INCI Nomenclature

The goal of the INCI Nomenclature Program is to develop unique, informative, standardized and globally accepted names (called INCI Names) for the label declaration of ingredients used in cosmetic and personal care products. INCI Names are published in the *International Cosmetic Ingredient Dictionary and Handbook* which is the authoritative worldwide reference of ingredient information for industry, government, consumers, academia and the medical community. The International Nomenclature Committee (INC) is charged with the responsibility of creating the INCI nomenclature system, and assuring the integrity of the data incorporated into the *Dictionary.* The guiding princples below outline the approach followed by the INC in developing INCI Names. These conventions have evolved since the onset of ingredient labeling in the late 1970s, and continue to be revised as new ingredient innovation and technologies emerge. Central to the development of an INCI name is ingredient composition. Safety and suitability of the intended use of an ingredient is not reviewed as part of the INCI process.

INCI NOMENCLATURE CONVENTIONS

The conventions used to determine INCI names for cosmetic ingredients are listed below and are divided into three areas: **General Conventions, Specific Conventions** (which are grouped primarily by chemical class), and **Miscellaneous Conventions**. These conventions are continually reviewed and modified when necessary to reflect changes in the industry, technology, and new ingredient developments. Every effort is made to ensure ingredients are named consistent with these principles. As new conventions are developed that give rise to INCI names that are different from those previously published, the older nomenclature is sometimes retained and considered to be “grandfathered”. Grandfathered names are generally published for reference only.

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GENERAL CONVENTIONS

1. Nomenclature assignments are based on the chemical composition of the intended product, and simple chemical names are used when possible. The assigned names are generally based on an ingredient's final composition and purity irrespective of the type of manufacturing process (e.g., chemical synthesis, biotechnology, etc.). An ingredient is considered a single constituent or well-defined substance in accordance with the criteria outlined in the Technical Guidance Document for identification and naming of substances under REACH:

   "A mono-constituent substance is a substance, defined by its quantitative composition, in which one main constituent is present to at least 80% (w/w). A mono-constituent substance is named after the main constituent (4.2.1)."

   a. Exceptions include organic and silicone polymers, botanical extracts, fermentation products and minerals, which are typically named by their starting materials and can include the process by which they are manufactured. For example, a botanical extract contains many compounds and is named as "Plant Extract" where "plant" is the starting material and "extract" is the process. For additional information, see the Conventions for Botanicals, Minerals, Polymers, and Silanes and Siloxanes.

2. Recognized chemical abbreviations are used where applicable. A list of the abbreviations used in the Dictionary may be found in the List of Acronyms.

3. Traditional stem names are retained as combining terms when consistent with other conventions. Commonly recognized trivial names will be utilized where appropriate, e.g., acylated derivatives of amino acids, Lauroyl Lysine, or acylated derivatives of hormones, N-Caffeoyl Serotonin. See also Rules 27a and 57.

4. Name/number combinations are used as INCI names for cosmetic ingredients only where the complexity and/or similarity of ingredients precludes assignment of reasonable nomenclature. The stem names are suggestive of the structure or the composition of the material, e.g., rh-Oligopeptide-6, Quaternium-27, Polyurethane-5, Polysilicone-1. Where descriptive terminology is desired for a particular component of a raw material that would fall under these classifications, alternate nomenclature may be provided. Established name/number or name/acronym combinations are also utilized, e.g., Red 4, CI 10020, HC Blue No. 10, Ceramide EOP.

5. Specific names previously established by the U.S. Pharmacopoeia (USP), National Formulary (NF), the Food Chemicals Codex (FCC), Merck Index, International Non-Proprietary Names for Pharmaceutical Substances (INN), World Health Organization (WHO), the Research Institute for Fragrance Materials (RIFM), and United States Adopted Names (USAN) are retained in many cases. Furthermore, established abbreviations and criteria are utilized for simplifying the nomenclature of families of complex ingredients where applicable. For example, the root word "alkonium" from the USAN convention to denote N,N-dimethyl N-alkyl benzyl in Benzalkonium Chloride is utilized to name other similar cosmetic ingredients such as Cocoalkonium Chloride. Compounds that are similar to materials described in recognized sources are given analogous names when possible.

Examples include the Research Institute for Fragrance Materials (RIFM) names for the fragrance compounds, Linalool, Longifolene.

6. USAN abbreviations and criteria are utilized for simplifying the nomenclature of families of complex ingredients where applicable, e.g., Poloxamer, Nonoxynol, Octoxynol, Meroxapol.

7. Compounds that are similar to materials described in recognized sources are given analogous names when possible, e.g., Cocoalkonium Chloride.

8. Names of ingredients that contain terminal numbers are generally hyphenated, (see Convention 4), and names for derivatives of hyphenated materials retain the original hyphenated term, e.g., Quaternium-18 Hectorite.

9. Hydration states are not usually expressed, with the exception of Hydrated Silica. For information on process terms, see Convention 73.

10. Compounded mixtures created by blending materials are named by listing each component in descending order of predominance. See the section on Labeling Reminders for further information. On a case-by-case basis, materials containing a significant amount of unintended product may be named as a mixture, e.g., excess glycerin in products obtained by the transesterification.

11. Water, ethyl alcohol and other common diluents or solvents contained in commercially available raw materials, except extracts and products derived by fermentation, have not historically been identified as part of the INCI Name. In recent years, the INC has included the identification of non-aqueous solvents in an effort to provide further transparency. See the Labeling Reminders section for additional information on the labeling of solvents and/or diluents that may be present in raw materials.
    a. The INCI name for water, regardless of source is Water. The only exception is the INCI name Sea Water because it is sufficiently different in composition from fresh water, and it also corresponds to an EU Trivial Name, Maris Aqua. (See the Trivial Names section). Botanical waters are named in accordance with the Botanical Conventions.
    b. Purity standards or processes associated with water are not identified in the INCI name, e.g., purified water, deionized water, sterilized water.

12. For products marketed in the United States, the phrase “and other ingredients” may only be used in the label declaration when confidentiality has been granted by the U. S. Food and Drug Administration in accordance with procedures established in 21 CFR 701.3 and 720.8(a). Currently, there are no similar exclusions in the European Union Regulation (EC) No 1223/2009. For products marketed in Japan, the phrase “and other ingredients” may only be used in the label declaration when confidentiality has been granted by MHLW in accordance with procedures established in MHLW Notice No.990 (Sept/29/2000).

13. In order to facilitate clarity and ease of use when labeling, INCI names have been designed to require a minimum of punctuation and capitalization. Slashes are used to designate compounds (not blends) that are produced as a mixture or are composed of more than one entity, e.g., Dipentaerythrityl Dicaprylate/Caprate, Glyceryl Cocoate/Citrate/Lactate,

Styrene/MA Copolymer, Silicon/Cerium/Titanium/Zinc Oxides. Additionally, slashes are used to identify botanical materials that are hybrids. The terms are described in alphabetical order, separated by a slash. For additional information, see Convention 21 on the identification of alkyl groupings, and Convention 44(b) on the listing of monomers.

14. Wherever new nomenclature has been adopted, every effort has been made to use the shortest name consistent with these rules. Shorthand abbreviations will be considered for names with exceedingly long character length.

15. The International Cosmetic Ingredient Nomenclature Committee, in conjunction with the Personal Care Products Council, reserves the right to provide specific nomenclature in certain cases to make the nomenclature more informative to the consumer. In particular, terminology for ingredients related to drug active substances may be retained, (e.g., see Convention 50, Prostaglandin Derivatives).

SPECIFIC CONVENTIONS

Alkanolamides

16. Alkanolamides are named by the specific alkyl amide stem and the appropriate abbreviation, e.g., "*Acetamide MEA*," "*Lauramide DEA*," "*Cocamide DIPA*."

Alkoxylated Materials

17. Alkoxylated materials are named by including the alkoxylation level as the average number of moles of ethylene oxide and/or propylene oxide, and/or ethyleneimine. Ethoxylates, propoxylates, and ethyleneimine are commonly expressed by the degree of polymerization. Mixed alkoxylated ethers (i.e., contain both EO and PO) are named based on the order of addition. For example, PPG-y Glycereth-x means glycerin is first treated with x moles EO then y moles PO. PEG/PPG-x/y means that a material is treated simultaneously with EO and PO, e.g., PEG/PPG-52/32 Dimethyl Ether. PPG-x-PEG-y indicates that the material is first ethoxylated, and then propoxylated.

18. a. Ethoxylated alcohols are named by adding the suffix "eth" to the conventional stem name followed by the average number of moles of ethylene oxide, e.g., Steareth-10. Historically, where the moles of ethoxylation is 1,2, or 3, the numerical designation is sometimes omitted, e.g., Sodium Laureth Sulfate, and the definition specifies the average number of moles as 1 to 3.

b. The term Alkoxynol-n refers to an ethoxylated alkyl phenol where n is the average ethoxylation value e.g., Nonoxynol-10. The following table references the alkoxynol stem to its alkyl group:

Alkoxynol	**Alkyl Group**
Octoxynol	Tetramethylbutyl
Nonoxynol	Nonyl
Dodoxynol	Dodecyl or Tributyl
Pentadoxynol	Pentadecyl

19.

a. The polyethylene glycol fraction of all ethoxylated compounds not named as above is abbreviated as the acronym "PEG" followed by the number of moles of ethylene oxide irrespective of the location of ethoxylation. When the ethoxylating agent is 2-chloroethanol, names are generally designated by the term "hydroxyethyl." See Convention 38.

    i. In the case of amines, where the ethoxylation does not lead to the formation of polyoxyethylene chains comprised of three or more repeating units, the "eth" suffix may be used in combination with the alkylamine term, e.g., alkylamineth-x where x denotes the moles of ethoxylation.

b. Polypropylene glycol is abbreviated as the acronym "PPG." This combining form is followed by the average number of moles of propylene oxide, e.g., PPG-24 Butyl Ether. When the propoxylating agent is 2-chloropropanol, names are generally designated by the term "hydroxypropyl." See Convention 38.

c. Polyethylene imine is abbreviated as the acronym "PEI". This combining form is followed by the average number of moles of ethylene imine (aziridine), e.g., Hydroxyethyl PEI-10.

d. Homopolymers of ethylene glycol and propylene glycol are named as PEG-X and PPG-Y, respectively, with X or Y equal to the average total number of moles of alkoxylate in the material. Homopolymers of aziridine are named as PEI-X, with X equal to the average total number of moles of ethylene imine in the material.

e. Alkoxylated esters are named as PEG and PPG derivatives, e.g., PPG-10 Stearate, PEG-40 Stearate. Mixed alkoxylation esters are named in the order of addition of the alkoxylating agent. An example of the random simultaneous addition of the alkoxylating agent is e.g.,PEG/PPG-8/3 Diisostearate, PEG/PPG-10/2 Ricinoleate. An example of the ordered sequential addition of the alkoxylating agent is PEG-4 PPG-13 C13-15 Alcohol.

f. PEG and PPG polymers or their derivatives in which one of the terminal primary alcoholic groups (CH2OH) has been oxidized to the carboxy group (-COOH), are named by adding the terms "carboxylic acid" or "carboxylate" to the parent name of the original polymer, e.g., Steareth-10 oxidized to carboxylic acid would be named Steareth-10 Carboxylic Acid.

g. Poloxamers, Meroxapols, Poloxamines and Minoxapols are named in accordance with convention 6 above. The term "Poloxamer" denotes a block copolymer consisting of polypropylene glycol terminated with polyethylene glycol. The term "Meroxapol" denotes a block copolymer consisting of polyethylene glycol terminated with polypropylene glycol. The term "Poloxamine" denotes a block copolymer of ethylene diamine reacted first with polypropylene glycol and then polyethylene glycol, e,g, $[(PEG)_X\text{-}(PPG)_Y]_2\text{-}NCH_2CH_2N\text{-}[(PPG)_Y\text{-}(PEG)_X]_2$. "Minoxapol" is the reverse of "Poloxamine", e.g., $[(PPG)_X\text{-}(PEG)_Y]_2\text{-}NCH_2CH_2N\text{-}[(PEG)_Y\text{-}(PPG)_X]_2$. The numerical suffix designation is obtained by the following rule: The first two digits multiplied by 100 correspond to the approximate average molecular mass of the poly(oxypropylene)

portion; the third digit multiplied by 10 corresponds to the percentage by weight of the poly(oxyethylene) portion.

h. Block and random copolymers of polyethylene glycol and polypropylene glycol not named in 19g. are named as PEG-X/PPG-Y Copolymer (block), and PEG/PPG-X/Y (random) where X is the average ethoxylation value and Y is the average propoxylation value, e.g., PEG/PPG-240/60 Copolymer. The sequence (block or random) and the terminal groups are described in the monograph definition of each ingredient.

i. Terpolymers with a center anchor, in which there is further block or random alkoxylation of an alkoxylated polymer, are named, for example, as PEI-y PEG-x/PPG-y Copolymer. (e.g., PEI-14 PEG-10/PPG-7 Copolymer)

j. Ethoxylated glycerin is named as "Glycereth-x" where x denotes the average moles of ethylene oxide. Esters formed by the reaction of a fatty acid with an ethoxylated glycerin molecule are named by adding the suffix "ate" to the fatty acid grouping, e.g., Glycereth-5 Cocoate. When glycerin is derivatized prior to ethoxylation, (e.g., esterified with a fatty acid), the ethoylation is designated by PEG-x, e.g., PEG-7 Glyceryl Cocoate, PEG-3 Glyceryl Trioleate.

Alkyl Groupings

20. The nomenclature for ingredients which are inherent mixtures (e.g., unfractionated fatty acids, or fatty alcohols from natural oils) is determined on the basis of the chemical identity of the raw material as purchased, (i.e., source and purity). Inherent mixtures that reflect the original distribution of components (i.e., when there is no fractionation) are named according to the common name of the source, e.g., Coconut Acid, Coconut Alkane, Soy Acid, Tallow Alcohol. Derivatives of these materials are named in a similar manner, e.g., Ammonium Palm Kernel Sulfate, PEG-5 Avocadoate, Tallowaminopropylamine. If the original natural distribution has been significantly cut or enriched, the mixture is named on the basis of the predominant component, e.g., Sodium Myreth-3 Sulfate. The predominant component was historically defined as one that is clearly present at the highest concentration in relation to the other components. Current practice defines the predominant component as a single constituent present at 80% or more of the composition. See Convention 1.

21. Nomenclature for materials that result from feedstocks that are mixtures, and where a single component does not predominate, (e.g., mixtures of fatty acids), is designated by the names of the major alkyl groups that make up 80% of the composition separated by a slash, e.g., Caprylic/Capric Glycerides, Glyceryl Isostearate/Myristate, Pentaerythrityl Stearate/Caprate/Caprylate/Adipate., Coconut/Palm Kernel Alkanes, Coco/Sunfloweramidopropyl Betaine, Palm/Stear/Behenamidoethyl Diethonium Hydrolyzed Wheat Protein. When a mixture is constituted by a broad range of alkyl groups, "C" type nomenclature is used to designate a name, e.g., C14-30 Alkyl Beeswax, C10-16 Alkyl Glucoside. See Conventions 22 and 39.

    An exception to this convention is the historical usage of the terms "cetearyl" and "cetoleyl" to identify a feedstock mixture of cetyl/stearyl alcohol and cetyl/oleyl alcohol, respectively. Historically, the name Stearic Acid has been applied to materials commercially sold as stearic acid where the composition is predominantly C16. Also, the term "vegetable" has been

historically applied to a limited number of ingredient names, e.g., Vegetable Oil, Hydrogenated Vegetable Glycerides, Hydrolyzed Vegetable Protein, and their derivatives, and these names have been "grandfathered". Current conventions stipulate the identification of the specific oil source(s) in the name, see Convention 43a.

22. Materials containing mixtures of even-carbon, straight-chain length fractions in which there is a predominant component are named by the common name for the predominant fatty stem. Materials containing mixtures of even- and odd-carbon chain length fractions are designated by alternative nomenclature when there is not a predominant component. Historically, the latter names were identified as "pareth" , e.g., C12-15 Pareth-3. The current nomenclature approach utilizes "alketh" as a stem name, e.g., C12-15 Alketh-3. See Conventions 21 and 39.

23. Straight-chain alkyl groups are described by their common stem names. The following table describes the nomenclature applied to straight-chain acids and alcohols.

Saturated:

Chain Length	**Acid**	**Alcohol**
C6	Caproic	Hexyl
C7	Heptanoic	Heptyl
C8	Caprylic	Caprylyl
C9	Pelargonic	Nonyl
C10	Capric	Capryl
C11	Undecanoic	Undecyl
C12	Lauric	Lauryl
C13	Tridecanoic	Tridecyl
C14	Myristic	Myristyl
C15	Pentadecanoic	Pentadecyl
C16	Palmitic	Cetyl
C17	Margaric	Heptadecyl
C18	Stearic	Stearyl
C20	Arachidic	Arachidyl
C22	Behenic	Behenyl

Unsaturated:

Chain Length	**Acid**	**Alcohol**
C11	Undecylenic	Undecylenyl
C16	Palmitoleic	Palmitoleyl
C18	Oleic	Oleyl
C18	Linoleic	Linoleyl
C18	Linolenic	Linolenyl
C20	Arachidonic	Arachidonyl
C22	Erucic	Erucyl
C22	Cetoleic	Cetoleyl

24. Branched-chain alkyl groups are described in INCI names by the prefix "iso" followed by the common stem name for the comparable straight-chain group. In such cases, usage of the term "iso" implies the isomeric nature of the carbon chain, (i.e., the same number of carbons

in a nonlinear structure) rather than methyl substitution on the second carbon (i.e., in the *iso* position.)

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25. The following table has been included to clarify the nomenclature for derivatives of caproic, caprylic, and capric acids.

Chainlength	**Stem Name**	**Acid**	**Ester**
C6	Capro	Caproic	Caproate
C8	Capryl	Caprylic	Caprylate
C10	Capr	Capric	Caprate

Chainlength	**Acyl**	**Alkyl**	**Ampho**
C6	Caprooyl	Caproyl	Caproo
C8	Capryloyl	Caprylyl	Caprylo
C10	Caproyl	Capryl	Capro

Amphoteric Compounds

26. The term “ampho” has been used as a combining term in the nomenclature for amphoteric surfactants derived from imidazoline intermediates. In naming these compounds, “ampho” denotes N-hydroxyethyl ethylenediamine and is combined with the names for the substituent groupings, e.g., Sodium Cocoamphoacetate.

Biological Materials (Excluding Botanicals and Biotech Materials)

27. Biological materials are named by a specific component (e.g., Hyaluronic Acid, Phosphatidyl Choline, Sphingosine) when the material has been isolated, purified and chemically characterized. General nomenclature for biological materials (e.g., Glycosaminoglycans, Fish Serum Extract) is utilized to name materials in accordance with the extent of their purification.

    a. Trivial names for biological compounds are generally utilized in INCI names rather than systematic nomenclature, e.g., lysine, melatonin, lecithin. Trivial names are also used for derivatives where possible, e.g., N-Feruloyl Serotonin, N-Nicotinoyl Dopamine, Palmitoyl Arginine. See also Convention 3.

    b. Ingredients derived from human tissue contain “human” as part of the INCI name, e.g., Human Umbilical Extract. See also Convention 61g.

    c. Materials derived from animal sources are named, in most cases, by the common name of the animal, rather than the genus/species of the animal, e.g., Donkey Milk. Genus/species information may be included in the definition. For mammalian derived cells, the name of the organ is typically used unless a specific cell type has been isolated, e.g., Liver Cell Extract, Leukocyte Extract, Human Keratinocytes,

    d. INCI names for fungi are identified by genus and species, e.g., Mucor Circinelloides Oil, Ganoderma Lucidum (Mushroom) Extract. Historically, the term “mushroom” is also included in the relevant INCI names since it is a term recognized by the consumer. Yeast has historical usage as an INCI name and is a grandfathered term. However, products derived by yeast fermentation are named by the genus term “Saccharomyces” (see

Convention 28b.)

e. Yeast has historical usage as an INCI name and is a grandfathered term. It is retained in publication for its correlation to the EU Trivial Name, Faex. Products derived by yeast fermentation are named by the genus term "Saccharomyces" (see Convention 28b.)

f. Extracts of algae have historically been named as Algae Extract, in addition to being named by genus terms, e.g., Ascophyllum, Laminaria, etc. These names are grandfathered; the current naming practice is to include both the genus and species terms in the name. The INCI name "Plankton" is also a grandfathered term, and the current practice is to also identify these materials by genus/species.

g. Coral, jellyfish, and sea anemone are invertebrates of the phylum, *Cnidaria*, and are named by their common name in accordance with Convention 28(c). Additional information about the classification of these species is included in the monograph definition when available.

h. Proteins are named by the common name, e.g., Collagen, Elastin, Keratin, Albumen, etc. Historically, protein materials that have undergone complete hydrolysis were named as amino acids by source, e.g., Keratin Amino Acids, Silk Amino Acids. These names have been grandfathered and the current naming practice does not distinguish by the extent of hydrolysis, e.g., Hydrolyzed Collagen, Hydrolyzed Milk Protein, Hydrolyzed Soy Protein.

i. Gelatin is one of the original names published in the Dictionary and is considered to be a "grandfathered" term. Usage of Gelatin as an ingredient name has been replaced by Hydrolyzed Collagen.

j. Milk is the liquid produced by the mammary glands of animals and is named according to the common name of the animal followed by the term, "Milk". (See Convention 29q.)

Biotech Materials and Ferments

28. Biotechnology involves the usage of microorganisms, or single cells in culture, for the industrial production of a material. Diverse ingredients may be produced through biotech processes, and distinct names may be assigned when the bioengineered material differs significantly from its traditional counterpart. (See also Synthetic Peptides, Convention 56h-k, for the nomenclature of peptides derived by recombinant technology.)

    Biotech materials may be derived by the action of microorganisms, such as bacteria or yeasts, on a substrate to produce materials by fermentation, metabolism, hydrolysis, lysis, or other process. The process may involve the use of nutrients and other materials such as enzymes. The resulting product is referred to as a "culture" or "ferment." The "ferment" may be further processed by extraction, filtration, or other procedure to yield the final product. The conventions used to provide INCI Names for biotech materials are as follows:

    a. When the end product produced from a given "ferment" or "culture" has a common or usual name, such name may be used, e.g., Yogurt, Gellan Gum, Xanthan Gum, Wine.

    b. When the end product does not have a common or usual name, the product is named using the genus of the microorganism followed by a slash, and the name of the substrate (if applicable), followed by the word "ferment." Typical fermentation substrates (e.g.,

peptone) are not included as part of the INCI name, whereas atypical substrates are included (e.g., ammonium sulfate, polysorbates, etc.) On a case-by-case basis, the genus and species name of the microorganism may be used when the use of the genus only may be misleading and the species is needed for clarity, particularly where pathogenic organisms are involved, e.g., Candida Bombicola Ferment, Escherichia Coli/Glucose Ferment Filtrate, Bifida/Enterococcus Faecium/Lactobacillus/Streptococcus Thermophilus/Soymilk Ferment Curd. Substrates will be identified by their common, usual, or other technical name, e.g., Lactococcus/Carrot Ferment. In the absence of a common name, the substrate may be named by the Latin genus/species term, e.g., Aspergillus/Camellia Sinensis Leaf Extract Ferment.

c. If a component(s) of the fermentation process has been isolated and purified to a significant extent (e.g., >80% based on dry weight), and analytical evidence is provided, the name for one or more of the components may be used, e.g., Glycosphingolipids, Beta-Glucan, Dextran, Sodium Hyaluronate.

d. Products derived by fermentation and further processed by extraction or filtration are named accordingly, e.g., Lactobacillus/Oat Ferment Extract Filtrate. When cells are lysed by mechanical treatment, heat treatment, osmotic pressure, by the use of chemicals, or enzymes, the term “lysate” is included in the name, e.g., Lactobacillus Ferment Lysate.

e. Conditioned Media is the growth media collected from eukaryotic cell cultures and are named according to the source of cells being cultured, e.g., Human Cord Blood Cell Conditioned Media, Camellia Sinensis Callus Culture Conditioned Media. No distinction is made regarding the growth conditions or manufacturing method, (e.g., cells grown under hypoxia or induced by ozone). Further distinction is given to indicate the presence of stem cells when the material is confirmed by appropriate analytical methodology. See 28f.

f. The naming of materials derived from stem cells is based on species and source tissue and is contingent upon full analytical characterization of the cell population using appropriate current methodologies, e.g., FACS, flow cytometry with appropriate markers and gating strategy. The INCI name is assigned based on whether the product is the media, the cells, or both. Examples include Horse Adipose Stromal Cell Conditioned Media, Human Bone Marrow Stem Cell Conditioned Media, Human Fibroblast Induced Pluripotent Cell Extract, Human Umbilical Mesenchymal Stem Cell Conditioned Media, Red Junglefowl Induced Pluripotent Cell Culture Conditioned Media, Sheep Adipose Stromal Cell Conditioned Media.

g. Exosomes are small vesicles found in the cells of eukaryotic organisms. With appropriate analytical characterization, (e.g., electron microscopy, flow cytometry, nanoparticle tracking analysis) they are named according to species and source tissue, e.g., Human Adipose Stromal Cell Exosomes, Human Amniotic Fluid Induced Pluripotent Cell Exosomes.

Plants can make small, nano-sized, vesicles which are a structure found within or outside of a cell, consisting of liquid or cytoplasm enclosed by a lipid bilayer. These vesicles have not been characterized to the extent as those derived from mammalian cells, therefore

they are named as vesicles. They are named based on the plant source that they are isolated from, e.g., Brassica Oleracea Italica (Broccoli) Vesicles, Dendropanax Morbiferus Leaf Vesicles. If these vesicles are released outside the cells then they are considered extracellular vesicles and are named based on the plant source they are released from, e.g., Panax Ginseng Adventitious Root Extracellular Vesicles, Rosa Damascena Callus Extracellular Vesicles.

h. Ingredients derived by plant tissue culture are named according to their method of production as follows:
    i. "Plant Callus Extract" is an extract of a callus, or any plant cells that are forced to go through a callus stage in culture unless re-differentiated, (see ix. below)
    ii. "Plant Callus Extract Powder" is an extract of callus cells which have been dried, and ground
    iii. "Plant Callus Culture Extract" is an extract of a whole culture (cell + media) of callus cells.
    iv. "Plant Callus Powder" is a callus (or callus cells), that has been dried and ground without extraction.
    v. "Plant Cell Culture" is a cell suspension obtained using high shear and enzymatic treatment and without a callus formation.
    vi. "Plant Cell Culture Extract" is the extract of a whole cell suspension culture (cell + media).
    vii. "Plant Cell Culture Conditioned Media" is the isolated conditioned media from a Plant Cell Culture.
    viii. "Plant Cell Extract" is an extract of the cells (without the media).
    ix. Callus cells which are caused to differentiate into a specific plant part after callus formation are named by the plant part rather than callus term.

i. When the material is derived from a microorganism culture (with no additive), the name will consist of the genus and/or species term followed by the relevant term to indicate post-fermentation processing, (e.g., Lactobacillus Ferment Filtrate.)

j. Products derived by spontaneous fermentation (i.e., where a microorganism is not utilized) are named based on the material being fermented followed by the relevant term to indicate post-fermentation processing, (e.g., Sapindus Mukorossi Fruit Ferment Extract). The definitions for these ingredients indicate that the fermentation occurs spontaneously.

k. Materials produced through the cultivation of algae (or other microorganisms) are named on the basis of their composition and purity. The name is based on the identity of the species and the end-product, e.g., Mortierella Oil, Chlorella Protothecoides Oil, Euglena Gracilis Polysaccharide. See also 28 (a), and 43 (j).

l. Products derived by the fermentation of a microorganism which has been recombinantly modified are named by the prefix r- followed by the name of the microorganism.

Botanicals

29. Botanicals are cosmetic ingredients directly derived from plants. Generally, these ingredients have not undergone chemical modification and include extracts, juices, waters,

distillates, powders, oils, waxes, saps, tars, gums, unsaponifiables, and resins. Where evidence of isolation is presented, a botanical ingredient may be named as a chemical entity, e.g., Genistein, or other appropriate terminology, e.g., Soy Isoflavones, depending on the extent of purification of the isolated material. See Convention No. 1 for the definition of a single constituent substance under REACH.

a. The INCI names for botanicals are based on the Linné system or Latin binomial, whereby the Genus and species of the plant is used. In limited cases, the term related to the sub-species or variety has been historically used to differentiate materials that relate to the same Genus/species, e.g., *Brassica oleracea captitata.*

b. If an ingredient is derived from an interspecies botanical hybrid (same genus/different species) with no recognized Linnean name, the INCI name will reflect the Linnean names of both plants used to create the hybrid separated by a slash, e.g., Rubus Fruticosus/Idaeus Extract. If an ingredient is derived from an intraspecies botanical hybrid (same genus/same species but different varieties), the genus/species of the phenotypic parent will be used, e.g., Helianthus Annuus (Sunflower) Seed Oil. In cases where an ingredient is derived from a cultivated hybrid in which the species name is unclear (e.g., the parentage of the species is from one or more hybrids), a cultivar name may be used in conjunction with the genus term, e.g., Phalaenopsis Charm Sun Big Red Robe Flower Extract.

c. Historically, the primary reference used by the INC to establish the Latin binomial names for botanicals was Penso, G., *Index Plantarum Medicinalium Totius Mundi Eorumque Synonymorum*, O.E.M.F. Milano (1983) - ISBN No. 88-7076-027-8.

d. Due to the dynamic nature of plant identification, the scientific nomenclature for plants is continually being updated. In order to provide accurate information, and minimize the impact of INCI name changes, the current accepted scientific plant names, where they differ from the INCI name, are described in the monograph definition. Notable botanical authorities are consulted in this effort, along with the various sources listed below:
    - AlgaeBase, http://www.algaebase.org/search/species/
    - Flora of China, http://www.efloras.org/
    - Index Fungorum, http://www.indexfungorum.org/
    - Integrated Taxanomic Information Systems, http://www.itis.gov/
    - International Plant Names Index, http://www.ipni.org/ipni/plantnamesearchpage.do
    - Missouri Botanical Garden, http://www.tropicos.org/
    - MycoBank, http://www.mycobank.org/
    - Royal Botanical Garden, KEW, http://www.kew.org/
    - The Plant List, http://www.theplantlist.org/
    - United States Department of Agriculture Germplasm Resources Information Network (GRIN), http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl
    - United States Department of Agriculture Plants Database, http://plants.usda.gov/java/nameSearch

e. INCI names for botanicals include the part(s) of the plant from which the material is derived. When more than one part is utilized, the plant parts are listed in alphabetical

order, separated by a slash. When the material is derived from the entire plant, no part is specified, and the material is defined as being from the whole plant.

f. The INCI names for plant extracts prepared by solvent extraction are assigned names that identify the name of the plant and the solvent. When the extraction solvent is carbon dioxide, carbon dioxide is not included in the INCI name since it evaporates. Additionally, solvents are not identified in the INCI name in cases where the solvent has been driven off and not present in the final preparation.

g. Essential oils prepared by a steam distillation process yields two distinct fractions, a water-insoluble fraction, and a water-soluble fraction. The water-insoluble fraction contains the term oil in the name, e.g., Eucalyptus Globulus Leaf Oil. The water-soluble fraction contains water in the name, e.g., Camellia Japonica Leaf Water. When an ingredient is prepared by adding water to a material prepared by solvent extraction, the ingredient is named as a mixture, e.g., Water (and) Juniperus Communis Fruit Extract. The term "water" is typically utilized for materials that are derived from plants; although "water" may be used to name non-botanical materials that are produced by steam distillation, e.g., Caviar Water, Royal Jelly Water.

h. The term "powder" is applied to the names for botanical materials that have been mechanically ground, irrespective of particle size. The term "meal" and "flour" are commonly recognized consumer terms, and are utilized accordingly in names such as Corn Cob Meal, Soybean Flour, etc.

i. Where several botanical materials are combined before processing, e.g., extraction or distillation, the ingredient is named by the genus, species and part of each plant separated by a slash followed by the preparation term, e.g., Aesculus Hippocastanum Bark/ Daucus Carota Root/Foeniculum Vulgare Fruit Extract. Exceptions to this convention are the INCI names Rose Extract and Rose Flower Oil which have historical usage and are grandfathered; along with Camellia Seed Oil defined as the oil expressed from one or more species of *Camellia* and named in accordance with information obtained from JCIA.

j. The term "soybean" has historical usage in INCI names to describe both *Glycine soja* and *Glycine max*.

k. Botanicals are named by a specific component, e.g., Apigenin, Isoquercetin, when the material has been isolated, purified and chemically characterized. General nomenclature for botanicals (e.g., Soy Isoflavones, Hydrolyzed Ginseng Saponin, Cassia Angustifolia Seed Polysaccharide) is utilized to name materials in accordance with the extent of their purification. See 54d for Conventions related to optical isomers.

l. Gums are polysaccharides of natural origin found in woody elements of plants or seed coatings, and in various seaweeds. Gums of natural origin are designated by common name that identifies the source, e.g., Acacia Senegal Gum, Ghatti Gum, Natto Gum. Common names for gums derived by fermentation include Gellan Gum, Xanthan Gum. Ingredients derived by reaction with a gum generally do not include the term "gum" in the INCI name, e.g., Hydroxypropyl Guar.

m. Ingredients derived from plant tissue culture are named in accordance with their process;

the naming principles are fully described in Biotechnological Materials and Ferments.

n. The term “defatted” is used for ingredients which have been treated to remove lipid material which is typically accomplished through solvent extraction. For example, Defatted Hydrangea Macrophylla Flower refers to a plant extract in which the final preparation is the remaining plant material as opposed to the extract.

o. Seedcake is the term applied to the residue obtained after the oil has been processed from the seed.

p. Resins are secreted by specialized plant structures and consist of a mixture of terpenoid and phenolic compounds. Resins are often referred to as a sap, balsam, or exudate.

q. With the exception of soymilk which has historical usage in INCI nomenclature, plant-based milks are named as mixtures, where the plant component is named in accordance with the preceding botanical conventions and the other components in the emulsion are identified in descending order of predominance. (See Convention 27j.)

30. Harmonized INCI names for botanicals are designated by the Latin binomial as determined above, followed by the common name (where historically used) in parentheses, followed by the plant part (if applicable) and the type of preparation, e.g., Prunus Persica (Peach) Leaf Extract. See the Labeling Reminders section for an explanation of usage of common plant names.

    In general, Latin binomial names are not used for botanicals that have been chemically modified. Botanicals that have a widely recognized common name (e.g., Olive Oil), and have undergone chemical modification may be named by common name and type of process, e.g., Acetylated Castor Oil, Hydrogenated Rapeseed Glycerides, Hydrolyzed Corn Starch, Oxidized Hazel Seed Oil, Ozonized Olive Oil, Saccharomyces/Grape Ferment Extract. In the absence of a previously monographed common name, or common name not widely known, the genus/species name may be utilized to name derivatives, e.g., Schinziophyton Rautanenii Oil Polyglyceryl-6 Esters.

    In the EU, botanicals are named by the Latin binomial as explained above, followed by the plant part (if applicable) and type of preparation, e.g., Prunus Persica Leaf Extract. (See the discussions on international harmonization and botanicals in the Labeling Reminders section.)

    When several materials relate to the same genus/species are used, the variety or sub-species in the Linné system may be identified, e.g., Citrus aurantium dulcis, Citrus aurantium amara.

    There are a few cosmetic ingredients of herbal medicine origin in Japan in which the medicinal effect of the plant is specific to the sub-species. For these ingredients, the sub-species is included in the name, e.g., Coix Lacryma-Jobi Ma-Yuen Seed, Coix Lacryma-Jobi Ma-Yuen Seed Oil.

31. The INCI names for extracts represent the “material extracted”. The extracting solvent(s) if

present in the final preparation is included in the INCI name assignment in descending order of concentration. In cases where a solvent is not present, the INCI name is based on the removed material, i.e., material extracted.

Ceramides

32. The term ceramide as part of an INCI is assigned to those classes and structures of natural lipids derived from skin as reported by Philip W. Wertz, Ph.D., Marion C. Miethke, M.D., Sherri A. Long, M.D., John M. Strauss. M.D., and Donald T. Downing, Ph.D., "The composition of ceramides from human stratum corneum and from comedones," *The Journal of Investigative Dermatology*, 84 410-412 (1985). The term "ceramide" is also utilized in accordance with the naming system proposed by Motta, S., et al (1993) Biochimica et Biophysica Acta, 1182, 147-151.

    a. A synthetic N-acylated sphingoid base that is identical to any one of the many constituents of the natural ceramides as reported by Wertz, has historically been assigned an INCI labeling name in accordance with the Wertz system, e.g., Ceramide 1, Ceramide 1A, Ceramide 2, Ceramide 3, Ceramide 4, Ceramide 5, Ceramide 6II. The term ceramide as part of the INCI name will be assigned to a N-acylated sphingoid base that contains, as the predominant component, the D-erythro isomer of at least one of the many natural ceramides described by Wertz. A predominant component is one that is present at the highest concentration in relation to other synthetic materials of similar structure and related compositions present in a mixture. The Motta system for naming ceramides is also incorporated into INCI nomenclature. The Motta system utilizes a series of acronyms to designate the various fatty acid/sphingoid base combinations. The sphingoid base is typically 6-hydroxy sphingosine, phytosphingosine, sphinganine or sphingosine, and the fatty acid can be saturated or unsaturated, and normal, or contain an alpha- or omega- hydroxyl grouping. Ceramides containing an omega-hydroxy fatty acid can exist in the free form or be esterified with either linoleic acid or a mixture of predominantly linoleic acid in combination with oleic acid and stearic acid. A number of different combinations of fatty acid/sphingoid base exist which give rise to a variety of INCI names, e.g., Ceramide NS, Ceramide EOS, etc. The chart below identifies the acronyms used in Motta-based ceramide nomenclature:

N	normal fatty acid
A	alpha-hydroxy fatty acid
O	omega-hydroxy fatty acid
E	esterified omega-hydroxy fatty acid
S	sphingosine base
P	phytosphingosine base
H	6-hydroxysphingosine base
G	sphinganine base (or dihydrosphingosine)

    b. Synthetic N-acylated sphingoid bases that do not have the D-erythro configuration, or otherwise are not constituents of natural ceramides as described by Wertz or Motta, will not be named using the term ceramide. In such cases, a chemical, or other appropriate name, to be determined by the International Nomenclature Committee (INC) on a case-by-case basis, will be assigned as the INCI labeling name.

Color Additives

33.

a. Color additives permitted for products to be marketed in the United States are identified in Title 21 of the *U.S. Code of Federal Regulations* (21 CFR). The INCI Names for color additives subject to batch certification are abbreviated names as identified in the *Federal Register* on June 6, 1985 (50 FR 23815). The abbreviated labeling names do not include "FD&C" or "D&C," "No.," or the type of lake "Aluminum, Zirconium, etc.," on their product labels, e.g., Blue 1 Lake is the INCI name for the batch certified colorant FD&C Blue No. 1 Aluminum Lake.

b. For U.S. FDA batch certified colorants, additional names have been added as synonyms in order to identify the non-certified commodity, e.g., Pigment Red 57 instead of Red 7.

c. Alternative Color Index (CI) names have been established for those color additives appearing in Annex IV of *Regulation (EC) No 1223/2009 on cosmetic products* and are required to be used on products labeled for the European Union.

d. Alternate INCI names have been established for synthetic organic color additives permitted in Japan, regulated by the Ordinance to Regulate Coal-Tar Colors Permitted for Use in Drugs, Quasi-drugs, and Cosmetics (MHLW Ordinance No. 30 of August 31, 1966 as amended by MHLW Ordinance No. 55 of December 13, 1972, by MHLW Ordinance No.1126 of July 29, 2003 and by MHLW Ordinance No. 59 of May 2004

e. Coated pigments are named as blends, e.g., Polyethylene Terephthalate (and) Aluminum Powder. Epoxy Resin Coated Aluminum Powder is contained in the Dictionary as one of the Japan Trivial Names.

34. Oxidative hair coloring intermediates are named as described in 21 CFR. Those intermediates not appearing in 21 CFR are named according to their chemical structure.

35. Preformed hair colors are named as described in 21 CFR. Those preformed hair colors not appearing in 21 CFR are given the Colour Index Name. Preformed hair colors not appearing in either 21 CFR or the Colour Index are assigned chemical names based on their structure. In the event that the chemical name is very complex, these colors are assigned an arbitrary color/number designation, prefixed by the letters "HC."

Denatured Alcohol

36. a. Specially Denatured (SD) Alcohols used in products marketed in the United States are named in compliance with Title 27 of the *U.S. Code of Federal Regulations* (27 CFR). The denaturants used in the manufacture of each SD Alcohol formula are specified in the ingredient monograph. Manufacturers using these SD Alcohols should consult 27 CFR and the *Federal Register* for permitted uses, restrictions, and proposed changes.

b. An alternate INCI name, Alcohol Denat., has been established for products marketed in European Union (EU) Member States. Alcohol Denat. is ethyl alcohol that is denatured in accordance with the national legislation of each EU Member State. The INCI Name Alcohol Denat. may also be used in the United States for ethyl alcohol denatured in accordance with 27 CFR. For additional information see "Regulatory and Ingredient Use

Information."

Glycerides

37. a. The term "Glyceride" has been utilized to describe a monoglyceride. (e.g., Acetylated Lard Glyceride, Canola Oil Glyceride, C10-40 Isoalkyl Acid Glyceride, Palm Glyceride.)

    b. The term "Glycerides" is used to designate mixtures of mono-, di- and/or triglycerides, (e.g., Acetylated Palm Kernel Glycerides, Caprylic/Capric Glycerides, Corn Glycerides, Isostearic/Myristic Glycerides, PEG-12 Palm Kernel Glycerides.)

    c. Triglycerides are designated by the term "triglyceride". Alternate nomenclature is utilized when triglycerides are formed utilizing a single fatty acid, (e.g., Trilaurin, Trimyristin, Tristearin.)

Glycols

38. a. Glycol is the INCI name for ethylene glycol and is used as a combining term for derivatives of ethylene glycol, e.g., Glycol Distearate, Glycol Salicylate.
    Alkylene 1,2-diols are usually named by the common name of the alkyl group followed by the term glycol, e.g., Lauryl Glycol. One exception includes hexylene glycol. See Convention 44f for the naming of polyethylene glycol.

    b. Diglycol is the INCI name for diethylene glycol,and is used as a combining term for derivatives of diethylene glycol, e.g., Ethoxydiglycol, Diglycol/Isophthalates/SIP Copolymer.

        i. Diglycol is typically used in polymer names where diethylene glycol is used as a starting monomer, e.g., Bis-HEMA Poly(Diglycol Adipate)/IPDI Copolymer.

        ii. Diglycol is typically used in ethers, e.g., Butoxydiglycol, Methoxydiglycol.

        iii. Diethylene Glycol is typically used in esters, e.g., Diethylene Glycol Benzoate, Diethylene Glycol Dimethacrylate

    c. PEG-2 is the INCI name for diethylene glycol when the reaction mechanism occurs through the use of an average of 2 moles of ethylene oxide. The exception to this principle is the usage of the suffix "-eth-2" to describe a 2-mole ethoxylate of a fatty alcohol, (see Convention 18a).

    d. Butylene glycol is the INCI name for 1,3-butanediol. The numbers are omitted from the INCI name for the parent compound and its derivative, e.g., Butylene Glycol Myristate. INCI names for all other configurations include the numerical prefix to specify the position of the hydroxyl groups, e.g., 1,2-Butanediol, 2,3-Butanediol, 1,4-Butanediol, PEG/Poly(1,2-Butanediol)-52/32 Dimethyl Ether, 1,4-Butanediol Bisdecanoate. See also Convention 4.

    e. Propylene Glycol is used as a combining term in INCI names when it is a starting material, e.g., Propylene Glycol Behenate, Dipropylene Glycol Caprylate, Tripropylene Glycol Citrate.

i. "-PG" or "PG-" is used in INCI names when the starting material is glycidol, or where a material is reacted with one mole of propylene oxide.

ii. Hydroxypropyl refers to 2-hydroxypropyl or 3-hydroxpropyl (e.g., Guar Hydroxypropyltrimonium Chloride), and is used when the starting materials are possibly 1-chloroisopropanol or 1-aminoisopropanol, or 3-chloropropanol or 3-aminopropanol. (See also Convention 19b)

Hydrocarbons

39. a. Hydrocarbon mixtures (notably solvents) not named by source or predominant feedstock as described in Conventions 20, 21, 22 are named on the basis of 80% of the composition utilizing a carbon number prefix which defines the 80% range as follows:
    i. Both numbers of the range will be even for materials containing only even-numbered carbon chains
    ii. Both numbers of the range will be odd for materials containing only odd-numbered carbon chains
    iii. One number of the range will be even and the other odd for materials containing both even- and odd-numbered chains
    b. A mixture of linear saturated hydrocarbons is named "Alkane" e.g., C14-22 Alkane. Ethoxylated derivatives of linear saturated alcohols are named in the same manner utilizing the term "Alketh", e.g., C12-15 Alketh-3.
    c. A mixture of branched saturated hydrocarbons is named "Isoalkane", e.g., C32-54 Isoalkane, where the mixture can contain one or more branched substituents.
    d. Cyclic saturated hydrocarbons are named "Cycloalkane".
    e. Mixtures of structurally different saturated hydrocarbons are named by each component separated by a slash, e.g., C9-16 Alkane/Cycloalkane.
    f. Mixtures of unsaturated hydrocarbons are named "Olefin" and include mono- and polyunsaturates, linear, branched, and cyclic, e.g., C18-26 Olefin, Poly(C4-12 Olefin).

Imidazolines

40. Common fatty stem terms are used to designate the alkyl portion of alkyl imidazoline compounds (e.g., Lauryl Hydroxyethyl Imidazoline) even though one carbon atom of the fatty radical becomes a member of the heterocyclic ring during the materials' manufacture.

Lanolin Derivatives

41. Names of lanolin derivatives usually contain the stem "lan", e.g., Laneth-10 Acetate. When fractionated, derivatives are named utilizing "lan" as a stem name unless a specific component has been isolated, e.g., Cholesterol.

Minerals

42 a. Naturally occurring minerals with a definite chemical composition and/or physical properties (which may include x-ray diffraction data) are named according to the established, published nomenclature. Some reference sources include:

- Cornelis Klein and Cornelius S. Hurlbut, Jr., *Manual of Mineralogy* (after James D. Dana), Twenty-First Edition (1985), John Wiley & Sons, Inc., New York.
- Carmichael, Robert S., *CRC Practical Handbook of Physical Properties of Rocks and Minerals*, (1989), CRC Press, Inc., Boca Roton, FL 33431.

- Schumann, Walter, *Gemstones of the World*, (1997), Sterling Publishing Co., Inc., New York.
- www.mindat.org
- http://minerals.usgs.gov/

b. Naturally occurring materials that are mixtures of mineral species are named on the basis of particle size using common names such as sand, clay, silt, and other similar terms. Historically, some inorganic materials have been named according to geographic origin when the composition and properties with regard to origin were properly documented and supported in the literature, e.g., Moroccan Lava Clay.

c. The term "synthetic" is applied to the names of inorganic materials such as rocks, gems, and minerals, (e.g., Synthetic Ruby) to indicate that the material is synthesized. These materials, while generally physically indistinguishable from their natural counterparts, are chemically similar but may vary in chemical composition. Bureau of Standards and X-ray diffraction pattern data must be supplied to support the characterization of compositional similarities between natural and synthetic materials.

d. Rocks, gems, and minerals that are mechanically ground (i.e., not ground by natural processes) are named by the common geological term followed by the term "powder", (e.g., Ruby Powder).

e. Doped minerals obtained via calcination are considered solid solutions and are named as a single entity by the constituent mineral oxides, e.g., Silicon/ Titanium/Cerium/Zinc Oxides.

f. Mineral extracts are designated by the name of the mineral and the term "extract", e.g., Loess Extract, Lignite Extract, Malachite Extract, when the manufacturing information indicates the mineral is extracted.

g. Allotropes of carbon are named according to their structural form, e.g., Diamond, Graphite, Fullerenes, Carbon.

h. Plant Ash is the name designated for ingredients composed of ash produced by the combustion of any plant material or mixture of plants.

i. Carbonaceous material obtained by heating wood or other organic matter in the absence of oxygen is named as Charcoal.

j. Clay as an INCI name refers to a group of phyllosilicate minerals produced by the chemical and physical weathering of rock. It consists chiefly of varying amounts of hydrated silica and alumina and is characterized by a particle size of less than 2 micrometers. Clays have historically been designated INCI names based on geographic region; these names have been "grandfathered", e.g., Heilmoor Clay. The current naming practice is to designate clay materials by the INCI name, "Clay". See also 42 (b).

k. Loose pieces of minerals and rocks are sediment and further characterized by particle size as follows:

i. Sand is a naturally occurring granular material composed of finely divided rock and mineral particles based on silica in the form of quartz, with a typical particle size between 0.0625 to 2.00 mm.
ii. Silt is sediment from inland bodies of water**.** It is a naturally occurring inorganic material whose origins are based on quartz and feldspar with typical particle sizes between 0.0625 to 0.00400 mm, e.g., Sea Silt.
iii. Mud is a mixture of water and some combination of soil, silt, and clay, e.g., Alluvial Mud, Salt Mine Mud.

l. Volcanic Soil is a mixture of minerals derived from volcanic deposits which are of varying size including but not limited to sand, silt and clay. Volcanic Sand is loose, granular particles of disintegrated lava deposits. Volcanic ash is the residue obtained from volcanic eruption.

m. Glass is an amorphous inorganic material based on silica (SiO2) that is combined with various additives, usually metal oxides (e.g., sodium oxide, calcium oxide, magnesium oxide). Glasses are produced by fusing silica together with the additives, then rapidly cooling to eliminate formation of a crystalline structure.

n. INCI names do not generally include descriptive terms related to particle size. Materials that result from milling are named as powders or flours irrespective of size. See Convention 67 for usage of the term colloidal. Additionally, "nano" is not used in the assignment of INCI names to trade materials. See Convention 73.

Oils, Fats, Lipids and Triglycerides

43. a. Triglycerides of plant or animal origin that are liquid at room temperature are generally known as fixed oils and are named by their source followed by the term oil, e.g., Olea Europea (Olive) Oil, Elaeis Guineensis (Palm) Oil, Elaeis Guineensis (Palm) Kernel Oil, Canola Oil, Cod Liver Oil. Oils which have been chemically modified by acetylation, hydrogenation, isomerization or oxidation are named in a similar fashion, e.g., Acetylated Castor Oil, Hydrogenated Palm Kernel Oil, Isomerized Palm Oil, Oxidized Corn Oil.

b. Triglycerides of animal origin that are solid at room temperature are generally known as fats and are named by their source followed by the term fat e.g., Deer Fat, Goat Fat, Buffalo Fat.

c. Essential oils that are water insoluble fractions of plant materials obtained by steam distillation are named by their source followed by the term oil, e.g., Rose Flower Oil, Salvia Officinalis (Sage) Oil. Water soluble fractions of essential oils are named as waters.

d. The term "oil" may be used to name non-triglycerides when it applies to ingredients that are commonly recognized, (e.g., Simmonsia Chinensis (Jojoba) Oil, Lanolin Oil, Mineral Oil, Tall Oil, Tar Oil.)

e. Plant butters derived by mechanically pressing the seeds are generally semi-solids at room temperature and are named by the genus/species term of the plant in accordance with Convention 30, e.g., Garcinia Indica Seed Butter. Exceptions include the common

name “Butter” which refers to the fat recovered from cow’s milk, and “Goat Butter” which refers to the fat recovered from goat’s milk.

f. Lipids isolated from plant or animal origin are named by the common name of the animal, e.g., Shark Lipids, Silkworm Lipids, or genus/species name of the plant, e.g., Oryza Sativa (Rice) Lipids. See also Convention 33, Ceramides.

g. Lipids produced by various strains of algae are named in accordance with the composition of the final product. If the product is constituted by a mixture of fatty acids, approximately 80% of the fatty composition is identified in alphabetical order separated by a slash, e.g., Capric/Lauric/Myristic/Oleic Triglyceride.

Polymers

44. Due to the wide variety of polymer chemistry types exhibited among synthetic and naturally occurring polymers and due to their inherent polydispersities, there is no uniform approach to distinguish between what constitutes an oligomer vs. a polymer solely on the basis of degree of polymerization (i.e. the number of repeat units in the polymer chain). Instead, the oligomer vs. polymer distinction on the basis of degree of polymerization is specific to individual polymer chemistry type, and it is typically associated with measurable differences in macroscopic physical properties, such as melting point, viscosity, etc., that occur as a function of degree of polymerization for that polymer chemistry type.

Polymeric materials are named according to the name in common usage if it is well known, or by the structure if well-defined, e.g., polyethylene terephthalate. Typically, polymers are named by the starting monomer instead of the composition of the final polymer, e.g., Polydecene instead of polydecane. Exceptions include copolymers named with vinyl alcohol as one of the monomers, e.g., Sodium MA/Vinyl Alcohol Copolymer, in which the starting monomer, vinyl acetate is hydrolyzed to form the alcohol. If no common name exists, and the structure is not well-defined, the polymers are named according to their composition as described below:

a. Homopolymers (consisting of one constituent monomer) are named by placing the term “poly” before the constituent monomer, e.g., Polyisobutene.

b. Copolymers consisting of two or more constituent monomers are named by listing the monomers in alphabetical order separated by a slash (/) followed by the word “Copolymer,” e.g., Acrylates/Acrylamide Copolymer.

c. Copolymers consisting of four or more monomers may be given an INCI name according to the predominant monomer, or resultant polymer class followed by an arbitrary number, e.g., Polyester-1, Polyquaternium-1, etc., with the monomers listed in the monograph definition in alphabetical order of the material. Copolymers with less than four monomers and with an excessive name length may also be considered for “poly-type” names as described above. Such nomenclature is granted at the discretion of the INC.

d. Crosspolymers consisting of two or more constituent monomers are named by listing the monomers in alphabetical order separated by a slash (/) followed by the word

"Crosspolymer," e.g., Acrylates/VA Crosspolymer.

i. The crosslinking agent can be used in the INCI name if the crosslinking agent is a polymer. In these cases, the crosslinking agent will appear as the last component of the INCI name followed by the word "Crosspolymer"; e.g., Lauryl Dimethicone/PEG-15 Crosspolymer, where the crosslinker is diallyl PEG-15. When the crosslinking agent is not a polymer, it will not be included in the INCI name, but will be included in the monograph definition of the material, e.g., Acrylic Acid/Isopropylacrylamide/ MIBK Acrylamide Crosspolymer-is a copolymer of acrylic acid, isopropylacrylamide, methyl isobutyl ketone (MIBK) acrylamide crosslinked with methylene bis-propenamide. Carbomer is an exception to this Convention because of its historic usage.

ii. In cases where a polymer cannot be formed in the absence of a crosslinking monomer, i.e., the crosslinking monomer is essential for the formation of the polymer repeating structure, the crosslinking monomer will be included in the INCI Name. For example, the crosslinked polyester formed by the condensation of Propanediol and Citric Acid would be named Propanediol/Citrate Crosspolymer. Exceptions include polymers named in accordance with Convention 44(c).

45. The term "Acrylates" has historically been used to describe linear, non-crosslinked copolymers that contain combinations of acrylic acid, methacrylic acid, and their simple esters. They are described as simple alkyls ranging from C1 to C4 (linear or branched). Similarly, the term "Crotonates" is used to describe copolymers that contain combinations of crotonic acid and its simple esters. When a monomer is represented solely by a single simple acrylic acid ester, the specific monomer name is applied.

46. The term "Aminoacrylates" refers to simple aminoacrylates, in which the substituted alkyl groups attached to amino nitrogen range from C1-4, and acrylates conforms to the definition as described above.

47. The name "Carbomer" is used to describe high molecular weight crosslinked homopolymers of acrylic acid. The crosslinking agent(s) are identified in the ingredient monograph definition.

48. A "Dendrimer" polymer is named from the core to the outside by the monomer layers. If a monomer unit is repeated, the number of generations or layers is indicated. If a previous convention exists for naming the core, then it is utilized. An example is PEG-5 Pentaerythrityl (the core) Dimethylol (the layer) Propionate-2 (generations) in which there are 5 repeating units of polyethylene glycol attached to pentaerythritol as the core. Dimethylol propionic acid is reacted to the core for two generations.

    A dendron attached to a polymer backbone is named by the backbone polymer with the added dendron side group described, e.g., Acrylates/HEMA Copolymer (the core) Dimethylol Propionate-4 (the layer and generation) Dendron.

49. The term Polyurea is used to name polymers typically formed by the condensation of a diisocyanate with a diamine.

Prostaglandin Derivatives

50. Ingredients which are analogues of prostaglandin compounds utilize the drug stem term as part of the corresponding cosmetic ingredient name, e.g., Bimatroprost and Cyclopropylbimatoprost; Closprostenol and Isopropyl Cloprostenate; Noralfaprostol and Isopropyl Dihydro Noralfaprostal; Travoprost and Ethyl Travoprostamide. The use of common drug stem names for related cosmetic substances is considered by the INC on a case-by-case basis.

Quaternary Ammonium Salts

51. Quaternary ammonium salts usually have the suffix "ium" in the stem of the cation. The term "monium" describes a monomethyl-substituted quaternary nitrogen; "dimonium" describes a dimethyl-substituted quaternary nitrogen; "trimonium" describes a trimethylsubstituted quaternary nitrogen.

Silanes and Siloxanes

52. Silanes and Siloxanes are named according to the following subcategories:

    a. Silanes are monomeric compounds containing one silicon atom. They are used as intermediates to prepare siloxanes and to modify the surfaces of other ingredients. Silanes are named by listing substituents in alphabetical order, and then the term 'silane' with the appropriate numerical prefix (e.g., Trimethoxycaprylylsilane).

    b. Silanols [silanes containing hydroxyl group(s)] are named according to the number of hydroxyl groups attached to the silicon atom. The other substituents included in the name (e.g., Hydrolyzed Keratin PG-Propyl Methylsilanediol, Silanetriol Lysinate).

    c. Siloxanes, commonly referred to as silicones, are polymers that are based on chains of alternating silicone and oxygen atoms that also contain organic substituents. The most common organic substituents are methyl ($-CH_3$) but many other types of organic substituents are possible. The most common siloxanes are linear polysiloxanes with two methyl substituents on each silicon atom (polydimethylsiloxanes). When the polydimethylsiloxanes are terminated with methyl groups, the INCI name is Dimethicone. Short chain Dimethicones (2-4 silicon atoms) are named chemically (e.g., Trisiloxane, Disiloxane). Dimethicones where some of the methyl groups along the chain are replaced with other organic groups are named as Dimethicone derivatives (e.g., Stearyl Dimethicone, PEG-8 Dimethicone). It is assumed the substituents on Dimethicone derivative are attached through a propyl linkage. Any other attachment is identified in the name.

    d. Dimethicones where the polysiloxane chain is terminated with substituents other than methyl groups are named using "Bis-" to indicate where the substituents are located (e.g., Bis-PEG-8 Dimethicone, Bis-Hydroxypropyl Dimethicone)

    e. Dimethicones where the polysiloxane chain is terminated with hydroxyl groups (-OH) are called Dimethiconols. Hydroxyl groups attached to silicon atoms are somewhat reactive. They can condense with each other to form a new siloxane bond (-Si-O-Si-), leading to chain extension. They can also react with organic acid to form a type of ester (e.g., Dimethiconol Behenate)

f. Methicone refers to linear siloxane polymers where each silicon atom in the siloxane chain has one methyl group and one hydrogen atom. Methicone is a reactive polymer that is used to create a hydrophobic coating on the surface of inorganic pigments. It is also the starting material for making alkyl siloxanes where the hydrogen atoms are replaced with the alkyl group (e.g., C26-28 Alkyl Methicone).

g. Cyclic dimethyl siloxane was historically named 'Cyclomethicone' to represent mixtures of species containing three to seven siloxane units. For pure components (>99%), the nomenclature is based upon the number of siloxane units: Cyclotrisiloxane, Cyclotetrasiloxane, Cyclopentasiloxane, and Cycloheptasiloxane. In the silicone industry, these cyclic dimethyl siloxanes are often referred with the following shorthand notation: D3, D4, D5, and D6.

h. Silsesquioxanes are highly branched siloxanes where each silicon atom is connected to three oxygen atoms and conform to the general formula $[RSiO_{3/2}]x$, where R is an organic substituent. They are sometimes referred to as Polyhedral Oligomeric SilseSquioxanes (POSS). The nomenclature is understood to include oligomeric silsesquioxanes that only contain 4-6 silsesquioxane units (cage structures). If the organic group for the silsesquioxane has a short, simple name then the INCI will be a single word, e.g., Polyphenylsilsesquioxane, Polypropylsilsesquioxane. For more complex organic groups, they will be used with the term Polysilsesquioxane (e.g., Acryloyloxypropyl Polysilsesquioxane, Glycidoxypropyl Polysilsesquioxane). Silisesquioxanes frequently contain hydroxyl groups attached to the silicon atoms that allow these silsesquioxanes to react with other types of siloxane polymers. These are named as copolymers (e.g., Dimethicone/Silsesquioxane Copolymer)

i. Silicates are inorganic polymers where each silicon atom is attached to four oxygen atoms and conform to the general formula $[SiO_{4/2}]x$. If no organic substituents are present, then the INCI name is Silicon Dioxide. Silicones that contain silicate units are named as such, with any substituents and/or terminal groups appropriately named (e.g., Trimethylsiloxysilicate).

j. The term 'Polysilicone' followed by an arbitrary number is used to describe complex silicone polymers that cannot be named by common names or established conventions for silicone compounds (e.g., Polysilicone-10).

Substituted Compounds and Prefix/Suffix Terms

53. Singly substituted derivatives usually do not include the prefix "mono." This term is used only when required to prevent ambiguity. The absence of a suitable prefix implies "mono," e.g., Glyceryl Stearate represents glyceryl monostearate, and Glyceryl Oleate/Laurate represents a monoester of glycerin with a blend of oleic and lauric acids.)

54. Multiple substitution is routinely described with the appropriate prefix, such as "di-," "tri-," or "tetra-," e.g., Glyceryl Distearate, Propylene Glycol Dilaurate, Pentaerythrityl Tetrabenzoate.

    a. Where there is substitution with a mixture of components, i.e., alkyl groups, the prefix is

used only once, wherever possible, and the moieties are separated by a slash, e.g., Ditrimethylolpropane Tetraisostearate/ Hydroxystearate to denote the tetraester of ditrimethylolpropane and a mixture of isostearic and hydroxystearic acids.

b. The simple numerical prefixes “di-“, “tri-“, “tetra-“ etc. are used to indicate a multiplicity of simple (i.e., unsubstituted) substituents provided that there is no ambiguity, e.g., Propylene Glycol Dilaurate, Triethyl Citrate.

c. The numerical prefixes “bis”-, “tris-“are generally utilized to denote multiple identical structural features of a compound, e.g., Tris-Biphenyl Triazine, Bis-Aminopropyl Dimethicone.

d. Optical isomers are usually not designated in INCI names although this information may be included in the monograph definition. However, there may be circumstances whereby it is necessary to identify the optical properties of the isomer, e.g., d-limonene under EU regulation 111/1.88, and the INC will address these situations as they arise.

e. The numbering of substituents is only employed where necessary to prevent ambiguity, e.g., 1,4-Butanediol, 2,3-Butanediol.

f. The prefixes *o-, m-, p- t-, n-*, N, N’, etc. are used only when necessary to prevent ambiguity.

g. Locants are included in the INCI name when there is more than one possible site for the reaction. e.g., N-Feruloyl Dopamine

55. Mixtures of mono-, di- and tri-esters of glycerin are designated by the suffix “-ates”, (e.g., Glyceryl Stearates.)

56. The dimethyl term is omitted and is assumed in all alkyl dimethyl amine oxide names (e.g., Stearamine Oxide). Tertiary amine oxides with different substituent groups are named completely (e.g., Dihydroxyethyl Stearamine Oxide).

57. Amino acids substituted on nitrogen are named by the identity of the substituent group and the trivial name of the amino acid. Since N-2 is the atom most easily modified, N-can be omitted from the name without ambiguity, e.g., Acetyl Tyrosine.

a. The suffix “ate” is added to the amino acid name when the substance is a salt, e.g., Sodium Glutamate, Potassium Aspartate, or an ester, e.g., Ethyl Glutamate, Acetylated Cetyl Hydroxyprolinate, Methyl Undecenoyl Leucinate.

b. When the hydroxyl group of the carboxyl has been replaced by an amino group, the “amide” suffix is added to the trivial name of the amino acid, e.g., Hexacarboxymethyl Lysinyl Lysinamide, Hydroxyphenyl Glycinamide, Prolinamidoethyl Imidazole.

c. When amino acids are derivatized, amino acid stem names are used as a combining term rather than chemical names, e.g., Glutamyl Hydroxyphenylhydrazide, Prolyl Histamine HCl, Palmitoyl Lysyl Aminovaleroyl Lysine.

58. The prefix “dimer” precedes the term “dilinoleic” to designate materials that are C36 di-acids; it has historical usage in INCI nomenclature, e.g., Dicetearyl Dimer Dilinoleate.

59. The prefix “nor” is used to designate “de-methyl” which means one methyl group removed relative to the parent compound for the purposes of nomenclature, e.g., Norvaline.

60. The prefix sesqui- is used for esters of alcohols and fatty acids that are mixtures of the monoester and diester, e.g., Butylene Glycol Sesquiisostearate, Methyl Glucose Sesquilaurate, PEG-8 Sesquioleate, Polyglyceryl-2 Sesquicaprylate.

Synthetic and Recombinant Peptides

61. Natural protein ingredients, and their derivatives, are named by the common name of the source, e.g., Albumen, Collagen, Fibroin, Mellitin, Milk Protein, Nacre Protein, Serum Protein, Silk, etc. See also 28h. Peptides, produced either by chemical synthesis or recombinant techniques, are named based on sequence and by the approach outlined below. When the peptide sequence shows close homology to a native protein, the name is based on the common name of the species of higher order where the protein is found.

    a. Synthetic peptides consisting of two to ten amino acid residues are named using the appropriate prefix, di-, tri-, tetra-, etc., followed by the term peptide and an arbitrary number, e.g., Dipeptide-2, Decapeptide-4, Pentapeptide-3. The constituent amino acids are identified in the monograph definition. There are a few peptides that are historically named by their amino acids, e.g., Glycyl Glycine, and these names have been grandfathered. Additionally, Glutathione is a grandfathered name for the peptide, glutamyl cysteinyl glycine, whereas Tripeptide-35 is composed of the same amino acids but of possible differing sequence.

    b. Synthetic peptides consisting of 11 to 100 amino acids are designated by the term oligopeptide, followed by an arbitrary number, and the constituent amino acids are identified in the monograph definition, e.g., Oligopeptide-13.

    c. Synthetic peptides consisting of more than 100 amino acids are designated by the term polypeptide, followed by an arbitrary number, and the constituent amino acids are identified in the monograph definition, e.g., Polypeptide-5.

    d. The amino acid residues composing the peptide are listed alphabetically in the monograph definition. The amino acid residues may include the following: Alanine, Arginine, Asparagine, Aspartic Acid, Cysteine, Glutamic Acid, Glutamine, Glycine, Histidine, Isoleucine, Leucine, Lysine, Methionine, Phenylalanine, Proline, Serine, Threonine, Trptophan, Tyrosine, Valine.

    e. When the peptide contains an amino acid that is not one of the natural amino acids identified above, (e.g., D-isomers or gamma amino acids) it is identified in the peptide name, e.g., Tripeptide-9 Citrulline, Acetyl Norleucyl Dipeptide-54 D-Phenylalanyl Dipeptide-25 Amide, Histidyl D-Tryptophanyl Dipeptide-29 D-Phenylalanyl Lysinamide.

    g. Peptide derivatives are named utilizing the parent peptide name, and the name of the modifying group as follows:

i. When the N-terminus is modified, the name of the modifying group precedes the peptide name, e.g., Myristoyl Hexapeptide-5, Palmitoyl Octapeptide-24

ii. When the C-terminus is modified, the name of the modifying group is identified after the peptide name according to its composition, e.g., Tripeptide-9 Citrulline, Caffeoyl Tetrapeptide-19 Caffeamide, Tetrapeptide-29 Argininamide, Acetyl Octapeptide-17 Amide, Tripeptide-83 Propyl Ester.

iii. When any hydroxyl group or amine group along the peptide chain is modified, it is named according to the composition of the reacting species.

g. Ingredients originating from human tissue, including materials starting with human cells in tissue culture, contain "human" as part of the INCI name. See 27(b). See 61(h) for ingredients made by recombinant technology.

h. Names for biologically inspired peptides are based on the source protein whether produced through recombinant techniques or chemical synthesis. Where there is alignment of a minimum of a 5 amino acid sequence of a peptide with a native protein and some homology to the parent protein throughout the peptide chain, the name for the peptide is based on the common name for the protein source. If there is alignment across many species, the name is based on the species of higher order.

The name is constructed by prefixes to designate recombinant and synthetic, followed by the peptide term as outlined in 61(a-f), followed by a number, whereby the number is unique and corresponds to the specific protein which is described in the ingredient definition.

i. The prefix "rh" is used to identify "recombinant human" peptides in which the original gene is isolated from a human cell, e.g., rh-Oligopeptide-1, rh-Polypeptide-, rh-Polypeptide-96. The terms "oligopeptide" and "polypeptide" are applied to the INCI name based on the number of amino acids in the sequence of the original gene.

ii. When the original gene is derived from another organism, the prefix "r-" is used, followed by the name of the organism, e.g., r-Mussel Polypeptide-1, r-Leucosporidium Polypeptide-1. The terms "oligopeptide" and "polypeptide" are applied to the INCI name based on the number of amino acids in the sequence of the original gene.

iii. When the gene is synthesized to be identical to a human gene and produced recombinantly, the prefix "sh" for "synthetic human" is used, e.g., sh-Polypeptide-96, sh-Oligopeptide-8. The terms "oligopeptide" and "polypeptide" are applied to the INCI name based on the number of amino acids in the sequence of the original gene.

iv. When the gene is a synthesized copy from another organism and the peptide is produced through recombinant technology, the prefix “sr-“ is used to indicate synthetic recombinant followed by the name of the organism, e.g., sr-Jellyfish Polypeptide-1, sr-Rice Polypeptide-1. The terms “oligopeptide” and “polypeptide” are applied to the INCI name based on the number of amino acids in the sequence of the original gene.

v. Biologically inspired peptides that are produced by chemical synthesis are designated by the prefix “s-“, followed by the name of the organism. The terms “oligopeptide”, “polypeptide” or “decapeptide” are applied to the INCI name based on the number of amino acids in the sequence of the final peptide, e.g., s-Centipede Decapeptide-1, s-Bovine Oligopeptide-1, s-Cod Oligopeptide-1. When the species is human, the prefix “sh” is used and the suffix “SP” is added to the name to indicate solid phase synthesis, e.g., sh-Oligopeptide-23 SP, sh-Pentapeptide-6 SP. The latter approach is employed to distinguish these peptides from earlier ones produced recombinantly as described in 60(h)(iii). In some cases, the suffix SP has been added to the peptide name for other organisms to further distinguish the synthetic nature of the peptide, e.g., s-Mussel Hexapeptide-1 SP, Acetyl s-Octopus Pentapeptide-1 SP.

vi. Peptides that are derived from two or more different peptides are considered fusion proteins. They are named by combining the INCI names of each appropriate individual peptide name, e.g., r-Clostridium Histolyticum Collagenase sh-Oligopeptide-60; r-Mussel Polypeptide-1 r-Mussel Oligopeptide-1 sh-Polypeptide-1.

i. Antibodies are immunoglobulins (Ig), composed of 4 polypeptide chains (2 “heavy" and 2 “light" chains) bound to each other by disulfide bonds. The heavy chains are typically glycosylated. Antibodies are not named as “polypeptides” due to their complexity and unique structure. Rather than amino acid sequence, they are named according to antigen specificity.

Antibodies (immunoglobulins) are named according to the antigen they specifically bind, the organism where they are raised or the hybridoma cells they are isolated from, and their type, whether monoclonal (from hybridoma cell cultures) or polyclonal (from serum). The basic naming approach is as follows: Anti-Protein/Antigen Organism Type Antibody. The common name for the antigen is used when available. As an example, a monoclonal antibody raised against Collagenase-1 in murine hybridoma is named: Anti-Collagenase-1 Mouse Monoclonal Antibody.

k. Proteins derived from a transgenic viable higher organism in which the gene expression is either stable or transient are named by the host organism, followed by the appropriate peptide name, and are defined by a transgenic process. Common names are often used to identify the host organism, e.g., Barley sh-Oligopeptide-1.

l. Peptides which maintain the full sequence of a protein and are sourced directly from an organism are identified by the name of the protein, e.g., Cobrotoxin, Alloferon-1.

m. Peptides which maintain the full sequence of a protein and are synthetically derived are

identified by the name of the protein with an "s-" prefix, e.g., s-Pentadiplandra Brazzeana Defensin-Like Protein, s-Mellitin, s-Mu-conotoxin CnIIIC.

n. Aptamers are synthetically produced single-stranded oligonucleotides that fold into a three-dimensional structure and bind to a specific target. They are named based on composition, e.g., DNA, RNA, followed by the term "aptamer" and a unique number, e.g., s-DNA Aptamer-2. The ingredient definition describes the number of constituent nucleotides and the target molecule to which it binds.

Transesters

62. Transesters are materials derived by the process of the transesterification of esters, usually triglycerides (fats and oils), and alcohols. They are generally identified by the term "esters", e.g., Apricot Kernel PEG-8 Esters, when the alcohol is less than a stoichiometric amount, there is no purification, and the material consists of a complex mixture of products, including mono- and di-glycerides and alcohols. Transesters can also be obtained by the transesterification of an oil with another oil, e.g., Moringa Oil/Hydrogenated Moringa Oil Esters. If a stoichiometric amount or excess of alcohol is used, the material will be named using Ester nomenclature, e.g., Ethyhexyl Cocoate.

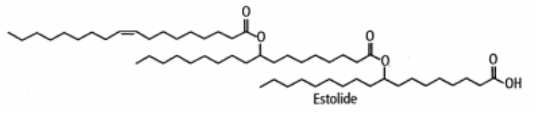
    A similar process is carried out by the process of the transamidation of esters, usually triglycerides (fats and oils), and amines. They are generally identified by the term "amides", e.g., Coconut Oil MIPA Amides, when the amine is less than a stoichiometric amount, there is no purification, and the material consists of a complex mixture of products, including mono- and di-glycerides and amides. If a stoichiometric amount or excess of amine is used and the reaction driven to completion, the material will be named using Amide nomenclature, e.g., Cocamide MIPA.

MISCELLANEOUS CONVENTIONS

63. Amidino is the root used to designate the structure R-C(NH2)=NH, e.g., Amidinoproline.

64. "Esylate" is the term used to designate ethanesulfonate, e.g., Sodium Esylate. "Tosylate" is the term used to designate toluenesulfonate, e.g., Cetrimonium Tosylate.

65. Estolides are esters formed by the acid catalyzed condensation of 2 or more hydroxyl fatty acids (e.g., 12-hydroxystearic acid), or by the acid-catalyzed condensation of 2 or more unsaturated fatty acids (e.g., oleic acid) to form oligomeric esters. The product is named "estolide" preceded by the name of the fatty acid which makes up the oligomer backbone.



Estolide

66. The compound commonly known as conjugated CLA is named as Isomerized Linoleic Acid.

67. Encapsulated materials are named as mixtures with the components identified in order of predominance.

68. Solutions that are characterized as the dispersion of very small particles in a continuous phase that remain suspended are named colloids, e.g., Colloidal Silver, Colloidal Platinum.

69. Zwitterions are internal salts and are identified as “betaines” and “sultaines”, e.g., Cocamidopropyl Betaine, Cocamidohydroxypropyl Sultaine.

70. Hydrocarbons derived by the complete hydrogenation of an unfractionated fatty acid are named according to the source of the fatty acids, e.g., Coconut Alkanes. See also Conventions 20 and 21.

71. “Lactylate” is the combining term used to describe the ester formed between two moles of lactic acid, e.g., Sodium Stearoyl Lactylate, Sodium Cocoyl Lactylate.

72. “Ascorbate” is used in INCI names for ingredients produced by the reaction of an alcohol with ascorbic acid to form an ether, e.g., Caprylyl 3-Glyceryl, or when a salt of ascorbic acid is formed, e.g., Calcium Ascorbate. “Ascorbyl” is used for esters between ascorbic acid and a fatty acid or phosphoric acid, e.g., Ascorbyl Stearate. Exceptions include the INCI names 2-O-Ethyl Ascorbic Acid, 3-O-Ethyl Ascorbic Acid, 3-O-Cetyl Ascorbic Acid.

73. Process terms are not usually utilized in INCI nomenclature, e.g., “heat-induced”. Exceptions include terms such as acetylated, epoxidized, extract, ferment, hydrolyzed, hydrogenated, lysate, ozonized.

74. For products marketed in the EU which contain ingredients that meet the definition for a nanomaterial as identified by the EC Regulation No. 1223/2009, the INCI name (Nano) may be applied as a suffix to the corresponding INCI name. For example, usage of titanium dioxide that meets the EC definition for nano would be declared on the finished product label as Titanium Dioxide (Nano).

75. Lactones are generally preceded by a Greek letter prefix to indicate the size of the lactone ring, e.g., Gamma- Caprolactone, Delta-Decalactone.

76. Glycosides are compounds which consist of a sugar (glycone) linked to a non-sugar or alcohol (aglycone) through a glycosidic bond formed through the condensation. The resulting compound is a named by the aglycone term first, followed by the sugar, where the “ose” suffix of the sugar name is replaced by “oside”. When the glycone is glucose, the resulting compound is named as a glucoside, e.g., Decyl Glucoside. Glucoside**s** is used when the sugar is a polymer of glucose. When the glycone is xylose, the compound is named as a xyloside, e.g., Octyldodecyl Xyloside, maltose would be a maltoside, etc.

    When the aglycone is a complex material, such as a flavonoid or a ceramide, the sugar term precedes the aglycone, Glucosyl Hesperidin, Glucosyl Naringen, Glucosyl Ceramide NP, etc. Early exceptions to this convention include the names Phloridzinyl Glucoside, Polydatin Glucoside.

    When the glycone is comprised of carbohydrates derived from a natural source, the material is named as a “glycoside”, preceded by the aglycone term, e.g., Cetearyl Wheat Bran Glycosides. Naturally occurring plant glycosides (e.g., saponins) may be named by their common or usual name, e.g., Ziyu Glycoside I.

LIST OF ACRONYMS

AEEA	Aminoethylethanolamine
AMP	Aminomethylpropanol
AMPD	Aminomethylpropanediol
AMPS	2-Acrylamido-2-Methylpropane Sulfonic Acid (Acryloyldimethyltaurate)
BHA	Butylated Hydroxyanisole
BHT	Butylated Hydroxytoluene
CD	Completely Denatured
CHDM	Cyclohexanedimethanol
CI	Colour Index
DATEM	Diacetyl Tartaric Acid Esters of Mono- and Diglycerides
DBM	Dibutylmaleate
D&C	Drug and Cosmetic
DEA	Diethanolamine
DEDM	Diethylol Dimethyl
DIBA	Dihydroxyisobutylamine
DIPA	Diisopropanolamine
DM	Dimethyl
DMAP	Dimethyl Aminopropyl
DMAPA	Dimethyl Aminopropylamine
DMDM	Dimethylol Dimethyl Dimethyl Hydantoin
DMHF	Formaldehyde Resin
DMPA	Dimethylolpropionic Acid
DMSO	Dimethyl Sulfoxide
DNA	Deoxyribonucleic Acid
ds	Double-stranded
DVB	Divinylbenzene
EDTA	Ethylenediamine Tetraacetic Acid
EDTHP	Ethylenediamine Tetrahydroxy Propylene
EDTMP	Ethylenediamine Tetramethylene Phosphonate
Ext. D&C	External Drug and Cosmetic
FD&C	Food, Drug, and Cosmetic
GLY	Glycine
HBr	Hydrobromide
HC	Hair Color
HCl	Hydrochloride
HDI	Hexamethylene Diisocyanate
HEA	Hydroxyethyl Acrylate
HEDTA	Hydroxyethyl Ethylenediamine Triacetic Acid
HEMA	Hydroxyethyl Methacrylate
HPMA	Hydroxypropyl Methacrylate
IPDI	Isophorone Diiisocyanate
MA	Maleic Anhydride
MDI	Methylene Diphenyl Diisocyanate

MDM	Monomethylol Dimethyl
MEA	Monoethanolamine
MEK	Methyl Ethyl Ketone
MIBK	Methyl Isobutyl Ketone
MIPA	Monoisopropanolamine
NTA	Nitrilotriacetic Acid
PABA	para-Aminobenzoic Acid
PCA	Pyrrolidone Carboxylic Acid
PEG	Polyethylene Glycol
PEI	Polyethylenimine
PG	Propylene Glycol
PPG	Polypropylene Glycol
PTFE	Polytetrafluoroethylene
PVM/MA	Polyvinyl Methyl Ether/Maleic Anhydride
PVP	Polyvinylpyrrolidone
RNA	Ribonucleic Acid
SD	Specially Denatured
SE	Self-Emulsifying
SIP	Sulfoisophthalate
SMDI	Saturated Methylene Diphenyldiisocyanate
TAED	Tetraacetylethylenediamine
TBHQ	tert-Butyl Hydroquinone
TDI	Toluene Diisocyanate
TEA	Triethanolamine
TIPA	Triisopropanolamine
TMHDI	Trimethylhexanediisocyanate
TMMG	Tetramethoxymethylglycouril
TMP	Trimethylolpropane
VA	Vinyl Acetate
VP	Vinyl Pyrrolidone

LIST OF INFORMATION SOURCES

BAN	British Approved Names as noted in USAN
BP	British Pharmacopoeia, BPC
CCIH	Canadian Cosmetic Ingredient Hotlist of Health Canada
21CFR	Title 21 of the U.S. Code of Federal Regulations, Food and Drugs
27CFR	Title 27 of the U.S. Code of Federal Regulations, Alcohol, Tobacco Products and Firearms, Part 20 - Distribution and Use of Denatured Alcohol and Rum, and Part 21 - Formulas for Denatured Alcohol and Rum
40CFR	Title of the U.S. Code of Federal Regulations, Protection of Environment
CI	The Colour Index
CIR	Cosmetic Ingredient Review, 1620 L St., NW, Washington, DC 20036-4702; ingredients included in a published Final Report. Journal citations include: Journal of the American College of Toxicology (JACT), Journal of Environmental Pathology and

	Toxicology (JEPT), and International Journal of Toxicology (IJT). Final Reports published by CIR, prior to inclusion in a scientific journal, are noted without a journal citation. The letter in brackets [ ] indicates the category of conclusion reached by the CIR Expert Panel for a particular ingredient.
CIR: [I]	CIR conclusion: “insufficient data to determine safety for use in cosmetics”
CIR: [I-UNS]	CIR conclusion: "use not supported by the data and information submitted to CIR"
CIR: [I-Z]	CIR conclusion: "insufficient data and no reported use in the FDA data base"
CIR: [S]	CIR conclusion: “safe for the uses identified and included in the Report at the time of the review”
CIR: [SQ]	CIR conclusion: “safe for use subject to specific qualifications enumerated in the conclusion”
CIR: [U]	CIR conclusion: “unsafe for use in cosmetics
CIR: [R]	CIR conclusion: “re-review for which the previous conclusion was confirmed”
CLP	Classification of Substances in Annex VI, Regulation (EC) No., 1272/2008
CTFA D	CTFA Compendium, Descriptions (4th Edition, 1990)
CTFA S	CTFA Compendium, Specifications (4th Edition, 1990)
EC	Regulation (EC) No. 1223/2009 of the European Parliament, Annexes II through VII
ECG	Regulation (EC) No 1223/2009 of the European Parliament, Glossary of Common Ingredient Names, March 2022
ECHA-R	European Chemicals Agency-Registered
Entrez GENE	NCBI Data Base for Gene-Specific Information
EP	European Pharmacopeia
FCC	Food Chemicals Codex
GenBank	Gene Bank, National Institutes of Health, Genetic Sequence Data Base
IECIC	Inventory of Existing Cosmetic Ingredients in China, 2021
IJT	International Journal of Toxicology
INN	International Nonproprietary Names for Pharmaceutical Substances, World Health Organization (WHO) Geneva
JAN	Japanese Accepted Names as noted in USAN
JCIC	Japanese Cosmetic Ingredients Codex,1993; and Supplements 1995 and 1997
JCLS	The Comprehensive Licensing Standards of Cosmetics by Category, 1994, and draft Ninth Amendment, 1996.
JID-1	Journal of Investigative Dermatology, 84, 410-412 (1985)
JP	The Pharmacopoeia of Japan
JSCI	Japanese Standards of Cosmetic Ingredients, 1985; Second Edition Supplement, 1986; Second Edition Supplement II, 1992.
JSQI	Japanese Standards of Quasi-Drug Ingredients, 1991
M3	Mitteilung 3, Third Report of the Dye-Stuff Commission of Colors for Cosmetics, German Research Association, 1968, Amended 1971
MF	Japan Ministry of Finance (MF) Ordinance No. 11/1937, on Regulation on the Sales of Alcohol
MHLW	Japan Ministry of Health, Labor, and Welfare (MHLW) Ordinance No. 30 (August 31, 1966) as amended by MHLW Ordinance No. 55 (December 13, 1972), On Coal-Tar Colors Permitted for Use in Drugs
MHLW-331	Japan Ministry of Health, Labor, and Welfare (MHLW) Ordinance No. 331
MI	Merck Index
MINIMATA	MINIMATA Convention Treaty on Mercury
NCBI	National Center for Biotechnology Information, Genome

NF	National Formulary
NFJ	National Formulary of Japan
OTC-I-AA	Antacid Drug Products for Over-the-Counter Human Use; Final Monograph; U.S. 21 CFR 331
OTC-I-AC	Anticaries Drug Products for Over-the-Counter Human Use; Final Monograph; U.S. 21 CFR 355
OTC-I-AF	Topical Antifungal Drug Products for Over-the-Counter Human Use; Final Monograph; U.S. 21 CFR 333.201
OTC-I-AK	Topical Acne Drug Products for Over-the-Counter Human Use; Final Monograph; U.S. 21 CFR 333.301
OTC-I-AL	Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Healthcare Antiseptic Drug Products; U.S. FR 31402-52
OTC-I-AM	Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for First Aid Antiseptic Drug Products; U.S. 56 FR 33644-80; Topical Antimicrobial Products, 43 FR 1210
OTC-I-AP	Antiperspirant Drug Products for Over-the-Counter Human Use; Final Monograph; U.S. 21 CFR 350
OTC-I-AR	Anorectal Drug Products for Over-the-Counter Human Use; Final Monograph; U.S. 21 CFR 346
OTC-I-AS	Skin Protectant Drug Products for Over-the-Counter Human Use; Final Monograph; U.S. 21 CFR 347
OTC-I-CR	Corn and Callus Remover Drug Products for Over-the-Counter Human Use; Final Monograph; U.S. 21 CFR 358.501
OTC-I-CT	Cough, Cold, Allergy Bronchodilator and Antiasthamatic Drug Products for Over-the-Counter Human Use; Final Monograph; U.S. 21 CFR 341
OTC-I-CV	Vaginal Contraceptive Drug Products for Over-the-Counter Human Use; See notice U.S. 55FR46919 (November 7, 1990) and U.S. 21 CFR 310.545 (28)
OTC-I-DE	Deodorant Drug Products for Internal Use for Over-the-Counter Human Use; Final Monograph; U.S. 21 CFR 357.801
OTC-I-DP	Dandruff, Seborrheic Dermatitis, and Psoriasis Drug Products for Over-the-Counter Human Use; Final Monograph; 21 CFR 358.
OTC-I-EA	External Analgesic Drug Products for Over-the-Counter Human Use, 21CFR 346.3, 346.10, and 346.16.
OTC-I-IA	Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; U.S. 21 CFR. 343
OTC-I-LX	Laxative Drug Products for Over-the-Counter Human Use; Tentative Final Monograph; US 50 Federal Register 2124-58 (January 15, 1985), amended 58 Federal Register 46598-96 (September 2, 1993), amended 59 Federal Register 15139-42 (March 31, 1994)
OTC-I-MD	Orally Administered Menstrual Drug Products for Over-the-Counter Human Use; Tentative Final Monograph; US 53 Federal Register 46194-202 (November 16, 1988)
OTC-I-OD	Oral Health Care Drug Products for Over-the-Counter Human Use; Tentative Final Monograph; 59 Federal Register 6084-124 (February 9, 1994) oral antiseptic drug products; Amendment to Tentative Final Monograph to Include OTC Relief of Oral Discomfort Drug Products; US 56 Federal Register 48302-47 (September 24, 1991)
OTC-I-OH	Oral Health Care Drug Products for Over-the-Counter Human Use; Tentative Final Monograph; US 53 Federal Register 2436-61 (January 27, 1988)

OTC-I-OP	Ophthalmic Drug Products for Over-the-Counter Human Use; Final Monograph; U.S. 21 CFR 349
OTC-I-OR	Orally Administered Drug Products for Relief of Symptoms Associated With Overindulgence in Food and Drink for Over-the-Counter Human Use; Tentative Final Monograph; US 56 Federal Register 66742-51 (December 24, 1991), amended 58 Federal Register 26886-88 (May 5, 1993)
OTC-I-TO	Topical Otic Drug Products for Over-the-Counter Human Use; Final Monograph; U.S. 21 CFR Part 344
OTC-I-SB	Skin-Bleaching Drug Products for Over-the-Counter Human Use; Tentative Final Monograph; US 47 Federal Register 39108-17 (September 3, 1982)
OTC-I-SK	Skin Protectant Drug Products for Over-the-Counter Human Use; Final Monograph; U.S. 21 CFR 347
OTC-I-ST	Stimulant Drug Products for Over-the-Counter Human Use; Final Monograph; U.S. 21 CFR 340
OTC-I-SU	Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph; 21 CFR 352
OTC-I-WR	Wart Remover Drug Products for Over-the-Counter Human Use; Final Monograph, U.S. 21CFR358
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals, (EC No. 1907/2006), Annexes IV, V and XIV
RIFM	Research Institute for Fragrance Materials
TSCA	Toxic Substances Control Act Chemical Substance Inventory
USAN	United States Adopted Names
UNII	Unique Ingredient Identifier; FDA/ USP Substance Registration System (SRS) for substances in drugs, biologics, foods and devices
Uniprot	Universal Protein Resource
USP	The United States Pharmacopoeia
WHO	World Health Organization

GLOSSARY OF ORGANS AND PARTS OF PLANTS AND FUNGI

Adventitious root: secondarily produced roots that grow from non-root organs

Aril: fleshy seed cover or fleshy appendage of a seed

Bark: tough protective covering of the woody stems and roots of trees and other woody perennial plants, consisting of cells produced by a cork cambium

Bean: fruit of the legume family (Fabaceae), a special type of capsule; also used for the seed of a legume

Berry: a fleshy fruit with (usually) many seeds, and that does not open to release seeds, (note: 'juniper berries' are fleshy cones, not fruits)

Bract: a modified leaf associated with a flower or inflorescence, often different in shape, form and/or color compared to regular leaves on the plant

Bran: the outer hard layers of the grain formed by the fused fruit and seed wall in grains and cereals (Poaceae)

Bud: a not yet developed shoot in the axil of a leaf, often covered with scales; a young flower that not yet has opened

Bulb: underground fleshy storage part of plant consisting of a very short stem and fleshy leaves covered by dried leaves.

Callus: an undifferentiated mass of cells (see callus culture); a thickened area of an organ of a plant; thickened scar tissue that covers a wound in a plant

Callus culture: an undifferentiated mass of cells produced through tissue culture

Calyx: the collective term for all sepals, the outermost parts of a flower

Capsule: a dry fruit that opens to disperse (usually many) seeds

Carpel: one or several carpels form the pistil; the organ consisting of the ovary, style, stigma, and ovules in flowering plants; female reproductive organ in flowers

Cell: the smallest functioning unit of organismal life; an eukaryotic cell includes at least a nucleus and a mitochondrion (both with DNA) and is surrounded by a cell wall

Clove: a segment of a bulb

Cob: a tightly packed spike-formed inflorescence with sessile grains (fruits) of the corn plant (*Zea mays*, Poaceae)

Cone: the part of a conifer that contains the seeds, ovules, or pollen-bearing organs, situated on bracts, usually dry, rarely fleshy

Cork: specialized water-repellent outermost layer of bark

Corolla: the collective term for all petals, the parts of a flower that are inside the sepals

Cotyledon: the first leaf of a seed plant

Drupe: a fleshy (usually one-seeded) fruit with a hard 'stone' surrounding the seed

Endosperm: energy storage tissue inside seeds

Embryo: the fertilized egg in the seed develops into an embryo which can germinate and grow into a seedling

Fiber: elongated, insoluble cells in plants, often divided into soluble and insoluble fibers

Flower: the reproductive shoot in flowering plants, usually with sepals, petals, stamens, and pistil(s)

Flower nectar: sugary solution secreted inside a flower

Frond: a fern leaf

Fruit: mature, ripened ovary of flowering plant, containing seeds

Fruit peel: fruit wall; fruit skin

Fruiting body: the body of a fungus

Gall: abnormal growth of plant tissue caused by insects, microorganisms, viruses, injury, etc.

Germ: the embryo in a seed; the part of a seed that can develop into new plant

Grain: dry one-seeded fruits produced by grasses (Poaceae), e.g., cereals such as wheat, barley, corn

Gum: water soluble solids produced by plants

Hairy root: the fine fibrous roots that develop from the infection of a root

Hip: fruit of a rose (Rosa sp., Rosaceae), formed from the thickened cup-shaped base of the flower, the hypanthium

Hull: a dry outer covering of a fruit or seed

Husk: a dry outer covering of a fruit or seed

Hyphae: the threads that form fungal mycelium, part of the non-fruiting bodies of fungi

Inflorescence: a branching or unbranched part of the plant where the flowers are attached

Juice: the liquid contained in the vegetative parts or fruits

Kernel: the softer part of the seed inside a harder cover in drupes or nuts; the grain of a grass (Poaceae)

Latex: a fluid produced by plants, often milky and white

Leaf: flattened photosynthetic organs, attached to stems

Legume: fruit of the legume family (Fabaceae), a special type of capsule
Liquid endosperm: energy storage tissue inside a seed that is in liquid form
Meristem: growth zone in plant organs consisting of undifferentiated, dividing cells
Meristem cell: young, dividing cells that can form many types of mature cells ('stem cells')
Mycelium: the hyphae of fungus
Nectar: sugary liquid produced in flowers or by other organs
Needle: needle-like leaf, common in conifers
Nut: dry fruit with one seed in which the fruit wall becomes very hard at maturity and does not open
Oleosomes: organelles in plant cells that store fatty and oily compounds
Palm heart: inner core of the stem of various palm species (Arecaceae)
Pedicel: the flower stalk
Petiole: the leaf stalk
Peduncle: the flower or fruit stalk
Petal: one of several parts (free or fused) of a flower that are inside the sepals, but outside the anthers and pistil, the corolla is formed from petals
Peel: the fruit wall of a fruit; the rind in *Citrus* fruits (Rutaceae)
Pericarp: fruit wall; ripened walls of a plant ovary/fruit, consists of exocarp (peel), mesocarp ("fruit") and endocarp (surrounds seed)
Pigment: chemical compound that provides a color
Pistil: the carpel, sometimes formed from fused carpels; the organ consisting of the ovary, style, stigma, and ovules in flowering plants
Phytoplacenta: novel word for placentas from plants, used in INCI to indicate a plant-sourced placenta as opposed to animal-sourced (the word phytoplacenta is not used in botanical literature)
Placenta: the part of the fruit where the seeds attach, sometimes enlarged, fleshy, and differently colored
Pod: a dry fruit that opens to expose the seeds
Protocorm : a tuber-like mass of cells that develop from the embryo and a precursor to the adult plant (found in orchids and clubmosses)
Pulp: a soft, fleshy part of a fleshy fruit, often formed by the fruit wall or the placenta (note, the term fruit may be used in INCI names, depending on context)
Resin: a viscous, non-water-soluble secretion (exudate) from a plant
Rhizome: a horizontal, underground plant stem that can develop adventitious roots and branches
Root: organ of a plant that absorbs and transports water and nutrients, lacks leaves and nodes, usually underground
Sap: the fluid transported through the vascular system of a plant
Seed: a propagating sexual structure resulting from the fertilization of an ovule, formed by embryo, endosperm, or seed coat. Some seeds can be derived from non-sexual reproduction through apomixis and similar processes.
Seed coat: seed wall; testa; protective outer layer of seed, formed from the integuments (outer layers of the ovule)
Seedling: a very young plant, developed from a germinated seed (embryo)
Shell: the hard, usually fibrous layer of some fruits, especially nuts or the stones of drupes
Shoot: growing branch with leaves and/or reproductive structures
Shoot sheath: sheath protecting developing shoots in grasses (Poaceae), developed from leaves
Silk: the silky, long styles of corn (*Zea mays*, Poaceae)
Skin: the surface membrane surrounding an organ, such as fruit or bulb (e.g., grape, onion)

Spore: a cell that can develop into a gametophyte, often with a thick cell wall
Sporangia: the spore-forming part in spore plants
Sprout: seedling; germinating seed; any new growth of a plant from a stem such as a new branch or a bud
Stalk: the stem of an herbaceous plant; the stalk below a flower or inflorescence
Stamen: the male reproductive organ in flowers, usually formed by a filament and anther
Stem: a slender or elongated structure that supports a plant or fungus or a plant part or plant organ.
Stolon: above-ground horizontal stem
Stone cell: isolated, heavily lignified rounded cells of the sclerenchyma type (common in pear fruits)
Straw: the stem of a grass (Poaceae) or related families
Strobili, strobilus: a reproductive cone-like structure, formed by overlapping bracts, characteristic of conifers, lycopods, horsetails, and hops (*Humulus*)
Style: a slender part of the pistil situated between the ovary and stigma
Symbiosome: the root nodule in legumes that contain symbiotic bacteria and the surrounding plant wall; within a plant cell, the vacuole that contains symbiotic bacteria (the symbionts) through endocytosis
Thallus: the part of a plant that is not developed into leaves, stems, roots, and other organs, often rather undifferentiated and flat (mostly used for algae and liverworts)
Tuber: a fleshy, enlarged piece of the rhizome or root
Twig: small branch or subdivision of a branch
Vine: a climbing plant; climbing part of plant
Wood: parts of woody stems or branches formed by lignification of cells
Xylem: the part of a vascular system in plants that transport mostly water

REGULATORY AND INGREDIENT USE INFORMATION

The INCI nomenclature system continues the use of ingredient names established to minimize the differences in the nomenclature recognized by regulatory authorities in the United States and the European Union (EU) and Japan. The following discussion is included for reference. Readers should also consult applicable national laws and regulations to ensure the INCI names used for labeling are appropriate for their intended markets. The types of ingredients most frequently affected by differing regulatory approaches are:

Colorants
Botanicals (Plant-Derived Ingredients)
Denatured Alcohols
U.S. Over-the-Counter (OTC) Drug Ingredients
Trivial Names
Fragrances/Parfum
Flavors/Aromas

Labeling names for ingredients in the above categories intended for sale in the United States may be different from those intended for sale in the European Union, Japan, or in other countries. Additional information on the labeling requirements for products marketed in the United States may be found in the Council's *Labeling Manual*. Information on the regulatory status of colorants in the

United States and many other countries may be found in the Council's *International Color Handbook*, Fourth Edition (2007). A reference guide to the cosmetic laws, regulations, and information sources for many countries may be found in the *International Regulatory/Resource Manual*, Sixth Edition (2007). The Council's online data bases are also excellent sources of comprehensive information: *InfoBase,* and the *IRDB.*

Colorants

U.S. Color Additives

The term "color additive" is defined, in part, by U.S. law as a material which:

(A) is a dye, pigment, or other substance made by a process of synthesis, or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and;
(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substances) of imparting color thereto. *Federal Food, Drug, and Cosmetic Act*, (FD&C Act) Section 201(t)(1).

In the United States, a cosmetic containing a colorant (except a coal-tar hair dye) that is not approved by the FDA is regarded as "adulterated" and subject to regulatory action by FDA. *Federal Food, Drug, and Cosmetic Act*, Section 601(e).

> NOTE -*An exception to this requirement exists for "coal-tar" (synthetic organic) colorants used in hair dyes, provided other regulatory requirements are met (see information in this section under U.S. Hair Colorants and the U.S. Hair Dye Exemption)*.

U.S. Color Additives approved for use in the United States are listed in Title 21 of the U.S. *Code of Federal Regulations*, 21 CFR, Parts 73, and 74.

A listing of the INCI names of U.S.-approved colorants may be found in the *Dictionary*, under Chemical Classes, listed under the following headings:

- ColorAdditives -Batch Certified by the U.S. Food and Drug Administration
- ColorAdditive Lakes -Batch Certified by the U.S. Food and Drug Administration
- ColorAdditives -Exempt from Batch Certification by the U.S. Food and Drug Administration

Color Additives Subject to Batch Certification

With the exception of "coal-tar" hair dyes, all "synthetic organic" color additives are subject to batch certification by the FDA. Each batch of an approved synthetic organic colorant must be tested and certified by the FDA as meeting standards and specifications found in 21 CFR 74.

Color Additives Exempt from Batch Certification

Some U.S.-approved colorants are exempt from batch certification by the FDA. In order to be legally used in the U.S., however, these colorants must meet specification and use restrictions stipulated in 21 CFR 73.

Abbreviated Labeling Names for U.S. Colorants

Official names for colorants subject to batch certification may be found in the listing of the color

additive in 21 CFR Parts 74, and 82. These names must be used by the colorant manufacturer to identify the color additive product (or raw material) that has been batch certified by the FDA. As discussed below, FDA currently does not object to abbreviated labeling for declaring the presence of certified batches of color additives in cosmetics. See http://www.fda.gov/cosmetics/cosmeticlabelinglabelclaims/industryrequestsfdaresponses/ucm075074.htm.

FDA originally proposed the use of abbreviated names for U.S. colorants in the *Federal Register* on June 6, 1985 (50 FR 23815). At that time, the FDA stated that firms may use the abbreviated names on product labels. By correspondence, dated June 7, 1999, the FDA reaffirmed its intention to permit cosmetic firms to use the abbreviated names on product labels while a final rule on the matter is pending. The abbreviated labeling names apply only to U.S. color additives that are subject to batch certification. Under this scheme, the cosmetic product manufacturer does not have to include "FD&C" or "D&C," "No.," or the type of lake "Aluminum, Zirconium, etc.," on their product labels. However, for color additive lakes, the term "Lake" must be included in the declaration. Examples of the abbreviated and the original names associated with U.S. colorants are:

Blue 1 or FD&C Blue No. 1
Red 6 or D&C Red No. 6
Ext. Violet 2 or Ext. D&C Violet No. 2
Red 40 Lake or FD&C Red No. 40 Aluminum Lake

Other Restrictions for U.S. Color Additives
There may be specific use restrictions for some U.S. approved colorants, such as: "for external use except eye area." Restrictions for U.S. approved colorants may be found in 21 CFR 73, and 74.

Proposed Use of CI Numbers for Labeling Color Additives in the U.S.
The Council has asked the U.S. FDA to recognize the advantages of allowing the use of Colour Index or CI numbers for labeling color additives on cosmetic products in the U.S. We believe that this would provide greater transparency in labeling and better value comparison under the U.S. FPLA. Current FDA policy specifies the listing of the appropriate U.S. name first, followed by the related CI number in parentheses. Users are instructed to use the formal or abbreviated nomenclature identified in the *Dictionary* for labeling color additives in the U.S. Prior to labeling changes, the user is encouraged to contact the Council for the most recent information on this issue. For additional information, see http://www.fda.gov/cosmetics/cosmeticlabelinglabelclaims/industryrequestsfdaresponses/ucm075032.htm.

EU Colorants

Colorants approved for use in the EU may be found in Annex IV of Regulation (EC) No. 1223/2009 of the European Parliament and the Council on Cosmetic Products. A listing of the INCI names for EU-approved colorants may be found in the *Dictionary*, under Chemical Classes, listed as Colorants - Approved in the EU.

Some approved EU colorants are chemically similar to those approved for the U.S.; however, their specifications and use limitations may differ. With a few exceptions, colorants are listed in Annex IV by their Colour Index numbers. The INCI labeling name for lakes and salts of EU colorants, not otherwise prohibited in Annex II or regulated by Annex V, is the same CI number as the colorant

found in Annex IV, without reference to the laking agent or salt. Some EU-approved colorants are subject to use restrictions. For example, use restrictions may prohibit use of a colorant in the eye area or on mucous membranes. The use restrictions for EU-approved colorants may be found in Annex IV.

Harmonized INCI Names for Colorants for U.S. and EU Markets

Industry previously proposed that a dual declaration of colorants with both the U.S. name and the EU name be allowed on labels of those cosmetic products intended for sale in both the U.S. and EU markets. Examples of harmonized names are as follows:

- Green 3 (CI 42053)
- Ultramarines (CI 77007)

NOTE: Although the U.S. FDA has indicated a willingness to accept this approach as an interim step while it considers the question of harmonized ingredient labeling, readers are directed to consult with authorities in EU member states to verify EU acceptance.

Persons using harmonized INCI labeling names on products intended for the U.S. and EU markets must ensure that the colorants conform with regulatory requirements for the U.S. and the EU, i.e., batch certification from FDA where required, and/or EU Annex IV limitations and requirements, which may differ.

Japan Colorants

Colorants approved for use in Japan include synthetic organic colorants regulated by the *Ordinance to Regulate Coal-Tar Colors Permitted for Use in Drugs, Quasi-drugs, and Cosmetics (Ministerial Ordinance No. 30 of 1966 as amended by MHLW Ordinance No. 126 of 2003*). A listing of approved Japan colorants may be found the Information List area under Chemical Classes, Color Additives - Approved in Japan.

While many of these colorants approved for use in Japan are chemically similar to those allowed for use in the U.S. and the EU, their specifications and use restrictions may differ. The INCI names for each type of Japan colorant, the straight colorant and each metal salt or lake of a straight colorant (e.g., sodium, potassium, calcium, barium, including the lakes) are assigned a different Japan colorant name. This is in contrast to EU colorants where the Colour Index Number includes the straight colorant and its salts or lakes. The U.S. colorant INCI names identify the straight colorant and its lakes by separate names, e.g., Red 22 for the straight color and the lake as Red 22 Lake without identification of the type of lake. *These differences must be noted when attempting to correlate colorants approved in Japan with those in the EU and the U.S.* To assure proper identification of the colorants, the individual monographs of each colorant should be consulted along with the Colorant Cross Index in the Information List area.

The U.S. Hair Dye Exemption

U.S. laws and regulations prohibit any cosmetic product intended for sale and distribution in the U.S. from containing a colorant that has not been previously approved by the FDA. An exception to this prohibition exists for “coal-tar” (synthetic organic) hair dyes in products whose labels display the

following statement:

“Caution - This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing eyelashes or eyebrows; to do so may cause blindness.” *Federal Food, Drug, and Cosmetic Act*, Section 601(a).

In addition to the above caution statement, the labeling must include adequate directions for conducting the “preliminary test.” The term “hair dye” specifically does not include eyelash or eyebrow dyes. *Federal FD&C Act*, Section 601(a).

“Coal-tar” is a historical term used in U.S. regulations that relates most synthetic organic chemicals to their original coal source. Today most of these colorants are synthesized from chemicals derived from petroleum sources. “Coal-tar” dyes do not include colorants derived from vegetable substances or metallic salts, such as henna, lead acetate, and bismuth citrate. Such ingredients do not fall under the “coal-tar” hair dye exemption under U.S. Regulations (U.S. 38 *Federal Register* 2996, January 1, 1973). The use of vegetable substances and metallic salts require FDA approval before use as a colorant for hair.

Botanicals

In the U.S., INCI names for botanicals often include a parenthetical English common name after the scientific name. The reason for the inclusion of the common name originates with the intent of the U.S. FPLA (Fair Packaging and Labeling Act) which calls for the usage of terms that are recognizable to the consumer. The parenthetical English common name is omitted for the labeling of INCI names in the EU. The following discussion is included to clarify the evolution of botanical names in INCI nomenclature.

INCI names for plants, fungi and algae are based on the Linnaean binomial system which uses a scientific genus and species name to identify an organism and its place in the biological taxonomy of life. Scientific names of wild botanical species are ruled by the International Code of Nomenclature for Algae, Fungi, and Plants, and cultivated plants are covered under the International Code of Nomenclature for Cultivated Plants. Scientific names have often been called Latin names, but the origin of the words in the name can be Greek as well as modern languages.

There are notable differences between INCI names and scientific names. The special punctuation, formatting, and rules called for in the taxonomic codes for scientific names are not utilized in INCI nomenclature in order to facilitate the ease of creating finished product labels for cosmetic products. For example, the scientific codes call for the scientific genus and species term to appear in italics, with the genus term capitalized and the species name in lower case (e.g., *Cocos nucifera*). In the biological nomenclatures, species can be split into varieties or subspecies, which is indicated by the abbreviation "var." or "ssp. / subsp." before the variety or subspecies name. Hybrids resulting from the cross-breeding between species are identified by the symbol “×” between each parent species name or before a special hybrid epithet (e.g., *Mentha* x *piperita*). Particular types of cultivated plants are indicated with group names, cultivar names, patent names, or trademark names, which not always are reflected in the INCI name (e.g., *Brassica oleracea* Italica Group).

Another departure from the scientific binomial system is the inclusion of the English common name in parentheses for many INCI names. Originally, the INCI names for plants were designated by their English common name. During the 1990s when the change was made to follow the Linnaean system, it was decided to retain the English common name in parentheses in order to harmonize the original names with the new science-based names (e.g., Cocos Nucifera (Coconut) Oil). As a matter of practice, the parenthetical term is only included for plants in the INCI system that already had the common name included. Further distinction is the inclusion of plant parts in INCI names (Bambusa Vulgaris Leaf/Stem Extract), and the use of slash marks to separate multiple plant parts, neither of which is indicated in the scientific names, which applies to the organism as a whole. The INCI conventions for botanicals are fully described in the Conventions Section.

Due to the dynamic nature of evolutionary plant classification and research, the scientific nomenclature for plants is continually being updated based on new research results. With the advent of new DNA-based and computer-assisted methods, species relationships can now be investigated in more detail, and the results have shown that many traditional scientific names need to be changed since some plants were not previously classified into natural, evolutionary groups. In cases where the species has to be placed in a different genus, the genus name changes, and sometimes the species name changes (e.g., from *Butyrospermum parkii* to *Vitellaria paradoxa*). If two species are merged, the younger name becomes a synonym. This has also led to the reclassifying and recircumscription of some families, which in the long run will lead to a more stable system of scientific names, and ultimately related INCI names.

Denatured Alcohol

"Alcohol Denat." is the established INCI labeling name for ethyl alcohol that is denatured (rendered non-potable) in accordance with national regulations in the EU member states and in the United States.

In the United States, the names and formula specifications for specially denatured (SD) alcohols, e.g., SD Alcohol 40-D, are listed in the U.S. Department of the Treasury Regulations under Title 27, U.S. *Code of Federal Regulations*, Parts 20 and 21 (27 CFR 20 and 21). The monographs for the SD alcohols provide information on the denaturants required to be used in the United States.

For the U.S. market, labelers may use either the specific "SD Alcohol" names or "Alcohol Denat." on product labels, however the regulations codified in 27 CFR Parts 20 and 21 must be followed. For products intended to be marketed in the United States and the EU, the name "Alcohol Denat." should be used.

The Cosmetic Drug Distinction and U.S. OTC Drugs

Many countries have regulatory requirements for cosmetics that are different from products that may function as drugs or have medicinal properties. Frequently, countries also define cosmetic and drug functions differently. The reader is directed to consult the laws and regulations of the region where a product is intended for market to ensure compliance.

In general, a substance or product that is intended to significantly affect the structure or function of the body, or to treat or cure disease is regulated as a drug. In contrast, a substance or a product that is intended to cleanse, promote attractiveness, or temporarily alter the appearance of the body is

regulated as a cosmetic. In the U.S., the intended function for an ingredient or finished product is determined on the basis of claims made by the finished product manufacturer; the claims or other representations made for a product ultimately determine its classification and how it is regulated. The reader is directed to consult the Personal Care Products Council *Labeling Manual*, 9th edition, 2013, for further information.

Some functions for ingredients listed in the *Dictionary*, may cause products containing them to be subject to drug, quasi-drug, "functional," or other regulations in addition to the basic regulations required for cosmetics. Examples of such functions in the U.S. are the OTC drug functions published in the *Dictionary*: antiacne, anticaries, antidandruff, antifungals, antimicrobials, antiperspirants, corn/callus/wart removers, drug astringents, oral healthcare drugs, skin protectants, external analgesics, skin bleaching agents, skin protectants, and sunscreens. Furthermore, based on labeling claims, a product may be subject to both the cosmetic and drug regulations in some countries.

The regulatory approach dealing with the distinction of a cosmetic from a drug varies from country to country. In the U.S., Over-the Counter (OTC) drug ingredients are regulated by the FDA under regulations associated with the U.S. OTC Drug Review Process. Products that comply with the final OTC monograph and other general FDA requirements may be marketed as an OTC drug product without specific FDA pre-market approval of a New Drug Application (NDA). The reader is directed to consult the appropriate OTC drug monograph for drug usage requirements.

Some U.S. OTC active drug ingredients have been reported to have a purely cosmetic purpose in cosmetic formulations, in addition to being safe and effective drug ingredients. Also, some U.S. OTC drug functions may be regulated as cosmetics in other countries. *Such functions may therefore be identified for ingredients that are not described as safe and effective by the U.S. OTC Drug Review Process.* The *Dictionary* distinguishes U.S. OTC Category I active drug ingredients an ingredient's monograph definition, along with referencing the OTC category in the Information Sources field of the ingredient monograph. When the U.S. drug name differs from the INCI name, a notation is included in the monograph definition.

In the EU, labeling claims, areas of application, and the purposes of their application define how the product will be regarded by Regulation. Regulation (EC) No. 1223/2009 contains a series of Annexes setting out the lists of substances subject to prohibitions as well as substances that are subject to restrictions or are provisionally allowed. The preamble of the EU Cosmetics Regulation identifies products that belong to the cosmetic category. Medicinal products are regulated in the EU by Directive 2004/27/EC. In Japan, cosmetics are regulated by the Ministry of Health, Labor, and Welfare (MHLW) under the Pharmaceutical Affairs Law and the amended Enforcement Regulations of the Pharmaceutical Law of 2001. Japan has a similar cosmetic and drug distinction as in the U.S. and the EU. In addition, it has a category of products referred to as "quasi-drugs" that by definition have a mild effect on the human body.

Many other countries follow the regulations of the EU, Japan, or the U.S. for selected requirements. Users of the *Dictionary* must consult the regulatory requirements of the country in which they intend to market their products. Sources of additional information for regulatory requirements may be found in the Council's *International Regulatory Resource Manual*, *International Color Handbook*, *Labeling Manual,* and also in the Council's subscription data bases, *International Regulatory Data Base* (IRDB) and the *InfoBase.*

Trivial Names

EU Trivial Names
The *Dictionary* contains some EU "trivial" names, or common names that should be easily recognized by consumers in the EU where twenty-two different languages are spoken. The trivial names are based primarily on designations taken from the *European Pharmacopoeia*. EU regulations specify that the trivial names must be used for ingredient labeling. For a complete listing of these names, key in (EU) in the ingredient search field of the INCI data base. Examples of INCI labeling names harmonized for the U.S. and EU markets are shown below:
Water (Aqua)
Beeswax (Cera Alba)
Sea Salt (Maris Sal)

EU Trivial Names and Canada
In Canada, INCI ingredient labeling requirements only apply to cosmetic products; INCI nomenclature is acceptable for drugs and natural health products for listing non-medicinal ingredients. A list of ingredients, using INCI names, must appear on the outer label of a cosmetic. An ingredient that has no INCI name must be listed by its chemical name. The label must be legible and follow all other labeling requirements of the Canadian Cosmetic Regulations and the Consumer Packaging and Labeling Act.

In addition to names, if an ingredient is listed in the schedule of Subsection 21.2(4) of the Act, it may be listed either by its EU trivial name in column 1 of the schedule or by the appropriate English *and* French equivalents set out in columns 2 and 3. There are 57 such designations. For example, the EU trivial name *Canola* could be listed, or *Canola Oil/Huile de colza* could be listed. Also, *Aqua* or *Water/Eau*. For additional information see Health Canada website at http://www.hc-sc.gc.ca.

Japan Trivial Names
The *Dictionary* also contains some Japanese "trivial" names, names that have traditional meaning for Japanese consumers. Many of these ingredients may be derived from multiple sources, and thus may refer to more than one INCI name. For example, the trivial name Orange Yu is defined as the essential oil obtained from the peel of the fruit of *Citrus spp*. As such, this Japanese trivial name may correspond to several INCI names including Citrus Aurantium Dulcis (Orange) Oil, Citrus Aurantium Amara (Bitter Orange) Oil, Citrus Grandis (Grapefruit) Peel Oil.

Additionally, some Japanese "trivial" names listed in the *Japanese Cosmetic Licensing Standard* relate to ingredients which are not associated with an INCI name, e.g., Aloe Yohjyu Matsu Ekisu. For a complete listing of Japanese trivial names, key in (JPN) in the ingredient search field of the INCI data base.

Fragrance/Parfum

The terms Fragrance and Parfum are used as INCI labeling names in the U.S. and the EU, respectively, and other global regions. These names are used to identify that a product contains a material or combination of materials to produce or to mask a particular odor.

In the EU, specific fragrance materials identified in Annex III to Regulation (EC) No 1223/2009 must be individually labeled if they are present in the formulation at concentrations greater than 0.001% in leave-on products or greater than 0.01% in rinse-off products. This applies regardless of the source or function of these ingredients. A complete list of these materials is described below by INCI name. Note, several entries on Annex III published in 2023 are identified by Group Names. The Group Names have been monographed as INCI Names. These names are indicated below in boldface followed by the related INCI names and must be used for the ingredient labeling of these materials for products marketed in the EU.

3-Propylidenephthalide
6-Methyl Coumarin
Acetyl Cedrene
Alpha-Isomethyl Ionone
Alpha-Terpinene
Amyl Cinnamal
Amyl Salicylate
Amylcinnamyl Alcohol
Anethole
Anise Alcohol
Benzaldehyde
Benzyl Alcohol
Benzyl Benzoate
Benzyl Cinnamate
Benzyl Salicylate
Beta-Caryophyllene
Butylphenyl Methylpropional
Camphor
Cananga Odorata Oil/Extract
- Cananga Odorata Flower Extract
- Cananga Odorata Flower Oil

Carvone
Cedrus Atlantica Oil/Extract
- Cedrus Atlantica Bark Extract
- Cedrus Atlantica Bark Oil
- Cedrus Atlantica Bark Water
- Cedrus Atlantica Leaf Extract
- Cedrus Atlantica Wood Extract
- Cedrus Atlantica Wood Oil

Cinnamal
Cinnamomum Cassia Leaf Oil
Cinnamomum Zeylanicum Bark Oil
Cinnamyl Alcohol
Citral
Citronellol
Citrus Aurantium Bergamia (Bergamot) Peel Oil
Citrus Aurantium Flower Oil
- Citrus Aurantium Amara (Bitter Orange) Flower Oil
- Citrus Aurantium Dulcis (Orange) Flower Oil

Citrus Aurantium Peel Oil
- Citrus Aurantium Amara (Bitter Orange) Peel Oil
- Citrus Aurantium Dulcis (Orange) Peel Oil
- Citrus Sinensis (Orange) Peel Oil

Citrus Limon (Lemon) Peel Oil
Coumarin
Dimethyl Phenethyl Acetate
Eucalyptus Globulus Oil
- Eucalyptus Globulus Leaf Oil
- Eucalyptus Globulus Leaf/Twig Oil
- Eucalyptus Oil

Eugenia Caryophyllus Oil
- Eugenia Caryophyllus (Clove) Bud Oil
- Eugenia Caryophyllus (Clove) Flower Oil
- Eugenia Caryophyllus (Clove) Leaf Oil
- Eugenia Caryophyllus (Clove) Stem Oil

Eugenol
Eugenyl Acetate
Evernia Furfuracea (Treemoss) Extract
Evernia Prunastri (Oakmoss) Extract
Farnesol
Geraniol
Geranyl Acetate
Hexadecanolactone
Hexamethylindanopyran
Hexyl Cinnamal
Hydroxycitronellal
Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde
Isoeugenol
Isoeugenyl Acetate
Jasmine Oil/Extract
- Jasminum Grandiflorum (Jasmine) Flower Extract
- Jasminum Grandiflorum (Jasmine) Flower Oil
- Jasminum Officinale (Jasmine) Flower Extract
- Jasminum Officinale (Jasmine) Extract
- Jasminum Officinale (Jasmine) Oil

Juniperus Virginiana Oil
- Juniperus Virginiana Wood Oil

Laurus Nobilis Leaf Oil
Lavandula Oil/Extract
- Lavandula Angustifolia (Lavender) Flower Extract
- Lavandula Angustifolia (Lavender) Flower Oil
- Lavandula Angustifolia (Lavender) Flower/Leaf/Stem Extract
- Lavandula Angustifolia (Lavender) Flower/Leaf/Stem Juice
- Lavandula Angustifolia (Lavender) Flower/Leaf/Stem Oil
- Lavandula Angustifolia (Lavender) Oil
- Lavandula Hybrida Extract
- Lavandula Hybrida Flower Extract

Lavandula Hybrida Oil
Lavandula Intermedia Flower/Leaf/Stem Extract
Lavandula Intermedia Flower/Leaf/Stem Oil
Lavandula Intermedia Oil

Lemongrass Oil

Cymbopogon Citratus Leaf Oil
Cymbopogon Citratus Leaf/Stem Oil
Cymbopogon Flexuosus Leaf Oil
Cymbopogon Flexuosus Leaf/Stem Oil
Cymbopogon Flexuosus Oil
Cymbopogon Schoenanthus Oil

Limonene
Linalool
Linalyl Acetate

Lippia Citriodora Absolute

Lippia Citrodora Flower Extract
Lippia Citrodora Flower/Leaf/Stem Extract
Lippia Citrodora Leaf Extract

Mentha Piperita (Peppermint) Oil
Mentha Spicata Flower/Leaf/Stem Oil
Mentha Spicata Leaf/Stem Oil
Mentha Viridis (Spearmint) Leaf Oil
Menthol
Methyl 2-Octynoate
Methyl Salicylate

Myroxylon Pereirae Oil/Extract

Myroxylon Pereirae (Balsam Peru) Oil
Myroxylon Pereirae (Balsam Peru) Resin
Myroxylon Pereirae (Balsam Peru) Resin Extract

Narcissus Extract

Narcissus Jonquilla Extract
Narcissus Poeticus Extract
Narcissus Pseudonarcissus (Daffodil) Flower Extract
Narcissus Tazetta Extract

Pelargonium Graveolens Flower Oil
Pinene

Pinus Mugo

Pinus Mugo Leaf Oil
Pinus Mugo Leaf/Twig Extract
Pinus Mugo Twig Oil
Pinus Pumilio Branch/Leaf Oil
Pinus Pumilio Leaf Extract

Pinus Pumila

Pinus Pumila Leaf/Twig Extract
Pinus Pumila Leaf/Twig Oil
Pinus Pumila Needle Extract

Pogostemon Cablin Oil

Rose Flower Oil/Extract

Rosa Alba Flower Extract
Rosa Alba Flower Oil
Rosa Canina Flower Oil
Rosa Centifolia Flower Extract
Rosa Centifolia Flower Oil
Rosa Damascena Flower Extract
Rosa Damascena Flower Oil
Rosa Gallica Flower Extract
Rosa Gallica Flower Oil
Rosa Hybrid Flower Extract
Rosa Moschata Flower Oil
Rosa Moschata Oil
Rosa Rugosa Flower Oil
Rose Flower Oil

Rose Ketones

Alpha-Damascone
Delta-Damascone

Salicylaldehyde
Santalol
Santalum Album (Sandalwood) Oil
Sclareol
Terpineol
Terpinolene
Tetramethyl Acetyloctahydronaphthalenes
Trimethylbenzenepropanol
Trimethylcyclopentenyl Methylisopentenol
Turpentine
Vanillin

Flavor/Aroma

The terms Flavor and Aroma are used as INCI labeling names in the United States and the EU, respectively. These names are used to identify that a product contains a material or combination of materials to produce or to mask a particular flavor.

Other Regulatory Information

MINIMATA Convention

The Minamata Convention on Mercury, which went into effect on January 19, 2013, is a global treaty to protect human health and the environment from the adverse effects of mercury. Consistent with the provisions of the treaty, and by petition from the U.S. Food and Drug Administration, mercuric oxide has been removed from the Dictionary. Soaps and cosmetics containing more than 1 part per million of mercury will be banned by 2020. Eye-area cosmetics are exempt because of concerns that there are no effective and safe substitute preservatives available for these product-types. Respective monographs in the Dictionary have been referenced to Minimata in the Information Sources field.

Specific Disclaimers

The ingredients in the *Dictionary* do not represent an approved list of cosmetic ingredients. The inclusion of any ingredient means only that it is offered for sale for use in cosmetic products. It does not imply that the substance is safe for use as a cosmetic ingredient, nor does it indicate that its use as a cosmetic ingredient complies with the laws and regulations of the United States or any other country.
The assignment of an INCI name does not imply that the ingredient is "approved," "certified," or "endorsed" by the Council or any other organization or governmental body. Conversely, the absence of an ingredient from the *Dictionary* does not imply that the ingredient may not or should not be used in finished cosmetic products. INCI names do not imply standards or grades of purity.

NOTE: The suitability for use of any ingredient, as a component of a finished cosmetic product or for any other purpose, is solely the responsibility of the cosmetic product manufacturer, the distributor, or other users of this publication.

Manufacturers intending to produce and/or market cosmetic products in the United States are urged to consult applicable regulations. These regulations may be found in the U.S. *Code of Federal Regulations*, Title 21 (21 CFR). Manufacturers are also urged to check notices in the U.S. *Federal Register* and to familiarize themselves with state laws and regulations that may provide additional information regarding the manufacture and sale of cosmetic products.

Firms marketing products in countries outside the United States should consult the laws and regulations in those countries for information on their legal requirements. For information on the laws and regulations of many countries, see the latest edition of the *International Regulatory/Resource Manual*, or consult the *International Cosmetic Legal and Regulatory Database,* http://irdb.personalcarecouncil.org/,both available from the Council.

The identification of a function in a monograph should not be construed as proof that the ingredient performs such function in a finished cosmetic product. The function of an ingredient is often affected by other ingredients in the formulation. Functions listed for ingredients are identified by the supplier or provided by users of this publication.

The INCI names in the *Dictionary* are recognized by the U.S. Food and Drug Administration as the labeling names that must be used for cosmetic ingredient labeling under U.S. regulation 21 CFR 701.3. This recognition of the *Dictionary* does not imply that the ingredients contained therein are considered to be "safe" or "approved" for use by the FDA.

Registry Numbers

INCI names are associated with CAS and EC numbers where possible.

CAS Registry Numbers are assigned by the Chemical Abstracts Service (CAS) to a given chemical substance. CAS Registry Numbers serve to index worldwide literature for chemical substances. CAS Registry Numbers are also assigned for reporting purposes under the U.S. Environmental Protection Agency's Toxic Substances Control Act (TSCA) and serve as identifiers for the registration of substances in various global jurisdictions.

EC Registry Numbers are 7-digit numbers that relate to substances registered under REACH by ECHA.

The relationship between a registry number and an INCI name is not always one-to-one. In some cases, more than one INCI name may have the same CAS number, or more than one CAS number may apply to an INCI name. For example, polymers may share a CAS number that is generic to variable chain lengths of a common monomer mixture. Alternatively, CAS numbers for specific stereoisomers in most cases will be related to a single INCI name. For further information about CAS numbers, please consult the CAS website: https://www.cas.org/.

Reported Ingredient Functions

The functions for an ingredient listed in the *Dictionary* are primarily those that are provided by the supplier and are classified on the basis of the function an ingredient may perform in a finished product. Many ingredients have multiple functions in formulation and therefore are included in several functional groupings. The definition of each function listed in the *Dictionary* is provided in the specific cross-reference section, Reported Functions. Ultimately, the suitability and intended use of an ingredient is the responsibility of the marketing company. Users interested in updating the function(s) for an ingredient should contact the Personal Care Products Council.

The use of an ingredient for a function other than those listed in the Dictionary may be acceptable. The inclusion of an ingredient under a given function in the Dictionary does not imply that the ingredient is "approved," "certified," or "endorsed" for that use by the Personal Care Products Council or any other organization or governmental body in the U.S., the EU, Japan, or any other country.

Ingredient Sources

The monographs for INCI names contain an information field that identifies the source(s) of the ingredient. These sources are:

- Animal
- Plant
- Mineral
- Synthetic
- Bacteria, Fungi, or other Single-Celled Organism

The selection of source(s) for cosmetic ingredients is based, in general, on the following criteria:

1. The source of an ingredient is determined from information found in the definition of the ingredient contained in each monograph or based on information provided by the supplier of the ingredient. In some cases, the source information is obtained from the *Merck Index* or other compendia.

2. All hydrocarbons and other substances derived from coal, coal tar, or refined from "crude oil" extracted from the earth are identified as *synthetic*.

3. Where the source of an ingredient is identified as animal, the type of animal is not identified.

4. The source for botanical ingredients is identified as plant.

5. Extracts are identified by the source of the material extracted.

6. Hydrolysates are identified by the source of the material hydrolyzed.

7. One or more sources may apply to a given INCI name when that material may be derived from more than one source. Different trade materials related to an INCI name may be obtained from different sources.

8. Synthetic is assigned as a source for ingredients that are prepared ("synthesized") by the reaction of a substance with one or more other substances to form a new chemical entity.

9. In cases when it is very clear that a raw material used to synthesize an ingredient is plant or animal derived, that source may be listed. For example, *animal* and *synthetic* are both listed as sources for Lanolinamidopropyl Betaine to indicate that one of the starting materials is derived from an animal source, in this case lanolin, and that the material is derived by a synthetic process. Similarly, *plant* and *synthetic* are both listed as sources for Soyamide DEA to indicate that the starting materials are derived from a plant source and a synthetic one.

10. If a supplier of an ingredient has information to document that an ingredient is obtained from a source different than the one(s) listed in the monograph, they may submit this information for consideration to the INC.

Additional sources for raw materials not cited in the monograph are possible, e.g., ingredients derived through microbial processes. Moreover, newer sources may be possible for ingredients traditionally made available through synthetic processes. It is not the intent of this publication to identify all possible sources for raw materials.

Reported Product Categories and Frequency of Use

The product categories and frequency of use data for an ingredient listed in the *Dictionary* are derived from FDA's Voluntary Cosmetic Registration Program (VCRP). The VCRP is a voluntary reporting system for cosmetic and personal care products that are in commercial distribution in the United States.

Names identified in an INCI monograph as "VCRP Reported Name" may include terms other than the INCI name because the information is obtained "as reported" by the manufacturer. The VCRP data is updated annually by PCPC for inclusion in the *Dictionary.* The VCRP regulations can be found in 21 CFR, parts 710 and 720.

The FDA VCRP is not a premarket approval program. The safety, suitability and intended use of an ingredient in a product category is the responsibility of the marketing company. *The listing of an ingredient in a product category in the Dictionary or noted as a VCRP reported ingredient does not imply that the ingredient is "approved," "certified," or "endorsed" for that use by the Personal Care Products Council or any other organization or governmental body in the U.S., the EU, Japan, or any other country.*

LABELING REMINDERS

The term "(and)" - The term "(and)" in the INCI name assignment for trade name mixtures is used between individual ingredients to identify the components of the blends. When labeling a finished product containing a trade name material that is a mixture or blend, each component of the mixture is to be listed in descending order of predominance with respect to all ingredients in the formulation. *The term "(and)" should not be used when listing the ingredients on the finished product label*. Information on the actual concentration of each component of such mixtures should be obtained from the supplier.

Solvents and Diluents - Solvents and diluents in raw materials, such as surfactants, polymers, and resins, are not always identified as part of the INCI name. However, diluents and/or solvents must be listed on the finished product package label in their proper order of predominance with respect to all other ingredients in the formulation. Information on the concentration of solvents and/or diluents contained in such raw materials should be obtained by the marketing company from the supplier.

Extracts - The INCI names for extracts represent the "material extracted". Many extracts are supplied with the extracting solvent and/or other diluents. The solvents and/or diluents in extracts must be listed in their proper order of predominance, along with all other ingredients in the formulation, on the package label. Information on the concentration of solvents and/or diluents in a specific extract must be obtained by the marketing company from the supplier.

Incidental Ingredients - Incidental ingredients include antioxidants, preservatives, or processing aids that are present for a specific function in a raw material but are not intended to have a technical or functional effect in the finished cosmetic and are typically present at an insignificant level in the finished cosmetic product. Incidental ingredients contained in cosmetic raw materials are often not included in the INCI name. Because some jurisdictions may require that incidental ingredients be included in product information files, finished product manufacturers should work with their ingredient suppliers to ensure the completeness of their product listings. For more information on requirements for incidental ingredients in the U.S., see 21 CFR 701.3 (l)(1) and (2).

Additional information on the labeling requirements for products marketed in the United States may be found in the Council's *Labeling Manual*. Information on the regulatory status of colorants in the United States and many other countries may be found in the Council's *International Color Handbook*, Fourth Edition (2007). A reference guide to the cosmetic laws, regulations, and information sources for many countries may be found in the *International Regulatory/Resource Manual*, Sixth Edition (2007). The Council's online data bases are also excellent sources of comprehensive information: *InfoBase,* and the *IRDB.*