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Memorandum

Date: September 15th, 2023

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

To: All Stakeholders

Re: 2024 Final Priority List

There are 18 reports proposed, covering 31 ingredients, on the 2024 Final Priorities List. While the priority list includes only the lead ingredients, groupings of ingredients for reports can be found on the following pages. 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
- Risk (e.g., margins of safety)
- 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 Final Priorities List

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Frequency of Use (FOU)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cannabidiol</td>
<td>32</td>
</tr>
<tr>
<td>Basic Blue 7</td>
<td>1</td>
</tr>
<tr>
<td>Trimethylbenzoyl Diphenylphosphine Oxide</td>
<td>127</td>
</tr>
<tr>
<td>Tetrabromophenol Blue</td>
<td>2</td>
</tr>
</tbody>
</table>

**For cause**

Data Year: 2023

<table>
<thead>
<tr>
<th>Ingredient</th>
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<tbody>
<tr>
<td>Polyacrylate-13</td>
<td>265</td>
</tr>
<tr>
<td>Polygonum Cuspidatum Root Extract</td>
<td>245</td>
</tr>
<tr>
<td>Xylitylglucoside</td>
<td>213</td>
</tr>
<tr>
<td>Phytosphingosine</td>
<td>210</td>
</tr>
<tr>
<td>Sodium Hyaluronate Crosspolymer</td>
<td>207</td>
</tr>
<tr>
<td>Polyacrylate Crosspolymer-6</td>
<td>205</td>
</tr>
<tr>
<td>Trimethylpentanediyl Dibenoate</td>
<td>202</td>
</tr>
<tr>
<td>Tosylamide/Epoxy Resin</td>
<td>189</td>
</tr>
<tr>
<td>Carnosine</td>
<td>184</td>
</tr>
<tr>
<td>Madecassoside</td>
<td>182</td>
</tr>
<tr>
<td>Sophora Flavescens Root Extract</td>
<td>179</td>
</tr>
<tr>
<td>Curcuma Longa (Turmeric) Root Extract</td>
<td>177</td>
</tr>
<tr>
<td>Lonicera Japonica (Japanese Honeysuckle) Flower Extract</td>
<td>175</td>
</tr>
<tr>
<td>Perfluorohexylethyl Triethoxysilane</td>
<td>172</td>
</tr>
</tbody>
</table>
2024 Final Priorities Groupings for New Reports

Planned 2024 Reports – per cause

**Cannabidiol**  – Previously proposed for Panel review by FDA

➔ Cannabidiol (CBD)  
Definition: Cannabidiol is the organic compound that conforms to the structure:  

![Cannabidiol structure](image)

**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  

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

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

![Basic Blue 7 structure](image)

**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:

![Chemical Structure](image)

**Reported Function:** Skin Conditioning Agent

**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

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**Tetrabromophenol Blue – SCCS insufficient data**

**FOU = 2**

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

![Chemical Structure](image)

**Reported Function:** Hair Colorant

**Notes:** (CAS No. 4430-25-5) There is a 2019 SCCS opinion ([https://health.ec.europa.eu/system/files/2021-08/sccs_o_232_0.pdf](https://health.ec.europa.eu/system/files/2021-08/sccs_o_232_0.pdf)) with a conclusion of safe when used as a hair dye in oxidative and non-oxidative hair coloring products at a final on-head concentration of up to 0.2%. Tetrabromophenol Blue has also been added to EU Annex III (entry 319) with the limitations recommended by the SCCS in 2019.

**Grouping proposal:** None
Planned 2024 Reports – per FOU

**Polyacrylate-13**

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

![Polyacrylate-13 structure](attachment:polyacrylate-13.png)

**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

**FOU = 265**

**Polygonum Cuspidatum Root Extract**

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

![Polygonum Cuspidatum](attachment:polygonum_cuspidatum.png)

**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)

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>FOU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polygonum Cuspidatum Root Extract</td>
<td>245</td>
</tr>
<tr>
<td>Polygonum Cuspidatum Extract</td>
<td>-</td>
</tr>
</tbody>
</table>

**FOU = 245**

**Xylitylglucoside**

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

![Xylitylglucoside structure](attachment:xylitylglucoside.png)

**Reported Functions:** Skin-Conditioning Agents - Humectant

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

**CIR draft grouping:** None

**FOU = 213**
**Phytosphingosine**

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

![Phytosphingosine chemical structure](image)

**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., Caprooyl 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)  
<table>
<thead>
<tr>
<th>FOU</th>
</tr>
</thead>
</table>
| Phytosphingosine | 210  
| Tetraacetylphytosphingosine | 17  
| Acetylphytosphingosine | 4  
| Phytosphingosine HCl | 2  

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**Sodium Hyaluronate Crosspolymer**

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

![Sodium Hyaluronate Crosspolymer chemical structure](image)

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 propylbisoxyamine 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)  
<table>
<thead>
<tr>
<th>FOU</th>
</tr>
</thead>
</table>
| Sodium Hyaluronate Crosspolymer | 207  
| Sodium Hyaluronate Crosspolymer-2 | 2  
| Sodium Hyaluronate Crosspolymer-3 | 1  

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**Polyacrylate Crosspolymer-6**

**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

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**Trimethylpentanediyl Dibenzoate**

**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

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**Tosylamide/Epoxy Resin**

**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:

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

**Notes:** According to chemical structure, minimum molecular weight is 1012 Da.
- **CIR draft grouping:** none
### Carnosine

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

![Carnosine Structure](image)

**Reported Functions:** Skin-Conditioning Agents - Miscellaneous

**Notes:** (CAS No. 305-84-0)
**CIR draft grouping:** None

### Madecassoside

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

![Madecassoside Structure](image)

**Reported Function:** Antioxidants; Skin Protectants; Skin-Conditioning Agents - Miscellaneous

**Notes:** (CAS No. 34540-22-2)
**Grouping proposal:** None

### Sophora Flavescens Root Extract

**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)

<table>
<thead>
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<tbody>
<tr>
<td>Sophora Flavescens Root Extract</td>
<td>179</td>
</tr>
<tr>
<td>Sophora Flavescens Extract</td>
<td>40</td>
</tr>
<tr>
<td>Sophora Flavescens Root Powder</td>
<td>1</td>
</tr>
</tbody>
</table>
### Curcuma Longa (Turmeric) Root Extract

**Definition:** Curcuma Longa (Turmeric) Root Extract is the extract of the roots of *Curcuma longa*.

**FOU = 177**

*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)  

<table>
<thead>
<tr>
<th>Ingredient</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Curcuma Longa (Turmeric) Root Extract</td>
<td>177</td>
</tr>
<tr>
<td>Curcuma Longa (Turmeric) Root Oil</td>
<td>17</td>
</tr>
<tr>
<td>Curcuma Longa (Turmeric) Root Powder</td>
<td>15</td>
</tr>
<tr>
<td>Curcuma Longa (Turmeric) Rhizome Extract</td>
<td>6</td>
</tr>
<tr>
<td>Curcuma Longa (Turmeric) Leaf Extract</td>
<td>5</td>
</tr>
</tbody>
</table>

### Lonicera Japonica (Honeysuckle) Flower Extract

**Definition:** Lonicera Japonica (Honeysuckle) Flower Extract is the extract of the flowers of *Lonicera japonica*.

**FOU = 175**

*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)  

<table>
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<tr>
<td>Lonicera Japonica (Honeysuckle) Flower Extract</td>
<td>175</td>
</tr>
<tr>
<td>Lonicera Japonica (Honeysuckle) Leaf Extract</td>
<td>5</td>
</tr>
</tbody>
</table>

### Perfluorohexylethyl Triethoxysilane

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

![](image)

*Reported Functions:* Binders; Skin-Conditioning Agents - Miscellaneous

*Notes:* (CAS No. 51851-37-7)

*Grouping proposal:* None