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### **Memorandum**

Date: June 12<sup>th</sup>, 2019

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

To: All stakeholders

Re: Final 2020 Priority List

The CIR Procedures require preparation of the Draft 2020 Priority List for public comment by June 1, 2019. The Draft 2020 Priority List was issued for public comment earlier (March 2019) in the process to allow more time for the acquisition of data. Comments at the April 2019 Expert Panel meeting were considered and incorporated, where appropriate, into a Draft Final 2020 Priority List. Comments at the June 2019 Expert Panel meeting, on that Draft Final version, were considered and incorporated here, in this Final 2020 Priority List. 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 13, 2019; and on CIR staff and Panel workflow. The Final Priorities for 2020 are essentially the same as those finalized for 2019; however, this list has been updated with 2019 frequency of use data, a report in progress (Caprylhydroxamic Acid) has been removed from the list, an ingredient (Benzisothiazolinone) was removed for zero FOU, and an ingredient (Calcium Sulfate) was removed for significantly declining FOU (between years 2018 and 2019). Additionally, three items were suggested for incorporation in this list. However, each was deferred to future prioritization, in order to gather more information.

While this Final Priority list includes only the lead ingredients, groupings are provided for each on the following pages of this document. There are 23 reports covering 185 ingredients on the Final 2020 Priorities List. Reports previously prioritized and on the CIR docket at the end of 2019, as well as a number of re-reviews of previous assessments, will supplement the total number of ingredients to be assessed in 2020.

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, additional data needed include: species, plant part, extraction method, solvent, and data on component chemical characterization. It is important that these data are specific to the cosmetic ingredient(s).

### **Final 2020 Priorities List**

<b><i>Ingredients</i></b>	<b><i>Frequency of Use (FOU)</i></b>
<b><i>For cause</i></b>	
BASIC BROWN 17 – a hair dye	51
<b><i>Per FOU</i></b>	
HONEY	1002
SACCHARUM OFFICINARIUM (SUGARCANE) EXTRACT	447
EQUISETUM ARVENSE EXTRACT	338
SACCHARIDE ISOMERATE	455
PORTULACA OLERACEA (PURSLANE) EXTRACT	481
UBIQUINONE	374
DIATOMACEOUS EARTH	213
SODIUM LEVULINATE	390
GLUCONOLACTONE	369
ACETYL HEXAPEPTIDE-8	379
HONEY EXTRACT	359
CHONDRUS CRISPUS EXTRACT	350
ROSA DAMASCENA FLOWER OIL	328
SALVIA OFFICINALIS (SAGE) LEAF EXTRACT	325
ROSA DAMASCENA FLOWER WATER	331
DICAPRYLYL ETHER	344
PEG/PPG-8/3 DIISOSTEARATE	290
POLYQUATERNIUM-51	310
DIACETONE ALCOHOL	223
ACETYL GLUCOSAMINE	276
POLYQUATERNIUM-6	280
OLEA EUROPAEA (OLIVE) LEAF EXTRACT	279

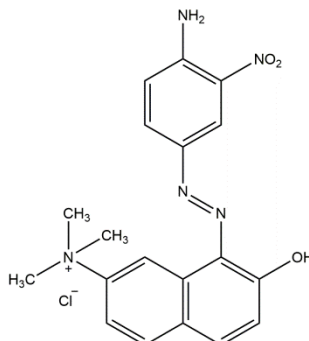
## Draft 2020 Priorities Groupings for New Reports

### Proposed 2020 Report – per cause

#### **Basic Brown 17** – per PCPC HCTC

FOU = 51

**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 2020 Reports – per FOU (all 2019 data)

#### **Honey**

FOU = 1002

**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; 1373 combined FOU)

<b>Honey (FOU priority ingredient)</b>	<b>1002</b>
<b>Honey Extract</b>	<b>359</b>
<b>Hydrogenated Honey</b> (mix of saccharides)	<b>6</b>
<b>Hydrolyzed Honey</b> (mix of saccharides)	-
<b>Honey Cocoates</b>	-
<b>Honey Powder</b>	<b>6</b>
<b>Hydrolyzed Honey Protein</b>	-

## Saccharum Officinarum (Sugarcane) Extract

FOU = 447

**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; 447 combined FOU)

<b>Saccharum Officinarum (Sugarcane) Extract (FOU priority ingredient)</b>	<b>447</b>
<b>Saccharum Officinarum (Sugarcane) Wax</b>	-

## Equisetum Arvense Extract

FOU = 338

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



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

**Notes:**

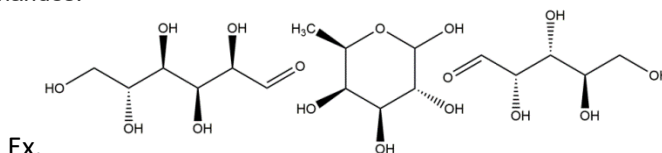
**Grouping proposal:** Horsetail Ingredients (6 ingredients, 368 combined FOU)

<b>Equisetum Arvense Extract (FOU priority ingredient)</b>	<b>338</b>
<b>Equisetum Arvense Juice</b>	-
<b>Equisetum Arvense Leaf Extract</b>	<b>8</b>
<b>Equisetum Arvense Leaf Powder</b>	-
<b>Equisetum Arvense Powder</b>	<b>1</b>
Horsetail ( <i>Equisetum Arvense</i> ) – not in INCI; VCRP only	<b>21</b>

## Saccharide Isomerate

FOU = 455

**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).

**Grouping proposal:** Saccharide Humectants (7 ingredients, 636 combined FOU)

Saccharide Isomerate (FOU priority ingredient)	455
Saccharide Hydrolysate (mix of saccharides)	30
Anhydrogalactose	-
Anhydroglucitol	-
Anhydroxylitol	151
Arabinose	-
Psicose	-

## Portulaca Oleracea Extract

FOU = 481

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



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

**Notes:** Common name, Purslane

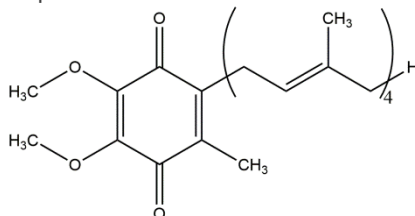
**Grouping proposal:** Portulaca oleracea-Derived Ingredients (4 ingredients, 481 combined FOU)

Portulaca Oleracea Extract (FOU priority ingredient)	481
Portulaca Oleracea Flower/Leaf/Stem Extract	-
Portulaca Oleracea Juice	-
Portulaca Oleracea Water	-

## Ubiquinone

FOU = 374

**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, 381 combined FOU)

**Ubiquinone (FOU priority ingredient)** 374

**Disodium Ubiquinone (salt for of Ubiquinone)** -

**Hydroxydecyl Ubiquinone (93% structural similarity to Ubiquinone)** 7

## Diatomaceous Earth

FOU = 213

**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

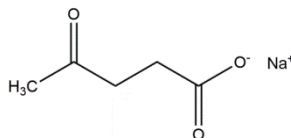
**Notes:**

**Grouping proposal:** None

## Sodium Levulinate

FOU = 390

**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, 516 combined FOU)

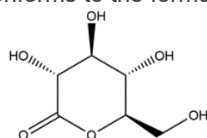
**Sodium Levulinate (FOU priority ingredient)** 390

**Levulinic Acid** 126

## Gluconolactone

FOU = 369

**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.

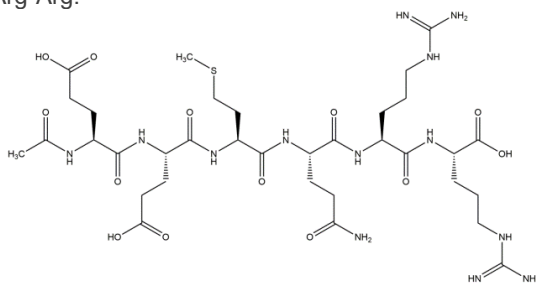
**Grouping proposal:** Glycolactones (5 ingredients, 369 combined FOU)

<b>Gluconolactone (FOU priority ingredient)</b>	<b>369</b>
Galactonolactone	-
Glucarolactone	-
Glucoheptonolactone	-
Ribonolactone	-

## Acetyl Hexapeptide-8

FOU = 379

**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, 379 combined FOU)

<b>Acetyl Hexapeptide-8 (FOU priority ingredient)</b>	<b>379</b>
Acetyl Hexapeptide-8 Amide	-

## Chondrus Crispus Extract

FOU = 350

**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)

**Grouping proposal:** Red Alga (73 ingredients, combined 865 FOU)

<b>Chondrus Crispus Extract (FOU priority ingredient)</b>	<b>350</b>
<b>Chondrus Crispus (aka "irish moss" in VCRP)</b>	<b>6</b>
<b>Chondrus Crispus Powder</b>	<b>42</b>
<b>Hydrolyzed Chondrus Crispus Extract</b>	<b>2</b>
<b>Ahnfeltiopsis Concinna Extract (aka AHNFELTIA CONCINNA EXTRACT)</b>	<b>15</b>
<b>Asparagopsis Armata Extract</b>	<b>40</b>
<b>Betaphycus Gelatinum Extract</b>	-
<b>Botryocladia Occidentalis Extract</b>	-
<b>Calliblepharis Ciliata Extract</b>	-
<b>Calliblepharis Jubata Extract</b>	-
<b>Ceramium Kondoii Extract</b>	-
<b>Ceramium Rubrum Extract</b>	-
<b>Chondracanthus Teedei Powder</b>	-
<b>Chondracanthus Tenellus Extract</b>	-
<b>Chondracanthus Tenellus/Saccharina Angustata/Ulva Linza Extract</b>	-
<b>Chondrus Elatus Extract</b>	-
<b>Chondrus Elatus/Saccharina Angustata/Monostroma Nitidum Thallus Extract</b>	-
<b>Corallina Officinalis Extract</b>	<b>79</b>
<b>Corallina Officinalis Powder</b>	-
<b>Digenea Simplex Extract</b>	<b>1</b>
<b>Dilsea Carnosa Extract</b>	-
<b>Eucheuma Serra Extract</b>	-
<b>Eucheuma Serra/Grateloupia Sparsa/Saccharina Angustata/Ulva Linza/Undaria Pinnatifida Extract</b>	-
<b>Eucheuma Serra/Saccharina Angustata/Ulva Linza Extract</b>	-
<b>Furcellaria Lumbricalis Extract</b>	-
<b>Galaxaura Rugosa Extract</b>	-



Galaxaura Rugosa/Sargassum Pacificum/Turbinaria Ornata Extract	-
Gelidiella Acerosa Extract	17
Gelidium Amansii Extract	-
Gelidium Cartilagineum Extract	27
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	-
Hypnea Musciformis Extract	133
Kappaphycus Alvarezii Extract	9
Lithothamnion Calcareum Extract	-
Lithothamnion Calcareum Powder	-
Lithothamnion Corallioides Powder	-
Mesophyllum Lichenoides Extract	-
Palmaria Palmata Extract	78
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	42
Porphyra Umbilicalis Powder	-
Porphyra Yezoensis Extract	10
Porphyra Yezoensis Powder	-
Rhodomenia Palmata Extract (synonym for Palmaria Palmata Extract?)	-
Rissoella Verruculosa Extract	-
Sarcodiotheca Gaudichaudii Extract	-
Sodium Porphyra Yezoensis Extract	-

## Rosa Damascena Flower Oil

FOU = 328

**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, 888 combined FOU)

Rosa Damascena Flower Oil (FOU priority ingredient)	328
Hydrolyzed Rosa Damascena Flower Extract	-
Rosa Damascena Bud Extract	-
Rosa Damascena Extract	49
Rosa Damascena Flower	4
Rosa Damascena Flower Extract	153
Rosa Damascena Flower Powder	1
Rosa Damascena Flower Water	331
Rosa Damascena Flower Water Extract	-
Rosa Damascena Flower Wax	22

## Salvia Officinalis (Sage) Leaf Extract

FOU = 325

**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:**

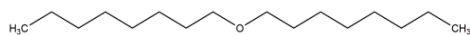
**Grouping proposal:** Salvia officinalis-Derived Ingredients (8 ingredients, 423 combined FOU)

Salvia Officinalis (Sage) Leaf Extract (FOU priority ingredient)	325
Salvia Officinalis (Sage) Extract	83
Salvia Officinalis (Sage) Flower/Leaf/Stem Extract	-
Salvia Officinalis (Sage) Flower/Leaf/Stem Juice	-
Salvia Officinalis (Sage) Flower/Leaf/Stem Water	1
Salvia Officinalis (Sage) Leaf	8
Salvia Officinalis (Sage) Leaf Water	6
Salvia Officinalis (Sage) Root Extract	-

## Dicaprylyl Ether

FOU = 344

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.

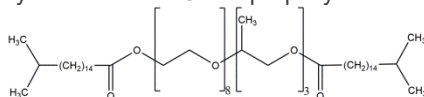
**Grouping proposal:** Fatty Ethers (8 ingredients, 360 combined FOU)

Dicaprylyl Ether (FOU priority ingredient)	344
Dicetyl Ether	-
Didecyl Ether	-
Diisononyl Ether	-
Dilauryl Ether	-
Dimyristyl Ether	-
Distearyl Ether	16
Cetyl Dimethylbutyl Ether	-

## PEG/PPG-8/3 Diisostearate

FOU = 290

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. These ingredients are linear alkoxy chains, capped at both ends with stearyl esters.

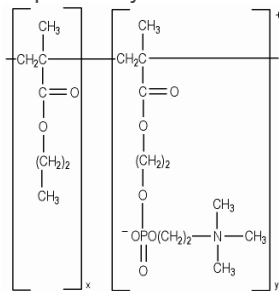
**Grouping proposal:** Fatty Ester End-Capped Alkoxylates (13 ingredients, 313 combined FOU)

PEG/PPG-8/3 Diisostearate (FOU priority ingredient)	290
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	18
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 = 310

**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

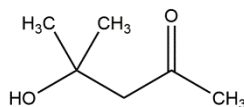
**Grouping proposal:** Acryloyloxyethyl Phosphorylcholine Polymers (8 ingredients, 341 combined FOU)

Polyquaternium-51 (FOU priority ingredient)	310
Polyquaternium-61	9
Polyphosphorylcholine Glycol Acrylate	22
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 = 223

Diacetone Alcohol is the ketone that conforms to the formula:



**Reported Functions:** Fragrance Ingredients; Solvents

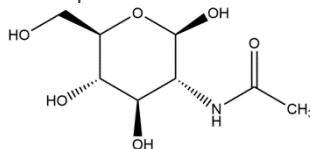
**Notes:** N/A

**Grouping proposal:** None

## Acetyl Glucosamine

FOU = 276

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



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

**Notes:** N/A

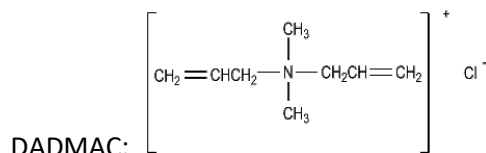
**Grouping proposal:** Glucosamine and Acetyl Glucosamine (3 ingredients, 416 combined FOU)

Acetyl Glucosamine (FOU priority ingredient)	276
Glucosamine	9
Glucosamine HCl	131

## Polyquaternium-6

FOU = 280

**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 = 279

**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

**Grouping proposal:** *Olea europaea*-Derived Ingredients (20 ingredients, 743 combined FOU)

<b>Olea Europaea (Olive) Leaf Extract (FOU priority ingredient)</b>	<b>279</b>
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	19
Olea Europaea (Olive) Fruit Extract	202
Olea Europaea (Olive) Fruit Juice	-
Olea Europaea (Olive) Fruit Oil Ethyl Ester	-
Olea Europaea (Olive) Fruit Unsaponifiables	40
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	-