

ADMIN

Priorities

EXPERT PANEL MEETING

September 11-12, 2023



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Memorandum

Date: August 18th, 2023

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

To: All Stakeholders

Re: 2024 Draft Final Priority List

The CIR Procedures require preparation of the 2024 Draft Priority List for public comment by June 1, 2023. This list was provided to the Panel and reviewed at the March 2023 meeting; comments made at the March and June meetings have been considered and incorporated into this 2024 Draft Final Priority List. The priority list is typically based on stakeholder requests for cause (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 February 2 (in response to a Freedom of Information Act request). In lieu of submitting an additional hair dye ingredient, this year, the Hair Color Technical Committee (HCTC) concurred with the inclusion of Tetrabromophenol Blue in the 2024 Priorities List (*HCTC agree hair dye 2024.pdf*).

At a previous meeting, a liaison from the FDA proposed that the Panel assess the safety of Cannabidiol (CBD) and other cannabinoids as used in cosmetics. At that time, there were zero formulations reported to the VCRP containing cannabinoid ingredients; accordingly, the Panel chose to defer review at that time. However, Cannabidiol is currently reported to be used in 32 formulations and is included in this Priorities List. At the June meeting, a liaison from FDA proposed that the Panel assess the safety of Trimethylbenzoyl Diphenylphosphine Oxide, a skin conditioning ingredient currently reported to be used in 127 formulations. ECHA launched a 45-d consultation for their plan for this ingredient to be added to the substances of very high concern (SVHC) list on February 17, 2023. This ingredient has been added to this Priorities List.

While the priority list includes only the lead ingredients, groupings of ingredients, drafted by CIR Staff, can be found on the following pages. There are 18 reports proposed, covering 31 ingredients, on the 2024 Draft Final Priorities List. Reports previously prioritized and on the CIR docket at the end of 2023, as well as an extensive number of re-reviews of previous assessments, will supplement the total number of reports/ingredients to be assessed in 2024. 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 (SLR) 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 (natural complex substances (NCS)), 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.

2024 Draft Final Priorities List

Ingredient	Frequency of Use (FOU) Data Year: 2023
<i>For cause</i>	
Cannabidiol	32
Basic Blue 7	1
Trimethylbenzoyl Diphenylphosphine Oxide	127
Tetrabromophenol Blue	2
<i>Per FOU</i>	
Polyacrylate-13	265
Polygonum Cuspidatum Root Extract	245
Xylitylglucoside	213
Phytosphingosine	210
Sodium Hyaluronate Crosspolymer	207
Polyacrylate Crosspolymer-6	205
Trimethylpentanediyl Dibenzoate	202
Tosylamide/Epoxy Resin	189
Carnosine	184
Madecassoside	182
Sophora Flavescens Root Extract	179
Curcuma Longa (Turmeric) Root Extract	177
Lonicera Japonica (Japanese Honeysuckle) Flower Extract	175
Perfluorohexylethyl Triethoxysilane	172

2024 Draft Final Priorities Groupings for New Reports

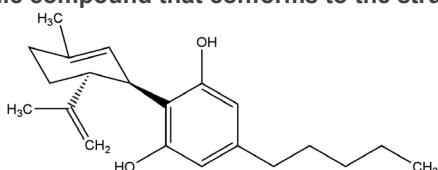
Proposed 2024 Reports – per cause

Cannabidiol – Previously proposed for Panel review by FDA

→Cannabidiol (CBD)

FOU = 32

Definition: Cannabidiol is the organic compound that conforms to the structure:



Reported Functions: Antiacne Agents; Antioxidants; Drug Astringents - Skin Protectant Drugs; Skin Protectants; Skin-Conditioning Agents - Miscellaneous

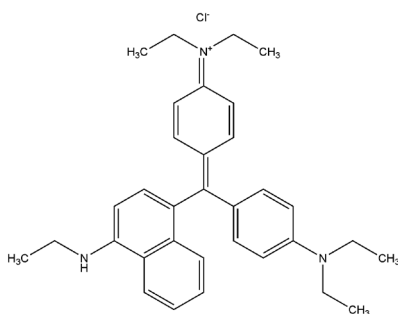
Notes: (CAS No. 13956-29-1) At a previous meeting, a liaison from the FDA proposed that the Panel assess the safety of Cannabidiol (CBD). At that time, there were zero formulations reported to the VCRP containing cannabinoid ingredients; accordingly, the Panel chose to defer review.

Grouping proposal: None

Basic Blue 7 – on EU Annex II – forbidden from use in cosmetics

FOU = 1

Definition: Basic Blue 7 is classed chemically as a triarylmethane color. It conforms to the structure:



Reported Function: Hair Colorant

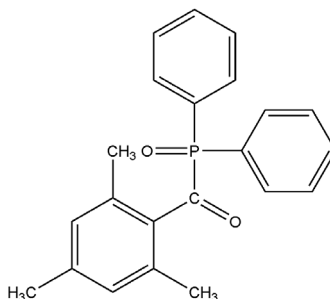
Notes: (CAS No. 2390-60-5) on EU Annex II – forbidden from use in cosmetics

Grouping proposal: None

Trimethylbenzoyl Diphenylphosphine Oxide – FDA request

FOU = 127

Definition: Trimethylbenzoyl Diphenylphosphine Oxide is the organic compound that conforms to the structure:



Reported Function: Hair Colorant

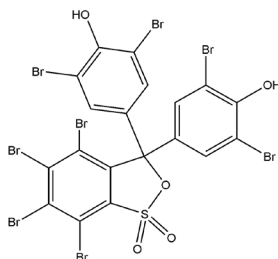
Notes: ECHA launched a 45-d consultation for their plan for Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (Trimethylbenzoyl Diphenylphosphine Oxide) to be added to the substances of very high concern (SVHC) list on February 17, 2023. There are new DART concerns.

Grouping proposal: None

Tetrabromophenol Blue – SCCS insufficient data

FOU = 2

Definition: Tetrabromophenol Blue is the organic compound that conforms to the structure:



Reported Function: Hair Colorant

Notes: (CAS No. 4430-25-5) "Based on the data provided, the SCCS is of the opinion that the use of Tetrabromophenol Blue with a maximum on-head concentration of 0.2% in non-oxidative hair dye formulations does pose a risk to the health of the consumer due to the low Margin of Safety.

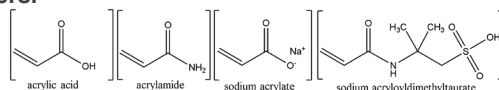
Tetrabromophenol Blue is a mixture of octa-, hepta-, and hexa-bromo phenolsulfonphthaleins, and does not contain any Tetrabromo-homologue, therefore the INCI name is misleading. The criteria for meeting the specifications of other batches, similar to the present mixture should be defined. No acceptable dermal absorption study under oxidative conditions was provided. An assessment of the use of Tetrabromophenol Blue in oxidative hair dye formulations cannot be performed without an adequate dermal absorption study and stability data in an oxidative environment." -Conclusion of the SCCS opinion at its 15th plenary meeting of 26-27 June 2012.

Grouping proposal: None

Proposed 2024 Reports – per FOU**Polyacrylate-13**

FOU = 265

Definition: Polyacrylate-13 is the copolymer of acrylic acid, acrylamide, sodium acrylate, and sodium acryloyldimethyltaurate monomers.



Reported Function: Film Formers

Notes: The Panel has previously assessed the safety of structurally similar ingredients in the [Safety Assessment of Acryloyldimethyltaurate Polymers as Used in Cosmetics](#), finalized in 2017 (e.g., Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer, defined as: a copolymer of acrylamide, sodium acryloyldimethyltaurate, and acrylic acid monomers), concluding that such copolymers are safe as used.

Grouping proposal: None

Polygonum Cuspidatum Root Extract

FOU = 245

Definition: Polygonum Cuspidatum Root Extract is the extract of the roots of *Polygonum cuspidatum*. The accepted scientific name for *Polygonum cuspidatum* is *Fallopia japonica*.



Reported Functions: Antioxidants; Skin-Conditioning Agents – Miscellaneous

Notes: These 2 botanical ingredients are derived from the same plant species, 1 from the root and the other from the whole plant.

CIR draft grouping/clustering: (2 ingredients proposed with a total FOU = 245)

Polygonum Cuspidatum Root Extract

Polygonum Cuspidatum Extract

FOU

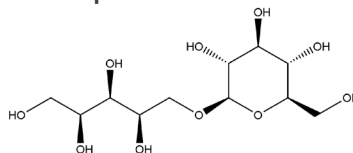
245

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Xylitylglucoside

FOU = 213

Definition: Xylitylglucoside is the organic compound that conforms to the structure:



Reported Functions: Skin-Conditioning Agents - Humectant

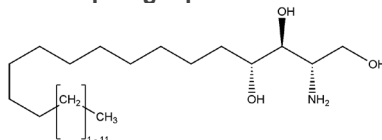
Notes: (CAS No. 1095751-96-4)

CIR draft grouping: None

Phytosphingosine

FOU = 210

Definition: Phytosphingosine is a synthetic sphingolipid that conforms generally to the structure:



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

Notes: (CAS Nos. 554-62-1; 13552-11-9) The Panel has previously assessed the safety of structurally-related ingredients in the Safety Assessment of Ceramides as Used in Cosmetics, published in IJT in 2020 (e.g., Caproyl Phytosphingosine, defined as: the product obtained by the reaction of Caproic Acid and Phytosphingosine), concluding that such copolymers are safe as used. While Phytosphingosine contains a free amine functional group, the ceramides differ as corresponding amides.

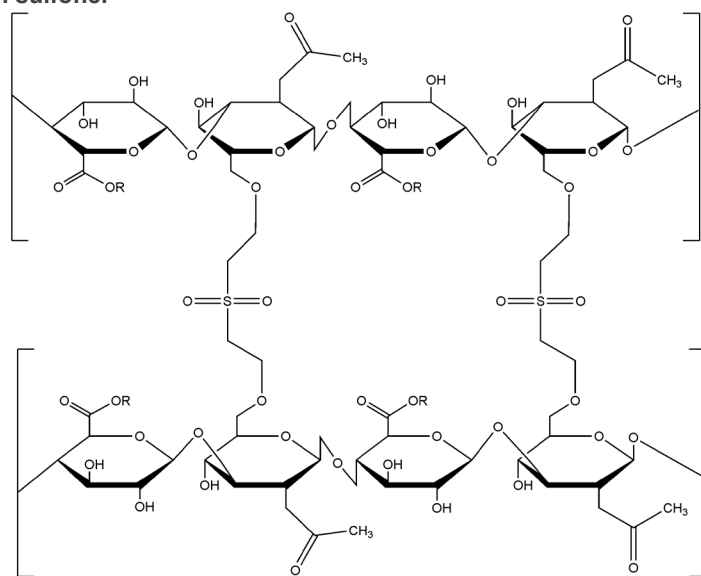
CIR draft grouping: (4 ingredients proposed with a total FOU = 233)

	FOU
Phytosphingosine	210
Tetraacetylphytosphingosine	17
Acetylphytosphingosine	4
Phytosphingosine HCl	2

Sodium Hyaluronate Crosspolymer

FOU = 207

Definition: Sodium Hyaluronate Crosspolymer is the sodium salt of a polymer of Hyaluronic Acid crosslinked with divinyl sulfone.



wherein R is hydrogen or sodium

Reported Functions: Skin-Conditioning Agents – Humectant; Skin-Conditioning Agents - Miscellaneous

Notes: (CAS No. 105524-32-1) These 3 ingredients share the same polyhyaluronate backbone and differ only by the crosslinker (diglycidyl ether for Sodium Hyaluronate Crosspolymer-2 and propylbisoxamine for Sodium Hyaluronate Crosspolymer-3). (The Panel has recently addressed the safety of Sodium Hyaluronate.)

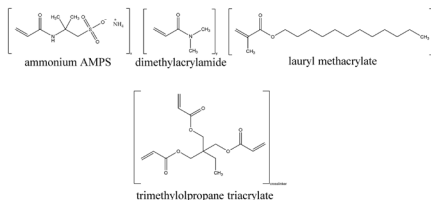
CIR draft grouping: (3 ingredients proposed with a total FOU = 210)

	FOU
Sodium Hyaluronate Crosspolymer	207
Sodium Hyaluronate Crosspolymer-2	2
Sodium Hyaluronate Crosspolymer-3	1

Polyacrylate Crosspolymer-6

FOU = 205

Definition: Polyacrylate Crosspolymer-6 is a copolymer of ammonium AMPS (2-acrylamido-2-methylpropane sulfonic acid), dimethylacrylamide, lauryl methacrylate, and laureth-4 methacrylate, crosslinked with trimethylolpropane triacrylate.



Reported Functions: Emulsion Stabilizers; Viscosity Increasing Agents - Aqueous

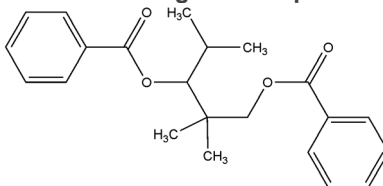
Notes:

CIR draft grouping: none

Trimethylpentanediyl Dibenzoate

FOU = 202

Definition: Trimethylpentanediyl Dibenzoate is the organic compound that conforms to the structure:



Reported Functions: Plasticizers

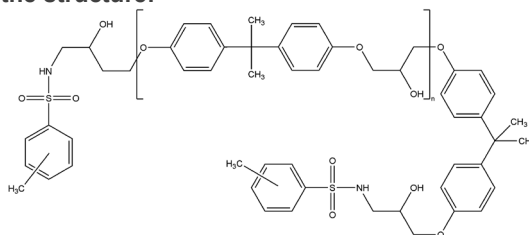
Notes: (CAS No. 68052-23-3)

CIR draft grouping: none

Tosylamide/Epoxy Resin

FOU = 189

Definition: Tosylamide/Epoxy Resin is the toluenesulfonamide of the condensation product of 4,4'-isopropylidenediphenol/epichlorohydrin copolymer, also known as the epoxy resin. The polymeric end-product conforms generally to the structure:



wherein $n = 0$ to 5

Reported Functions: Dispersing Agents – Nonsurfactant; Film Formers; Plasticizers

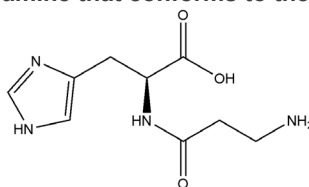
Notes: According to chemical structure, minimum molecular weight is 1012 Da.

CIR draft grouping: none

Carnosine

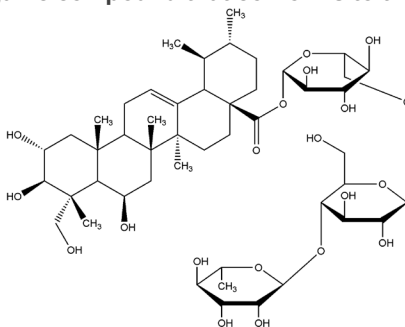
FOU = 184

Definition: Carnosine is the heterocyclic amine that conforms to the structure:

**Reported Functions:** Skin-Conditioning Agents - Miscellaneous**Notes:** (CAS No. 305-84-0)**CIR draft grouping:** None**Madecassoside**

FOU = 182

Definition: Madecassoside is the organic compound that conforms to the structure:

**Reported Function:** Antioxidants; Skin Protectants; Skin-Conditioning Agents - Miscellaneous**Notes:** (CAS No. 34540-22-2)**Grouping proposal:** None**Sophora Flavescens Root Extract**

FOU = 179

Definition: Sophora Flavescens Root Extract is the extract of the roots of *Sophora flavescens*.**Reported Functions:** Antioxidants; Skin-Conditioning Agents – Miscellaneous**Notes:** These 3 botanical ingredients are each from the same species, *Sophora flavescens*, sometimes referred to as shrubby sophora. Of these 3, 2 ingredients are derived from the root, and the other is derived from the whole plant.**CIR draft grouping: (3 ingredients proposed with a total FOU = 220)**

Sophora Flavescens Root Extract

FOU
179

Sophora Flavescens Extract

40

Sophora Flavescens Root Powder

1

Curcuma Longa (Turmeric) Root Extract

FOU = 177

Definition: Curcuma Longa (Turmeric) Root Extract is the extract of the roots of *Curcuma longa*.**Reported Functions:** Skin-Conditioning Agents - Miscellaneous**Notes:** (CAS No. 84775-52-0) The ingredients in this group are each derived from the same species.**CIR draft grouping: (5 ingredients proposed with a total FOU = 220)**

	<u>FOU</u>
Curcuma Longa (Turmeric) Root Extract	177
Curcuma Longa (Turmeric) Root Oil	17
Curcuma Longa (Turmeric) Root Powder	15
Curcuma Longa (Turmeric) Rhizome Extract	6
Curcuma Longa (Turmeric) Leaf Extract	5

Lonicera Japonica (Honeysuckle) Flower Extract

FOU = 175

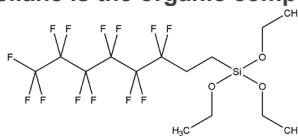
Definition: Lonicera Japonica (Honeysuckle) Flower Extract is the extract of the flowers of *Lonicera japonica*.**Reported Functions:** Skin-Conditioning Agents - Miscellaneous**Notes:** (CAS No. 223749-79-9 (generic)) The ingredients in this group are each derived from the same species (also known as Japanese Honeysuckle).**CIR draft grouping: (2 ingredients proposed with a total FOU = 180)**

	<u>FOU</u>
Lonicera Japonica (Honeysuckle) Flower Extract	175
Lonicera Japonica (Honeysuckle) Leaf Extract	5

Perfluorohexylethyl Triethoxysilane

FOU = 172

Definition: Perfluorohexylethyl Triethoxysilane is the organic compound that conforms to the structure:

**Reported Functions:** Binders; Skin-Conditioning Agents - Miscellaneous**Notes:** (CAS No. 51851-37-7)**Grouping proposal:** None



Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director – Cosmetic Ingredient Review (CIR)

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

DATE: March 27, 2022

SUBJECT: Hair Dye Ingredients on the 2024 CIR Priorities

The Hair Coloring Technical Committee (HCTC) acknowledges that the Expert Panel for Cosmetic Ingredient Safety has included Basic Blue 7 and Tetrabromophenol Blue on the 2024 draft ingredient priority list. Tetrabromophenol Blue is on our list of ingredients to recommend for CIR review. We agree that this ingredient should be reviewed in 2024. We do not have any additional hair dye ingredient recommendations for the 2024 priorities.