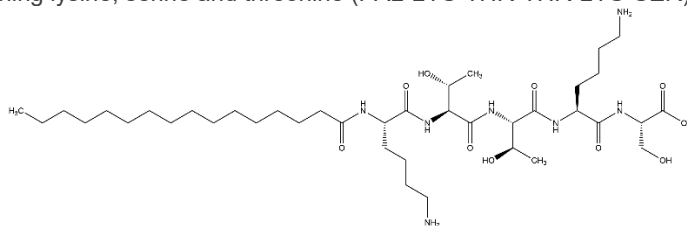
Notes: Related to *Althaea officinalis* or marshmallow.

CIR draft grouping: (8 ingredients proposed with a total FOU = 287)

	<u>FOU</u>
<i>Malva Sylvestris (Mallow) Extract</i>	198
<i>Malva Sylvestris (Mallow) Flower Extract</i>	72
<i>Malva Sylvestris (Mallow) Flower/Leaf/Stem Extract</i>	5
<i>Malva Sylvestris (Mallow) Flower/Leaf Extract</i>	4
<i>Malva Sylvestris (Mallow) Leaf Extract</i>	4
<i>Malva Sylvestris (Mallow) Oil (VCRP name only)</i>	2
<i>Malva Sylvestris (Mallow) Leaf Powder</i>	1
<i>Malva Sylvestris (Mallow) Flower</i>	1

Palmitoyl Pentapeptide-4**FOU = 198**

Definition: Palmitoyl Pentapeptide-4 is the reaction product of palmitic acid and Pentapeptide-4. Pentapeptide-4 is a synthetic peptide containing lysine, serine and threonine (PAL-LYS-THR-THR-LYS-SER).



Reported Functions: Skin-Conditioning Agents - Miscellaneous

Notes: (CAS Nos. 214047-00-4 & 521091-64-5) the 3 proposed ingredients all share the same peptide sequence

CIR draft grouping: (3 ingredients proposed with a total FOU = 202)

Palmitoyl Pentapeptide-4

FOU**198**

Pentapeptide-4

1

Myristoyl Pentapeptide-4

3

Salix Alba (Willow) Bark Extract

FOU = 197

Definition: Salix Alba (Willow) Bark Extract is the extract of the bark of *Salix alba*.



Reported Functions: Hair Conditioning Agents; Skin-Conditioning Agents - Occlusive

Notes: (CAS No. 84082-82-6) Willow tree

CIR draft grouping: (2 ingredients proposed with a total FOU = 238)

Salix Alba (Willow) Bark Extract

Salix Alba (Willow) Leaf Extract

FOU

197

41

Centaurea Cyanus Flower Extract

FOU = 196

Definition: Centaurea Cyanus Flower Extract is the extract of the flowers of the cornflower, *Centaurea cyanus*.



Reported Functions: Cosmetic Astringents; Skin-Conditioning Agents - Miscellaneous

Notes: (CAS No. 84012-18-0) "Cornflower"

CIR draft grouping: (3 ingredients proposed with a total FOU = 265)

Centaurea Cyanus Flower Extract

Centaurea Cyanus Flower Water

Centaurea Cyanus Flower Petals (VCRP name only)

FOU

196

68

1

Lactobacillus Ferment

FOU = 196

Definition: Lactobacillus Ferment is the product obtained through fermentation by the microorganism, *Lactobacillus*.

Reported Functions: Not Reported

Notes: (CAS No. 2380025-37-4 (generic)) Probiotics?

CIR draft grouping: (4 ingredients proposed with a total FOU = 213)

Lactobacillus Ferment

Lactobacillus Ferment Lysate

Lactobacillus Ferment Lysate Filtrate

Lactobacillus Ferment Filtrate

FOU

196

8

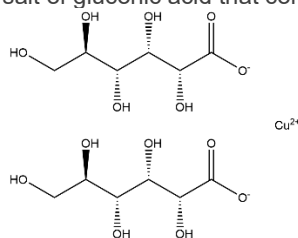
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3

Copper Gluconate

FOU = 192

Definition: Copper Gluconate is the copper salt of gluconic acid that conforms to the formula:



Reported Function: Skin-Conditioning Agents – Miscellaneous

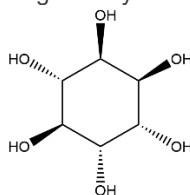
Notes: (CAS No. 527-09-3)

Grouping proposal: None

Inositol

FOU = 190

Definition: Inositol is the cyclic polyol that conforms generally to the formula:



Reported Function: Hair Conditioning Agents; Humectants

Notes: (CAS Nos. 643-12-9 & 87-89-8)

Grouping proposal: None

Paeonia Suffruticosa Root Extract

FOU = 189

Definition: Paeonia Suffruticosa Root Extract is the extract of the roots of *Paeonia suffruticosa*.



Reported Functions: Skin-Conditioning Agents - Miscellaneous

Notes: (CAS No. 223747-88-4 (generic))

CIR draft grouping: (5 ingredients proposed with a total FOU = 216)

	FOU
<i>Paeonia Suffruticosa</i> Root Extract	189
<i>Paeonia Suffruticosa</i> Extract	13
<i>Paeonia Suffruticosa</i> Bark Extract	7
<i>Paeonia Suffruticosa</i> Seed Oil	5
<i>Paeonia Suffruticosa</i> (Tree Peony) Root Bark Extract (VCRP name only)	2

Nelumbo Nucifera Flower Extract

FOU = 182

Definition: Nelumbo Nucifera Flower Extract is the extract of the flower of *Nelumbo nucifera*.



Reported Functions: Skin-Conditioning Agents - Miscellaneous

Notes: (CAS No. 85085-51-4 (generic)) "Lotus"

CIR draft grouping: (13 ingredients proposed with a total FOU = 285)

	<u>FOU</u>
<i>Nelumbo Nucifera Flower Extract</i>	182
<i>Nelumbo Nucifera Seed Extract</i>	26
<i>Nelumbo Nucifera Leaf Extract</i>	17
<i>Nelumbo Nucifera Root Extract</i>	16
<i>Nelumbo Nucifera Flower Water</i>	14
<i>Nelumbo Nucifera Flower Oil (VCRP name only)</i>	9
<i>Nelumbo Nucifera Callus Culture Extract</i>	7
<i>Nelumbo Nucifera Germ Extract</i>	8
<i>Nelumbo Nucifera Extract</i>	2
<i>Nelumbo Nucifera Stamen Extract</i>	1
<i>Nelumbo Nucifera Flower/Leaf/Stem Juice</i>	1
<i>Nelumbo Nucifera Seed Powder</i>	1
<i>Nelumbo Nucifera Root Water</i>	1