

Memorandum

Date: June 8th, 2018

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

To: All stakeholders

Re: Final 2019 Priority List

The CIR Procedures require preparation of the Draft 2019 Priority List for public comment by June 1, 2018. The Draft 2019 Priority List was prepared and issued for public comment earlier in the process (at the March 2018 meeting) to allow more time for the acquisition of data. The list is based on stakeholder requests; frequency of use data (FOU) from FDA's Voluntary Cosmetic Registration Program (VCRP) received from the FDA on February 5, 2018; and on CIR staff and Panel workflow. While this list includes only the lead ingredients, groupings are provided for each on the following pages of this document.

There are twenty-six reports covering 187 ingredients on the Final 2019 Priorities List. Reports previously prioritized and on the CIR docket at the end of 2018, as well as a number of re-reviews of previous assessments, will supplement the total number of ingredients to be assessed in 2019.

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

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).

Final 2019 Priorities List

<i>For cause</i>	<i>Frequency of Use (FOU)</i>
BENZISOTHIAZOLINONE – a potential preservative	not reported in 2018 VCRP (6 uses in 2015)
CAPRYLHYDROXAMIC ACID – reported allergenicity	147
BASIC BROWN 17 – a hair dye	45
<i>Per FOU</i>	
HONEY	949
SACCHARUM OFFICINARIUM (SUGARCANE) EXTRACT	406
EQUISETUM ARVENSE EXTRACT	369
SACCHARIDE ISOMERATE	365
PORTULACA OLERACEA (PURSLANE) EXTRACT	363
UBIQUINONE	343
DIATOMACEOUS EARTH	337
SODIUM LEVULINATE	331
GLUCONOLACTONE	329
ACETYL HEXAPEPTIDE-8	318
CALCIUM SULFATE	317
HONEY EXTRACT	306 (to be grouped w/Honey)
CHONDRUS CRISPUS EXTRACT	299
ROSA DAMASCENA FLOWER OIL	298
SALVIA OFFICINALIS (SAGE) LEAF EXTRACT	292
ROSA DAMASCENA FLOWER WATER	289 (to be grouped with Rosa Damascena Flower Oil)
DICAPRYLYL ETHER	288
PEG/PPG-8/3 DIISOSTEARATE	277
POLYQUATERNIUM-51	274
DIACETONE ALCOHOL	268
ACETYL GLUCOSAMINE	265
POLYQUATERNIUM-6	265
OLEA EUROPAEA (OLIVE) LEAF EXTRACT	257

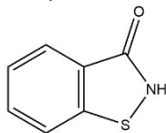
2019 Priorities Groupings for New Reports

Proposed 2019 Reports – per cause

Benzisothiazolinone – per request

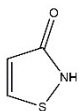
FOU = not reported

Definition: Benzisothiazolinone is the heterocyclic compound that conforms to the structure:



Reported Function: Preservative

Notes: This isothiazolinone-type preservative differs significantly in structure from others as a bicyclic



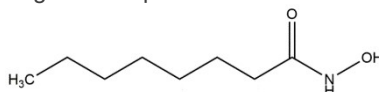
aromatic (isothiazolinone structure:). The α,β -unsaturated carbonyl of this ingredient makes it a Michael-Acceptor (i.e. alert for sensitization potential), but the aromatic ring is likely to attenuate that activity in comparison to the other isothiazolinone-type preservatives.

Grouping proposal: None

Caprylhydroxamic Acid – per *Contact Dermatitis* 77:159-162, 2017

FOU = 147

Definition: Caprylhydroxamic Acid is the organic compound that conforms to the structure:



Reported Function: Chelating Agent (i.e. prevent oxidative deterioration of formula)

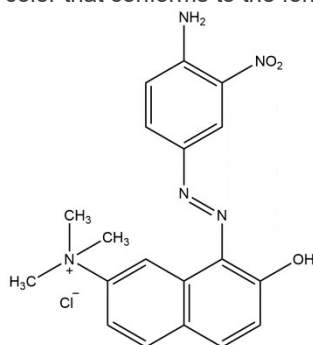
Notes: The study authors in Finland concluded that they, “found a new contact allergen, caprylhydroxamic acid, which caused an epidemic of allergic contact dermatitis in patients using moisturizers containing this preservative”

Grouping proposal: None. There are other hydroxamic acid chelating agents in the *Cosmetic Ingredient Dictionary and Handbook*. However, all of those are aromatic (whereas this ingredient is aliphatic) and not reported to be in use in the 2018 snapshot of the FDA VCRP.

Basic Brown 17 – per PCPC HCTC

FOU = 45

Definition: Basic Brown 17 is the monoazo color that conforms to the formula:



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.

Grouping proposal: None

Proposed 2019 Reports – per FOU

Honey

FOU = 949

Definition: Honey is a saccharic secretion gathered and stored by honey bees of the species, *Apis mellifera*, *Tetragonisca angustula*, *Scaptotrigona pectoralis*, or *Melipona Becheii*.



Reported Functions: Flavoring Agents; Humectants; Skin-Conditioning Agents - Humectant; Solvents

Notes: Primarily saccharides, but a complex mixture of proteins, amino acids, vitamins, minerals, etc.

Grouping proposal: Honey Ingredients (7 ingredients; 1,265 combined FOU)

Honey (FOU priority ingredient)	949
Honey Extract	306
Hydrogenated Honey (mix of saccharides)	6
Hydrolyzed Honey (mix of saccharides)	-
Honey Cocoates	-
Honey Powder	4
Hydrolyzed Honey Protein	-

Saccharum Officinarum (Sugarcane) Extract

FOU = 406

Definition: Saccharum Officinarum (Sugarcane) Extract is the extract of the sugar cane, *Saccharum officinarum*.



Reported Functions: Exfoliants; Skin-Conditioning Agents - Miscellaneous; Solvents

Notes: Sugarcane wax is used as a commercial source of long chain fatty alcohols, acids, esters, aldehydes, and ketones. Policosanols and D-003 along with some steroids and terpenoids have also been identified and isolated from sugarcane wax. Policosanols are a mixture of long chain primary aliphatic alcohols (1 - 8) ranging from 2.5 - 80%. Octacosanol constitutes 50 - 80% of the total policosanols. Other major pharmacologically active components of sugarcane wax are long chain aliphatic fatty acids (9 - 18) present at lower concentrations. Although fatty acid and fatty alcohol are reported as major constituents various phytosterols, steroids, and higher terpenoids have also been reported in sugarcane wax.

Pharmacognosy Reviews. 2015;9(17):45-54

Grouping proposal: Saccharum officinarum-Derived Ingredients (2 ingredients; 406 combined FOU)

Saccharum Officinarum (Sugarcane) Extract (FOU priority ingredient) 406

Saccharum Officinarum (Sugarcane) Wax -

Equisetum Arvense Extract

FOU = 369

Definition: Equisetum Arvense Extract is the extract of the whole herb, *Equisetum arvense*.



Reported Functions: Skin-Conditioning Agents - Miscellaneous

Notes:

Grouping proposal: Horsetail Ingredients (6 ingredients, 396 combined FOU)

Equisetum Arvense Extract (FOU priority ingredient) 369

Equisetum Arvense Juice -

Equisetum Arvense Leaf Extract 5

Equisetum Arvense Leaf Powder -

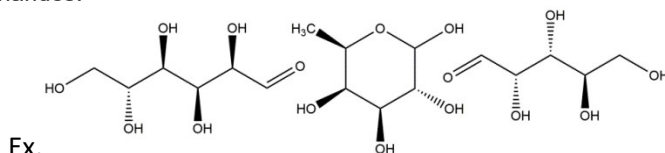
Equisetum Arvense Powder -

Horsetail (Equisetum Arvense) – not in INCI; VCRP only 22

Saccharide Isomerate

FOU = 365

Definition: Saccharide Isomerate is a carbohydrate complex formed from a base catalyzed rearrangement of a mixture of saccharides.



Reported Functions: Skin-Conditioning Agents - Humectant

Notes: Many of the saccharide ingredients used as humectants in cosmetic formulation have been previously assessed for safety (e.g., calcium gluconate, fructose, fucose galactose, galactosyl fructose, galacturonic acid, gluconic acid, glucose, isomalt, kefiran, lactitol lactose, lactulose, maltose, mannose, melibiose, potassium gluconate, rhamnose, ribose, sodium gluconate, sucralose, sucrose, trehalose, xylobiose, and xylose were found safe as used in 2014 ([Final Report](#))).

Grouping proposal: Saccharide Humectants (7 ingredients, 498 combined FOU)

Saccharide Isomerate (FOU priority ingredient)	365
Saccharide Hydrolysate (mix of saccharides)	21
Anhydrogalactose	-
Anhydroglucitol	-
Anhydroxylitol	112
Arabinose	-
Psicose	-

Portulaca Oleracea Extract

FOU = 363

Definition: Portulaca Oleracea Extract is the extract of the whole plant, *Portulaca oleracea*.



Reported Functions: Skin-Conditioning Agents - Humectant

Notes: Common name, Purslane

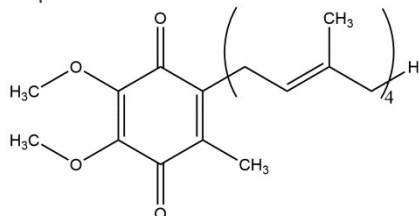
Grouping proposal: Portulaca oleracea-Derived Ingredients (4 ingredients, 363 combined FOU)

Portulaca Oleracea Extract (FOU priority ingredient)	363
Portulaca Oleracea Flower/Leaf/Stem Extract	-
Portulaca Oleracea Juice	-
Portulaca Oleracea Water	-

Ubiquinone

FOU = 343

Definition: Ubiquinone is the organic compound that conforms to the formula:



Reported Functions: Antioxidants; Skin-Conditioning Agents – Miscellaneous

Notes: Common name is Coenzyme Q10

Grouping proposal: Ubiquinone Ingredients (3 ingredients, 350 combined FOU)

Ubiquinone (FOU priority ingredient)

343

Disodium Ubiquinone (salt for of Ubiquinone)

-

Hydroxydecyl Ubiquinone (93% structural similarity to Ubiquinone)

7

Diatomaceous Earth

FOU = 337

Definition: Diatomaceous Earth is a mineral material consisting chiefly of the siliceous frustules and fragments of various species of diatoms, which may or may not be calcined.



Reported Functions: Antiacne Agents; Chelating Agents; Skin-Conditioning Agents - Miscellaneous

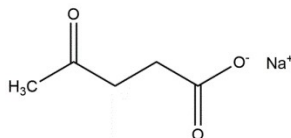
Notes:

Grouping proposal: None

Sodium Levulinate

FOU = 331

Definition: Sodium Levulinate is the sodium salt of Levulinic Acid



Reported Functions: Skin-Conditioning Agents - Miscellaneous

Notes: These are “keto acids,” alkyl moieties with a ketone and carboxylic acid functional group.

Grouping proposal: Levulinic Acid and Sodium Levulinate (2 ingredients, 425 combined FOU)

Sodium Levulinate (FOU priority ingredient)

331

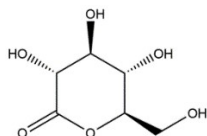
Levulinic Acid

94

Gluconolactone

FOU = 329

Definition: Gluconolactone is the lactone that conforms to the formula:



Reported Functions: Antiacne Agents; Chelating Agents; Skin-Conditioning Agents - Miscellaneous

Notes: 5 such oxidized monosaccharides are found in the Dictionary.

Grouping proposal: Glycolactones (5 ingredients, 329 combined FOU)

Gluconolactone (FOU priority ingredient)

329

Galactonolactone

-

Glucarolactone

-

Glucoheptonolactone

-

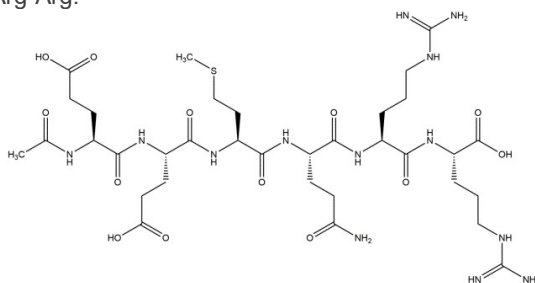
Ribonolactone

-

Acetyl Hexapeptide-8

FOU = 318

Definition: Acetyl Hexapeptide-8 is product obtained by the acetylation of Hexapeptide-8. Hexapeptide-8 is a synthetic peptide containing arginine, glutamic acid, glutamine and methionine. The specific sequence is Ac-Glu-Glu-Met-Gln-Arg-Arg.



Reported Functions: Skin-Conditioning Agents - Humectant

Notes: These two ingredients share the same sequence and only differ at the C-terminus

Grouping proposal: Acetyl Hexapeptide-8 and its Amide (2 ingredients, 318 combined FOU)

Acetyl Hexapeptide-8 (FOU priority ingredient)

318

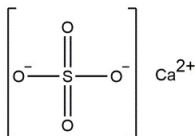
Acetyl Hexapeptide-8 Amide

-

Calcium Sulfate

FOU = 317

Definition: Calcium Sulfate is the inorganic salt that conforms to the formula:



Reported Functions: Abrasives; Bulking Agents; Opacifying Agents

Notes:

Grouping proposal: Calcium Sulfate and its hydrate (2 ingredients, 317 combined FOU)

Calcium Sulfate (FOU priority ingredient)

317

Calcium Sulfate Hydrate

-

Chondrus Crispus Extract

FOU = 299

Definition: Chondrus Crispus Extract is the extract of the whole plant [red alga], *Chondrus crispus*.



Reported Functions: Skin-Conditioning Agents - Miscellaneous

Notes:

- most are from the complex cell wall
- source of stabilizers and thickeners used in: salad dressing, soft serve ice cream, puddings, icings, sauces, creamed soups, laxatives, lotions, creams, etc.
- source of Agar (safe as used by CIR ([Final Report](#)))

Grouping proposal: Red Alga (73 ingredients, combined 876 FOU)

Chondrus Crispus Extract (FOU priority ingredient)	299
Chondrus Crispus (aka "irish moss" in VCRP)	5
Chondrus Crispus Powder	28
Hydrolyzed Chondrus Crispus Extract	2
Ahnfeltiopsis Concinna Extract (aka AHNFELTIA CONCINNA EXTRACT)	13
Asparagopsis Armata Extract	42
Betaphycus Gelatinum Extract	-
Botryocladia Occidentalis Extract	-
Calliblepharis Ciliata Extract	-
Calliblepharis Jubata Extract	-
Ceramium Kondoi Extract	-
Ceramium Rubrum Extract	-
Chondracanthus Teedei Powder	-
Chondracanthus Tenellus Extract	-
Chondracanthus Tenellus/Saccharina Angustata/Ulva Linza Extract	-
Chondrus Elatus Extract	-
Chondrus Elatus/Saccharina Angustata/Monostroma Nitidum Thallus Extract	-
Corallina Officinalis Extract	69
Corallina Officinalis Powder	-
Digenea Simplex Extract	1
Dilsea Carnosa Extract	-
Eucheuma Serra Extract	-
Eucheuma Serra/Grateloupia Sparsa/Saccharina Angustata/Ulva Linza/Undaria Pinnatifida Extract	-
Eucheuma Serra/Saccharina Angustata/Ulva Linza Extract	-
Furcellaria Lumbricalis Extract	-
Galaxaura Rugosa Extract	-

Galaxaura Rugosa/Sargassum Pacificum/Turbinaria Ornata Extract	-
Gelidiella Acerosa Extract	89
Gelidium Amansii Extract	-
Gelidium Cartilagineum Extract	22
Gelidium Sesquipedale Extract	-
Gigartina Skottsbergii Extract	-
Gigartina Stellata Extract	9
Gigartina Stellata/Kappaphycus Alvarezii Extract	-
Gloiopeltis Furcata Extract	-
Gloiopeltis Tenax Extract	-
Gloiopeltis Tenax Powder	-
Gracilaria Vermiculophylla Extract	-
Gracilaria Verrucosa Extract	-
Gracilariopsis Chorda Extract	-
Grateloupia Elliptica Extract	-
Grateloupia Livida Powder	-
Grateloupia Sparsa Extract	-
Hydrolyzed Asparagopsis Armata Extract	-
Hydrolyzed Corallina Officinalis	-
Hydrolyzed Corallina Officinalis Extract	5
Hydrolyzed Gracilariopsis Chiangii Extract	-
Hydrolyzed Porphyra Yezoensis	-
Hydrolyzed Rhodophyceae Extract	25
Hypnea Musciformis Extract	122
Kappaphycus Alvarezii Extract	5
Lithothamnion Calcareum Extract	12
Lithothamnion Calcareum Powder	11
Lithothamnion Corallioides Powder	-
Mesophyllum Lichenoides Extract	-
Palmaria Palmata Extract	72
Palmaria Palmata Powder	-
Phymatolithon Calcareum Extract	-
Pikea Robusta Extract	-
Polysiphonia Brodiei Extract	-
Polysiphonia Elongata Extract	-
Polysiphonia Lanosa Extract	-
Porphyra Columbina Extract	-
Porphyra Linearis Powder	-
Porphyra Tenera Extract	-
Porphyra Umbilicalis Extract	36
Porphyra Umbilicalis Powder	-
Porphyra Yezoensis Extract	9
Porphyra Yezoensis Powder	-
Rhodymenia Palmata Extract (synonym for Palmaria Palmata Extract?)	-
Rissoella Verruculosa Extract	-
Sarcodiotheca Gaudichaudii Extract	-
Sodium Porphyra Yezoensis Extract	-

Rosa Damascena Flower Oil

FOU = 298

Definition: Rosa Damascena Flower Oil is the volatile oil obtained from the flowers of *Rosa damascena*.



Reported Functions: Fragrance Ingredients; Skin-Conditioning Agents - Miscellaneous

Notes: ROSA DAMASCENA (DAMASK ROSE) FLOWER OIL according to the VCRP.

Grouping proposal: Rosa damascene-Derived Ingredients (10 ingredients, 806 combined FOU)

Rosa Damascena Flower Oil (FOU priority ingredient)	298
Hydrolyzed Rosa Damascena Flower Extract	-
Rosa Damascena Bud Extract	-
Rosa Damascena Extract	48
Rosa Damascena Flower	3
Rosa Damascena Flower Extract	148
Rosa Damascena Flower Powder	-
Rosa Damascena Flower Water	289
Rosa Damascena Flower Water Extract	-
Rosa Damascena Flower Wax	20

Salvia Officinalis (Sage) Leaf Extract

FOU = 292

Definition: Salvia Officinalis (Sage) Leaf Extract is the extract of the leaves of *Salvia officinalis*.



Reported Functions: Oral Care Agents; Skin-Conditioning Agents - Miscellaneous

Notes:

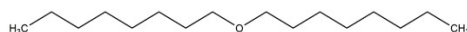
Grouping proposal: Salvia officinalis-Derived Ingredients (8 ingredients, 309 combined FOU)

Salvia Officinalis (Sage) Leaf Extract (FOU priority ingredient)	292
Salvia Officinalis (Sage) Extract	-
Salvia Officinalis (Sage) Flower/Leaf/Stem Extract	-
Salvia Officinalis (Sage) Flower/Leaf/Stem Juice	-
Salvia Officinalis (Sage) Flower/Leaf/Stem Water	-
Salvia Officinalis (Sage) Leaf	8
Salvia Officinalis (Sage) Leaf Water	9
Salvia Officinalis (Sage) Root Extract	-

Dicaprylyl Ether

FOU = 288

Definition: Dicaprylyl Ether is the ether that conforms to the structure:



Reported Functions: Skin-Conditioning Agents - Emollient

Notes: These ingredients are all simple alkyl ethers.

Grouping proposal: Fatty Ethers (8 ingredients, 304 combined FOU)

Dicaprylyl Ether (FOU priority ingredient)

288

Dicetyl Ether

-

Didecyl Ether

-

Diisononyl Ether

-

Dilauryl Ether

-

Dimyristyl Ether

-

Distearyl Ether

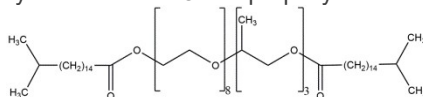
16

Cetyl Dimethylbutyl Ether

PEG/PPG-8/3 Diisostearate

FOU = 277

Definition: PEG/PPG-8/3 Diisostearate is the polyethylene glycol ether of the propoxylated diester of isostearic acid containing an average ethoxylation value of 8 and propoxylation value of 3.



Reported Functions: Surfactants - Emulsifying Agents

Notes: Glycereth-7 Diisononanoate ("Glycereth" means a glyceryl PEG ether) previously assessed ([Published Report](#)). These ingredients are linear alkoxyl chains, capped at both ends with stearyl esters.

Grouping proposal: Fatty Ester End-Capped Alkoxylates (13 ingredients, 282 combined FOU)

PEG/PPG-8/3 Diisostearate (FOU priority ingredient)

277

PEG-15 Butylene Glycol Diisostearate

-

PEG-10 Glyceryl Diisostearate

-

PEG-20 Glyceryl Diisostearate

-

PEG-30 Glyceryl Diisostearate

-

PEG-60 Glyceryl Diisostearate

-

PEG-12 Glyceryl Dimyristate

-

PEG-12 Glyceryl Dioleate

-

[PEG-3 Glyceryl Distearate] (VCRP listing only)

1

PEG-4 Glyceryl Distearate

-

PEG-12 Glyceryl Distearate

4

PEG-23 Glyceryl Distearate

-

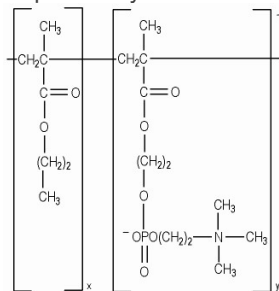
PEG-4 Polyglyceryl-2 Distearate

-

Polyquaternium-51

FOU = 274

Definition: Polyquaternium-51 is the polymeric quaternary ammonium salt that conforms generally to the formula:



Reported Functions: Film Formers; Skin-Conditioning Agents - Humectant

Notes: All of these ingredients share a acryloyloxyethyl phosphorylcholine monomer in common

Grouping proposal: Acryloyloxyethyl Phosphorylcholine Polymers (8 ingredients, 303 combined FOU)

Polyquaternium-51 (FOU priority ingredient) 274

Polyquaternium-61 9

Polyphosphorylcholine Glycol Acrylate 20

Acrylic Acid/Phosphorylcholine Glycol Acrylate Crosspolymer -

C4-18 Alkyl Methacrylate/Methacryloyloxyethyl Phosphorylcholine Copolymer -

Hydroxyethylcellulose/Phosphorylcholine Glycol Acrylate Copolymer -

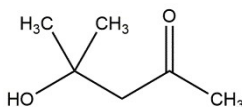
Phosphorylcholine Glycol Methacrylate/PEG-10 Dimethacrylate Crosspolymer -

Polyquaternium-10/Phosphorylcholine Glycol Acrylate Copolymer -

Diacetone Alcohol

FOU = 268

Diacetone Alcohol is the ketone that conforms to the formula:



Reported Functions: Fragrance Ingredients; Solvents

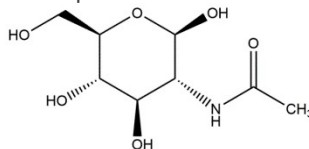
Notes:

Grouping proposal: None

Acetyl Glucosamine

FOU = 265

Definition: Acetyl Glucosamine is the organic compound that conforms to the formula:



Reported Functions: Skin-Conditioning Agents – Miscellaneous

Notes:

Grouping proposal: Glucosamine and Acetyl Glucosamine (3 ingredients, 403 combined FOU)

Acetyl Glucosamine (FOU priority ingredient) 265

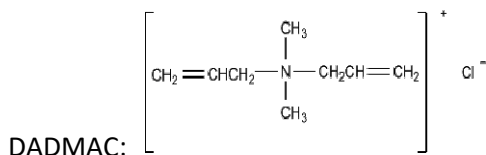
Glucosamine 7

Glucosamine HCl 131

Polyquaternium-6

FOU = 265

Definition: Polyquaternium-6 is a polymeric quaternary ammonium salt of Diallyldimethyl Ammonium Chloride (DADMAC)



Reported Functions: Antistatic Agents; Film Formers; Hair Fixatives

Notes: homopolymer

Grouping proposal: None

Olea Europaea (Olive) Leaf Extract

FOU = 257

Definition: Olea Europaea (Olive) Leaf Extract is the extract of the leaves of *Olea europaea*.



Reported Functions: Skin-Conditioning Agents – Miscellaneous

Notes: Olea Europaea (Olive) Fruit Oil has been previously assessed by CIR ([Published Report](#))

Grouping proposal: Olea europaea-Derived Ingredients (20 ingredients, 502 combined FOU)

Olea Europaea (Olive) Leaf Extract (FOU priority ingredient)	257
Olea Europaea (Olive) Bark Extract	-
Olea Europaea (Olive) Branch Extract	-
Olea Europaea (Olive) Bud Extract	-
Olea Europaea (Olive) Flower Extract	186
Olea Europaea (Olive) Flower Water	-
Olea Europaea (Olive) Fruit	6
Olea Europaea (Olive) Fruit Extract	-
Olea Europaea (Olive) Fruit Juice	-
Olea Europaea (Olive) Fruit Oil Ethyl Ester	-
Olea Europaea (Olive) Fruit Unsaponifiables	36
Olea Europaea (Olive) Fruit Water	-
Olea Europaea (Olive) Husk Powder	-
Olea Europaea (Olive) Leaf	-
Olea Europaea (Olive) Leaf Powder	3
Olea Europaea (Olive) Leaf Water	-
Olea Europaea (Olive) Sap Extract	-
Olea Europaea (Olive) Seed	-
Olea Europaea (Olive) Seed Powder	14
Olea Europaea (Olive) Wood Extract	-