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NSF Standard for Organic Personal Care Products

Organic Personal Care Products

1 General

1.1 Purpose

This Standard encourages participation in the manufacturing of personal care products using organically grown ingredients within the supply chain. It emphasizes open disclosure of impacts and benefits, and does not compromise proprietary, patented, or trade secret information. This Standard is to be used voluntarily by companies that may not be able to meet the current USDA organic food regulations.

Reason: *Term 'organic' deleted and terms 'using organically grown ingredients' added. Statement includes both 'organic' and 'made with organic' products thereby reducing confusion.*

1.2 Scope

This Standard specifies materials, processes, production criteria, and conditions that shall be met in order for personal care products to make organic label and marketing claims under this Standard.

Items covered by this Standard include, but are not limited to, rinse-off and leave-on personal care and cosmetic products that are applied or used externally on any part of the body (e. g., hair, face, hands, and feet) as well as oral care and personal hygiene products. This Standard does not differentiate between requirements for personal care products and requirements for cosmetics. Therefore, for the purposes of this Standard, cosmetics are considered personal care products.

This Standard does not ensure accuracy of claims specifying a product as “safer”, “better” or of a specific quality.

Like USDA National Organic Program (NOP) regulations, this Standard includes allowances and restrictions on processes, agricultural ingredients, synthetic ingredients, and methods of extraction based on the specific label claim to be made on the final product. The organic claim is a process claim, not a product claim. Testing will not necessarily determine whether or not a product is organic or meets this Standard.

1.3 Alternate products or materials

An ingredient of a personal care product varying in design from this Standard's specification may still qualify under the Standard. While specific materials are stipulated in this Standard, products or components that incorporate alternate materials may be acceptable when it is verified that the product or component meets the applicable requirements of the Standard based on the product's end use.

2 Normative references

The following documents contain provisions that, through reference, constitute provisions of this Standard. At the time this Standard was written, the editions listed below were valid. All documents are subject to revision, and parties are encouraged to investigate the possibility of applying the most recent editions of the documents indicated below.

2.1 Normative references

International Cosmetic Ingredient (ICI) Dictionary and Handbook, 11th edition, 2006¹

USFDA, National Organic Program (7 CFR Part 205)²

USEPA, *National Primary Drinking Water Regulations* (40 CFR part 141)³

WHO, *Guidelines for Drinking-Water Quality*⁴

2.2 Informational references

Food and Drugs Act, *Cosmetics Program*⁵

USFDA, Federal Food, Drug, and Cosmetic Act (FD & C Act) (21 U.S.C. subchapter VI)²

USFDA, Good Manufacturing Practices²

3 Definitions

Terms used in this Standard that have special technical meaning are defined here.

3.1 agricultural product: An agricultural commodity or product, either raw or processed.

3.2 alkaline: Having a pH greater than 7.0.

3.3 alkylation: A chemical process in which an alkyl group (containing only carbon and hydrogen) is added or substituted in a compound.

3.4 allowed synthetic: A substance that is included on the National List (National Organic Program, 7 CFR Part 205) of synthetic substances allowed for use in organic production or handling, and/or that is further allowed within this Standard for use in specific situations.

¹ American Cosmetic, Toiletry and Fragrance Association, 1101 17th Street, NW, Suite 300, Washington D. C. 20036-4702 www.ctfa.org

² USDA-AMS-TMP-NOP, Room 4008-South Building, 1400 Independence Avenue, SW Washington, D. C. 20250-0020. www.ams.usda.gov/nop/indexIE.htm.

³ USEPA, Office of Water, Washington, D. C. 20460

⁴ World Health Organization, 1211 Geneva 27, Switzerland

⁵ Health Canada, MacDonald Building, A.L. 3504D 123 Slater Street Ottawa, Ontario K1A 0K9 www.healthcanada.gc.ca/cosmetics

3.5 audit: A means to verify compliance with a standard or set of standards, rules, regulations, or other requirements against which a company or product is being measured and that the company must meet. Audits can range in duration depending on size or organization, and can be performed as a desk audit (review of documents and records) only, an on-site audit only, or a combination of both.

3.6 batch or lot: A specific quantity of a finished product or other material that is intended to have uniform character and quality, within specified limits, and/or is produced according to a single manufacturing order during the same cycle of manufacture.

3.7 biodegradable: Subject to biological decomposition into simpler biochemical or chemical components.

3.8 botano-chemical: Materials whose origin is plant-based and is not from petroleum.

Reason: Use of the term botano-chemical used in the Standard. Defining the term obviates the argument that petro-chemicals are also plant-based.

3.9 catalyst: A substance used to modify or increase the rate of chemical change in another material, but which is not consumed or incorporated into the finished material.

3.10 claims: Oral, written, or symbolic representations, statements, advertising, or other forms of communication presented to the public or to buyers of agricultural products that relate to the organic certification process.

3.11 commercially available: (Of a production input or ingredient) Obtainable in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic personal care production or handling.

3.12 commingling: Physical contact between unpackaged organically produced and non-organically produced agricultural products during production, processing, transportation, storage, or handling, other than during the manufacture of a multi-ingredient product containing both types of ingredients.

3.13 company: A public or private organization, group, individual, or other entity seeking certification to this Standard, or a subsidiary or division of such an entity.

Reason: Companies seek certification.

Reason: "Compliance" and "conformance" are two different concepts; deleting definition for 'compliance' and using "conformance" in the body of the standard

3.14 concentration: (verb) The removal of solvent from a juice or extract. (noun) Measure of the amount of dissolved substance contained per unit of volume.

3.15 contamination: The presence of soil or any other unwanted organic or inorganic matter.

3.16 cosmetic: (1) An article intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) an article, other than soap, intended for use as a component of any such articles.

3.17 essential oil: The non-aqueous oil obtained from plant matter that may be volatilized by steam. Citrus oil is considered an essential oil because of its composition.

3.18 ester: The reaction product of an acid and an alcohol.

3.19 ethoxylation: A chemical process in which a raw material is catalyzed with potassium hydroxide and dried under vacuum, after which ethylene oxide is added as a reagent to form a new material.

3.20 excluded method: A method not permitted in this Standard, including genetically engineered organisms (GEO) or their products.

Reason: Clarification. GEOs are excluded in 4.2.2 - Prohibited labeling practices in all categories.

3.21 extract: Soluble material of plant origin that is dissolved out of the plant material by soaking the plant in a suitable solvent, generally water or alcohol.

3.22 Good Manufacturing Practices (GMP): The practice of maximizing the quality of products and materials by maintaining and practicing appropriate quality control and quality assurance procedures.

Reason: Term 'purity' deleted and term 'quality' added. Purity can only be maintained through manufacturing; quality may be maximized.

3.23 handle: To sell, process, or package products covered by this Standard.

3.24 handling operation: An operation or portion of an operation that receives or otherwise acquires and processes, packages, or stores products covered by this Standard.

3.25 hydrogenation: A chemical reaction in which all or some unsaturated bonds between carbon atoms are reduced by attachment of a hydrogen atom to each carbon. The process results in the saturation of the carbon atoms, meaning that each carbon atom has four other atoms attached to it. When the process is carried to completion, it converts unsaturated fatty acids to saturated ones, creating waxes from vegetable oils.

3.26 hydrolysis: Decomposition of a chemical compound by reaction with water.

3.27 hydrosol: Volatile water-soluble material of plant origin that is separated as the aqueous condensate during steam distillation of an essential oil. Also known as hydrolat or, when produced from flowers, floral water.

Reason: Clarification. Though all floral waters may be hydrosols, not all hydrosols are floral waters.

3.28 ingredient: A substance used in the preparation of an agricultural product that is still present in the final commercial product.

3.29 inspector: A person employed to conduct inspections of applicants or of production or handling operations. Also known as an auditor.

3.30 inspection: The act of examining and evaluating the production or handling operation of an applicant to determine conformance to this Standard.

3.31 ionizing radiation: Electromagnetic radiation whose waves contain energy sufficient to overcome the binding energy of electrons in atoms or molecules. Also (imprecisely) called radioactivity.

3.32 juice: Liquid, predominantly aqueous, expressed from a plant material.

3.33 label/labeling: A display of written, printed, or graphic material on the primary container of a product, or any such material affixed to a product or to a bulk container containing a product, except for package liners or a display of written, printed, or graphic material that contains only information about the weight of the product.

3.34 batch/lot number: A distinctive combination of letters, numbers, or symbols, or any combination thereof from which one can determine the complete history of the manufacturing, processing, packaging, holding, and distribution of a batch or lot covered by this Standard.

3.35 mined minerals: Naturally occurring homogeneous substances (such as stone or salt) extracted from a hole or system of holes in the ground.

3.36 National List: A list of allowed and prohibited substances as provided for in National Organic Program, 7 *CFR* 205.600-606.

Reason: Section 600 only contains the criteria for the evaluation of materials. Section 3.4 of this Standard refers to the actual substances listed, which are contained in 7 *CFR* 601-606.

3.37 National Organic Program (NOP): The program authorized by the Organic Foods Production Act of 1990 and implemented by the Code of Federal Regulations 7 *CFR* part 205.

3.38 nonagricultural substance: A substance that is not a product of agriculture, such as a mineral.

Reason: ‘or a bacterial culture that is used as an ingredient in an agricultural product’ deleted. At the NOSB meeting Nov. 28-30, 2007, NOSB took another step toward affirming this simplification of the definition.

3.39 non-synthetic (natural): A substance that is derived from mineral, plant, animal matter and does not undergo a synthetic process as defined in section 6502(21) of the Act (7 U.S.C. 6502(21)). For the purposes of this part, non-synthetic is used as a synonym for natural as the term is used in the Act. (National Organic Program, 7 *CFR Part* 205).

3.40 organic: A term used to describe a finished product or ingredients within a product that have been produced and or processed according to this Standard or the NOP regulations.

3.41 organic content: The specific percentage of organic ingredients in a processed product.

3.42 organic production: A production system that is managed in accordance with this Standard or the NOP regulations.

3.43 organic system plan: A plan of management of an organic production or handling operation that has been agreed to by the producer or handler and the certifying agent, and that includes written plans concerning all aspects of agricultural production or handling described in this Standard or the NOP regulations.

3.44 over-the-counter: (Of drugs and non-drugs) Sellable without a prescription and without a visit to a medical professional.

3.45 personal care product: A non-medicinal consumable product that is intended to be used in the topical care and grooming of the body and hair and that is rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to a body, human or animal, for cleansing, beautifying, promoting attractiveness, or altering the appearance without affecting the body's structure or functions. Personal care products are specifically for use in such activities as

cleansing, toning, moisturizing, hydrating, exfoliating, conditioning, anointing, massaging, coloring/decorating, soothing, deodorizing, perfuming, and styling.

3.46 petroleum compound: A carbon compound derived/synthesized from a petroleum source that is part of a larger personal care ingredient, e. g., ethylene oxide in ethoxylated fatty alcohol.

3.47 principal display panel (PDP): The portion of the package label that is most likely to be seen by the consumer at the time of purchase. Many containers are designed with two or more different surfaces that are suitable for display as the PDP. These are alternate principal display panels.

3.48 processing: Cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, distilling, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing. Includes packaging, canning, jarring, or otherwise enclosing in a container, and other processing allowed in this Standard.

3.49 processing aid: (a) A substance that is added to a food during the processing of such food but is removed in some manner from the food before it is packaged in its finished form; (b) a substance that is added to a food during processing, is converted into constituents normally present in the food, and does not significantly increase the amount of the constituents naturally found in the food; or (c) a substance that is added to a food for its technical or functional effect in the processing but is present in the finished food at insignificant levels and does not have any technical or functional effect in that food.

3.50 products: Goods or ingredients covered by this Standard.

3.51 production location: A location or site that is involved in handling, processing, or final production or assembly of products or of ingredients to be included in a final product.

3.52 prohibited practice: A practice not specifically allowed under this Standard for the production of any final product or ingredient to be labeled under this Standard.

3.53 prohibited substance: A substance not allowed in any aspect of organic production or handling or not provided for in this Standard.

3.54 records: Information in written, visual, or electronic form that documents the activities undertaken by a producer, handler, or certifying agent to conform to this Standard.

3.55 reagent: A substance added to a compound in a processing step in order to change the chemical structure of the compound into a desired form, which is incorporated into the new material.

3.56 salt: Sodium chloride, unless otherwise specified.

3.57 saponification: Hydrolysis of a fat with alkali to form a soap and glycerin.

3.58 sewage sludge: A solid, semisolid, or liquid residue generated during the treatment of domestic sewage in a treatment works. Sewage sludge includes but is not limited to: domestic septage; scum or solids removed in primary, secondary, or advanced wastewater treatment processes; and material derived from sewage sludge. Sewage sludge does not include ash generated during the firing of sewage sludge in a sewage sludge incinerator, or grit and screenings generated during preliminary treatment of domestic sewage in a treatment works.

3.59 soap: A cleansing and emulsifying agent, made usually by action of alkali on fat or fatty acids, that consists essentially of sodium or potassium salts of such acids.

3.60 solvent: A substance that dissolves one or more other substances or that causes another substance to disperse.

3.61 split handling operation: An operation that handles both conventional and organic products.

3.62 steam fractionation: Splitting a compound with steam to produce new compounds, e. g., using steam to split a vegetable oil into fatty acids and glycerin.

3.63 sulfation: The manufacture of a sulfate ester of a fatty alcohol that is then neutralized with an alkali such as sodium hydroxide to produce a surfactant.

3.64 sulfonation: The manufacture of a sulfonate ester of a fatty alcohol that is then neutralized with an alkali such as sodium hydroxide to produce a surfactant.

3.65 surfactant: A compound designed to reduce the surface tension of a liquid or to reduce the interfacial tension between two liquids, or between a liquid and a solid.

3.66 synthetic: A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources. This term shall not apply to substances created by naturally occurring biological processes permitted under the NOP, nor does it apply to Ecological Agricultural-Based Oleochemical Ingredients defined and allowed in this Standard for products labeled “made with organic”.

3.67 volatile content: The amount of moisture and other volatile compounds present in plant material, generally measured by gentle drying (oven or microwave) until a constant weight is achieved. The loss on weight is considered the volatile content; similar to moisture content.

3.68 water: A clear, colorless, odorless, and tasteless liquid, chemically H₂O, essential for most plant and animal life; the most widely used of all solvents.

3.68.1 non-agricultural water: Water that has been added to a product or ingredient that was not included in the originating plant matter.

3.68.2 plant water: Water that has been absorbed by the plant during its growth and contained within the plant, and that could be counted as organic content within an ingredient or final product.

3.68.3 tap water: Water that meets or exceeds safe drinking water standards (USEPA National Primary Drinking Water Regulations (40 CFR part 141) or the WHO Guidelines for Drinking-Water Quality).

4 General requirements for organic personal care products

4.1 Scope

A personal care product ingredient using any organic claim shall be produced and handled in accordance with this Standard.

4.2 Prohibited practices

4.2.1 Non-organic ingredients

The non-organic ingredients shall not be produced using excluded methods, sewage sludge, ionizing radiation or genetically engineered organisms (GEOs) or its product, nor shall they contain any petroleum compounds except as allowed for specifically in this Standard.

Reason: 'genetically engineered organism or its product' added. It is important to exclude not only GEOs but their products as well.

4.2.2 Prohibited labeling practices in all categories

4.2.2.1 The labeling of whole products or ingredients as organic is prohibited if those products or ingredients are created using any of the following:

- Ingredients or processing aids produced using excluded methods;
- Ingredients that have been produced using applications of sewage sludge;
- Ingredients that have been processed with ionizing radiation;
- Ingredients that have been made using any GEOs or its product;

Reason: 'modified base ingredient' replaced with 'organism or its product'. It is important to exclude not only GEOs but their products as well.

- Ingredients with petroleum compounds, except as specifically allowed in this Standard;
- Synthetic substances not on the National List or permitted under this Standard;

4.2.2.2 Use of the phrase "organic when available" or a similar statement on labels or in market information when referring to products composed of non-organic ingredients used in place of specified organic ingredients;

4.2.2.3 Labeling as "organic" or "made with organic" any product containing both organic and non-organic forms of an ingredient specified as "organic" on the label.

Reason: 'made with organic' added. This rule should apply to both "organic" and "made with" products, as NOSB has recommended to NOP

5 Organic personal care product production and handling requirements

5.1 Scope

The producer or handler of a production, handling, or warehouse operation intending to sell, label, or represent agricultural products as "100 percent organic," "organic," or "made with organic" shall conform to the applicable provisions of this Standard. Production practices implemented in accordance with this Standard shall maintain or improve the natural resources of the operation, including soil and water quality.

Mechanical or biological methods, including but not limited to cooking, heating, drying, mixing, grinding, churning, separating, distilling, extracting, cutting, fermenting, preserving, dehydrating, freezing, chilling, or otherwise manufacturing, and the acts of packaging, jarring, or otherwise enclosing a product in a container may be used to process an organically produced personal care product for the purpose of retarding spoilage or otherwise preparing the agricultural product for market.

5.2 Organic production system plan

The producer or handler of a production or handling operation intending to sell, label, or represent agricultural products as “100 percent organic,” “organic,” or “made with organic” shall develop an organic production or handling system plan. An organic production or handling system plan shall include:

- A description of activities, practices, and procedures to be performed, including the frequency with which they shall be performed;
- A list of substances and/or ingredients to be used as production or handling input, indicating their compositions, organic content (expressed as a whole percentage, rounded down to the closest percent and excluding all non-organic materials), sources, location where they will be used, and documentation of commercial availability, as applicable;
- A description of the monitoring activities, practices, and procedures to be performed and maintained, including the frequency with which they shall be performed, to verify that the plan is effectively implemented;
- A description of the record-keeping system implemented to conform to Annex F;
- A description of the management activities and practices and the physical barriers established to prevent commingling of organic and non-organic products in a split operation, to prevent adulteration of the product as specified in Annex F, and to prevent contact of organic production and handling operations and products with prohibited substances; and
- Additional information as applicable that is required in order to demonstrate conformance to this Standard.

NOTE – A producer may substitute a plan prepared to meet the requirements of another federal, state, or local government regulatory program for the organic system plan, provided that the submitted plan meets all the requirements of this section.

5.3 Allowed Processes and Ingredients

All processes allowed under the NOP are allowed for this Standard. Of particular relevance are the following:

- Cooking vegetable oils or animal fats with NOP-allowed alkali to make soap;
- Utilizing NOP-allowed enzymes or alkali to hydrolyze organic proteins, and carbohydrates, and;
- Cooking organic oil and alcohol together, optionally in the presence of NOP-allowed alkali, to make organic ester ingredients.

Refer to Annex G, Table G.1, for an illustrative list of ingredients made by performing the above, and to see availability of these ingredients in organic versus conventional form.

Table 5.1 specifies Ecological Agricultural-Based Botano-chemical Processes that make ingredients that are not permitted under the NOP but are allowed for “Made with Organic” products under this Standard. The organic content contribution of the resulting ingredient to a

finished product is also specified. Organic forms of ingredients made by these processes shall be used in “Made with Organic” products, if commercially available.

Reason: ‘plant-chemical’ modified to ‘botano-chemical’. This parallels “petrochemical” and so will emphasize the intent. It is also a more standard form for this useful neologism.

Reduction to produce ingredient	Organic percentage of ingredient
Steam-splitting of oils to produce fatty acids*	98%
Mineral Acid-catalyzed esterification or transesterification	98%
Hydrogenation of oils	98%
Hydrogenolysis of methyl or ethyl esters of an oil with hydrogen to make fatty alcohols	98%
Glucosidation	98%
Sulfation	60%
Protein fragment (non-petroleum) acylation	85%

*Note that glycerin made by fat-splitting oils is an NOP List allowed substance.

See Annex G for clarification of particular ecological agricultural-based botano-chemical processes as well as which ingredients are available in organic form.

5.3.1 Preservatives

Table 5.2 – Preservative Ingredients Allowed in “Made with” Products

Benzoic Acid (natural source only)
Grapefruit Seed Extract
Potassium Lactate
Potassium Sorbate
Sodium Benzoate (natural source only)
Sorbic Acid
Benzyl Alcohol (natural source only)

Reason: ‘free of contaminants’ deleted from grapefruit seed extract cell. None of the other ingredients has this restriction, and absolute product purity is unobtainable in any case.

5.3.2 Mined Ingredients

Table 5.3 – Mineral Ingredients Allowed in “Organic” and “Made with” Products

Chalk
Clays
Pumice

Table 5.4 – Processed Mineral Ingredients Allowed Only in “Made with” Products

Titanium Dioxide
Zinc Oxide

5.3.3 Prohibited Ingredient Types/Classes and Prohibited Specific ingredients

Tables G.3 and G.4 in Annex G contain illustrative lists of ingredients that include petroleum compounds that are not specifically allowed elsewhere in the Standard.

5.3.4 Commercial Availability

This certification program adopts the list of materials deemed commercially unavailable that appears on the National List of Allowed and Prohibited Substances, 7 CFR Part 205.606, as amended.

Commercial availability determinations under this Standard shall be made in the same manner as such determinations are made under the NOP.

Reason: ~~'provided, that no material determined commercially unavailable by the NOP shall be determined at the same time to be commercially available under this Standard'~~ deleted. NOP does not make the determination of commercial availability; this is a function of accredited certifying agents. No master list is kept of such determinations, so there could be no reference material available to implement this policy.

6 Determining percent organic

6.1 Scope

The producer or handler of a product to be made and labeled under this Standard shall determine the percent organic content of the product. This section specifies methods of determining percent organic content.

6.2 Calculating organic percentage

The percentage of all organically produced ingredients in an agricultural product sold, labeled, or represented as "100 percent organic," "organic," or "made with organic [specified ingredients]," or as including organic ingredients shall be calculated by:

- Dividing the total net weight (excluding water and salt) of combined organic ingredients at formulation by the total weight (excluding water and salt) of the finished product;
- Dividing the fluid volume of all organic ingredients (excluding water and salt) by the fluid volume of the finished product (excluding water and salt) if the product and ingredients are liquid. If the liquid product is identified on the principal display panel or information panel as being reconstituted from concentrates, the calculation shall be made on the basis of single-strength concentrations of the ingredients and finished product; or
- For products containing organically produced ingredients in both solid and liquid form, dividing the combined weight of the solid ingredients and the weight of the liquid ingredients (excluding water and salt) by the total weight (excluding water and salt) of the finished product.

For organic agricultural ingredients that have undergone approved reactions as specified in this Standard, the percent organic contribution of these ingredients is specified in 6.5.

The percentage of all organically produced ingredients in an agricultural product shall be rounded down to the nearest whole number.

The handler who affixes the label on the consumer package shall determine the organic percentage of the product. The handler shall use information provided by the compliant operation in determining the percentage.

6.3 Water and salt

Water and salt shall be considered “neutral” in calculating the percent organic content. Therefore, they shall be excluded from the net weight or net volume.

6.3.1 Water

Water used as an ingredient or processing aid shall meet or exceed the USEPA National Primary Drinking Water Regulations (40 CFR part 141) or the WHO Guidelines for Drinking-Water Quality.

6.3.1.1 Reconstitution

When a standard of identity exists or there is an onsite scientific method used to remove moisture from a plant, water can be added back into that plant product and still be considered as part of the original plant. For instance, a concentrate that fulfills the organic requirements of this Standard can be rehydrated back to single strength or back to the same moisture content it had when harvested or first tested; the added water shall be considered part of the organic content of that ingredient or product.

Added water shall be included in the organic content of an ingredient only under the following circumstances:

- Reconstituting juice concentrates back to their USDA single strength standard of identity; and
- Reconstituting aloe concentrates to single strength based on Aloe Council compliance and standards.

Water content of extracts and hydrosols are specified in 6.4 of this Standard.

NOTE – Water added to rehydrate dried powders or dried plant material is counted as added water. Manufacturer-specific 'standards of identity' regarding water content, single strength values, or moisture content are not acceptable.

6.3.2 Salt

Salt is sodium chloride, not containing any additives or flow agents that are not specifically allowed on the National List.

6.4 Organic content of processed organic plant material

This section specifies the percent organic content of various processed products.

The maximum organic contribution of an organic plant material to any processed product shall not exceed the weight of the starting plant material.

6.4.1 Juice

The liquid expressed from organic plant material (juice) shall be considered fully organic.

6.4.2 Essential oil

Essential oils expressed, distilled, or extracted from organic plant material shall be considered fully organic.

6.4.3 Extract

6.4.3.1 Extraction with an acceptable, but non-certified solvent

The organic content of an extract shall be calculated by measuring the amount of starting organic plant material (O), the amount of extraction solvent (S), and the amount of finished product (P). The percent organic content of the finished product shall be determined by the equation $(P - S)/P * 100$.

NOTE –P - S shall always be less than O.

Example: Plan on extracting 100 lbs. of plant material (O). It is not necessary to measure the residue or extractable amounts in this plant material, but for this example assume it contained 80 lbs. of water plus extractable material and 20 lbs. of residue. This plant material is extracted with 200 lbs. of solvent (S). The resulting product would be 280 lbs. (P) and the organic content would be 28% $((280-200)/280 * 100$, rounded down to the nearest whole number).

6.4.3.2 Extraction with a certified organic solvent

An extract made from certified organic material with a certified organic solvent shall be considered fully organic. It shall qualify for O100 or O95 status depending on the category status of the solvent.

6.4.4 Hydrosol or distillate

The organic content of a hydrosol/distillate shall be equal to the weight of the water/volatiles present in the organic plant material at time of processing. The manufacturer shall determine the water/volatile content at the time of distillation/extraction of the plant material through freeze drying or gentle oven/microwave drying (e. g., 45 min at low power in a microwave). This water/volatile content is the maximum organic material present in the resulting hydrosol/distillate.

Example: 100 lbs of lavender is dried as specified above and yields 60 lbs of residue (i.e.. water + volatiles = 40 lbs). The maximum organic contribution to the resulting hydrosol/distillate is 40 lbs. If 90 lbs. of hydrosol/distillate is produced, 50 lbs. of that is water added during the process, and the organic content of the finished product is 44% $(40/90 * 100$, rounded down to the nearest whole number).

NOTE – The finished hydrosol/distillate could be labeled as O100 or O95 (as appropriate), but if this hydrosol/distillate is used as an ingredient in a multi-ingredient product, the organic contribution of this ingredient would only be 44% of the amount used.

6.5 Organic percentage of a reacted ingredient

The values in table 5.1 shall be used in calculating the organic percentage of a final product using reacted ingredients. Although most of the products of the specified reactions are likely to be restricted to the “made with” label category, the percentage listed shall not be the final determinant of that category.

Table 6.1 – Organic percentage of a reacted ingredient

Reaction used to produce ingredient	Organic percentage
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	of ingredient
Fat-splitting of oils to produce glycerin and fatty acids	98%
Etherification of glycerin and glycerin making polyglycerols	98%
Non-catalyzed esterification of alcohol (excluding fatty alcohol) & acid to produce various esters	98%
Mineral acid-catalyzed esterification	98%
Transesterification to produce various esters	98%
Hydrogenation of oils	98%
Hydrogenolysis of methyl or ethyl esters of an oil with hydrogen to make fatty alcohols	98%
Glucosidation	98%
Sulfation	60%
Protein fragment (non-petroleum) acylation	85%

7 Labels, labeling, and market information

7.1 Use of the term "organic"

The term "organic" shall only be used on labels and in labeling of raw or processed agricultural products, including ingredients, that have been produced and handled in accordance with the requirements of this Standard. The term "organic" shall not be used in a product name unless the product meets USDA-NOP criteria or criteria defined in this Standard.

7.2 Labeling and or representation of products

There are two possible types of representations of products.

- Representation made to the consumer of a final consumer packaged product; and
- Representation made to a down-line manufacturer that will use this product as an ingredient to be labeled later in one of the three different categories; "100% Organic," "Organic," or "Made With Organic."

7.2.1 Marketing ingredients to another manufacturer

When marketing ingredients to another manufacturer, the shipper shall disclose the following:

- The processes used to create the ingredient, whether organic or non-organic;

NOTE – In instances where this disclosure may include confidential information, a statement shall be issued as to the processes used to manufacture the ingredient, to assure the receiver that the ingredient/s conform to this Standard. The statement shall also precisely ascribe a percent organic content to the material.

- The percentage of "neutral" ingredients (water, mined minerals, and salt) in the product; and
- The exact percentage of organic content in the ingredient.

The above information shall be obtained from all the suppliers for each ingredient. Manufacturers shall also disclose all the information listed above for manufacturer-created ingredients. The manufacturer does not have to disclose who its suppliers are, but it shall relay information to

receivers in such a manner as to assist the next developer in performing precise calculations of organic contents.

7.2.2 Marketing consumer packages or products

In marketing consumer packages or products that are sold in bulk ready for final consumers' use, manufacturers shall disclose each organic ingredient used to calculate and support the percentage claims of the product, either on the label or on accompanying point-of-sale information. Additionally, non-organic ingredients shall be listed on the consumer packages or products.

When the percentage claim to be made on the label is calculated, the neutral ingredients shall be subtracted from the finished product, and the calculations shall be made based on all the remaining ingredients. The manufacturer does not have to disclose on the label what percentages of ingredients are neutral. See 6 for additional clarification.

7.2.3 Cautions for labels and representation

While an ingredient may be labeled as "organic" because nothing but "neutral" ingredients has been added to the organic ingredient, such an ingredient may not be counted as 100% organic when used as an ingredient of another product. The non-agricultural water or other neutral ingredients shall be subtracted before manufacturing calculations down the supply chain are made.

7.3 Product composition

A raw or processed agricultural product sold, labeled, or represented as "100 percent organic" shall be referred to the USDA-NOP.

A raw or processed agricultural product sold, labeled, or represented as "organic" shall be referred to the USDA-NOP.

Products sold, labeled, or represented as "made with organic [specified ingredients or food group/s]" shall conform to 5.3 and 6.2.

7.4 Packaged products labeled "100 percent organic" or "organic"

A raw or processed agricultural product sold, labeled, or represented as "100 percent organic" shall be referred to the USDA-NOP.

A raw or processed agricultural product sold, labeled, or represented as "organic" shall be referred to the USDA-NOP.

7.5 Packaged products labeled "made with organic"

7.5.1 Personal care packaged products labeled "made with organic"

Personal Care products in packages described in 7 CFR 205.301(c) may display on the principal display panel, information panel, and any other panel and on any labeling or market information concerning the product:

- The statement: "Made with organic [specified ingredients or ingredient groups]," provided that the statement does not list more than three organically produced ingredients. The text shall not exceed one-half the size of the largest type size on the panel. This statement shall be made in the same type size, style, and color without highlighting; or

Reason: 'or ingredient groups' added. This allows categorical claims, such as "made with organic oils, fragrances, and colors" if all ingredients in those categories were organically produced. This construction is more consistent with the NOP rule, reducing consumer confusion.

- The percentage of organic ingredients in the product. The size of the percentage statement shall not exceed ½ the size of the largest type size on the panel on which the statement is displayed and shall appear in its entirety in the same type size, style, and color without highlighting.
 - Organic percentage content statements shall not immediately precede, either horizontally or vertically, the primary product designator on a principal display panel (PDP).
 - The organic percentage content claim shall not exceed ½ the size of the primary product descriptor on the label.
- If applicable, the seal, logo, or other identifying mark of the certifying agent that certified the handler of the finished product may be used. The mark may be accompanied by the phrase "Certified to NSF 305."
 - The NSF standard logo.

7.5.2 Agricultural packaged products

Agricultural products in packages described in 7 CFR 205.301(c) shall:

- In the ingredient statement, identify each organic ingredient with the word "organic" or with an asterisk or other reference mark that is defined below the ingredient statement to indicate that the ingredient is organically produced. Water, mined minerals, and salt included as ingredients shall not be identified as organic.
- Identify the certifying agent that certified the handler of the finished product. This information shall appear on the information panel, below the information identifying the handler or distributor of the product and after the phrase "Certified to NSF 305" or a similar phrase.: The business address, Web address, or telephone number of the certifying agent may be included in this label.

7.6 Labeling of non-retail containers used only for shipping or storage of raw or processed agricultural ingredient products labeled as "100 percent organic," "organic," or "made with organic"

Non-retail containers used to ship or store raw or processed agricultural product labeled as containing organic ingredients shall display:

- The production lot number of the product if applicable;
- The name and contact information of the handler/shipper that sold the finished product;
- The name and contact information of the agent that certified the handler that assembled the final product;
- Identification of the product as organic; and

- If applicable, the phrase "Certified to NSF 305." This phrase shall be clearly visible on the container of any ingredients certified to this Standard.

Non-retail containers used only to ship or store raw or processed ingredients labeled as "100% organic," "organic," or "made with organic" may display the following:

- Special handling instructions needed to maintain the organic integrity of the product; and/or
- If applicable, the seal, logo, or other identifying mark of the agent that certified the organic production or handling operation that produced or handled the finished product.

7.7 Labeling of ingredients

Each organic personal care product shall list the ingredients on its label using the International Nomenclature for Cosmetic Ingredients (INCI) labeling system as found in the most recent edition of the International Cosmetic Ingredient (ICI) Dictionary and Handbook³ as applicable. The list of ingredients shall appear on the outer label of the personal care product. Extra descriptive or marketing terminology, unless specified in 7, shall not be deemed acceptable in the ingredient list.

7.7.1 Order of ingredients

Ingredients at a concentration of more than 1% shall be listed on the label in descending order of predominance, in their concentration by weight. Ingredients that are present at a concentration of 1% or less shall be listed in any order after the ingredients present at a concentration of more than 1% or as required by federal regulation.

Reason: Term 'random' replaced by the term 'any'. The object is not to require randomization, but to allow any non-percentage based ordering.

7.7.2 Cosmetics or personal care products in ornamental containers

In the case of a personal care product in an ornamental container that has no outside package (e. g., a perfume bottle without a box), the list of ingredients shall appear on a tag, label, or card affixed to the container.

7.7.3 Oddly-shaped personal care products

In the case of a personal care product that has no outside package and whose size, shape or texture, or that of its immediate container, makes it impractical for a tag, tape, or card to be affixed to the container (e. g., bath beads), the list of ingredients shall instead appear in a leaflet that shall accompany the personal care product at the point of sale.

Annex A¹
(informative)

**Key elements of a certification program
for organic personal care products**

A.1 General

Conformance to this Standard indicates that a manufacturer designs, develops, produces, and markets products in accordance with the requirements of this Standard. Conformance to this Standard alone does not imply certification.

Product manufacturers may pursue certification to other organic standards independently of certification to NSF 305.

A third-party certifying organization is a company that provides guidance and certification to this Standard for organic personal care production and claims from companies desiring to use an organic label claim. Third-party certifying organizations may have their own individual certification policies. These policies may be revised from time to time to reflect new materials, information, or methods as the industry evolves.

The primary goals of the third-party certifying organization should be to provide a service that verifies content claims in products intended to increase the use of organic and sustainable practices and materials; to ensure clear labeling for organic claims of non-USDA-qualified products, and to support increasing use of organic ingredients and production methods.

A.2 Product certification process

A.2.1 Conformity assessment to NSF 305

The manufacturer should identify a certification organization to perform the conformity assessment of the product development process for compliance with NSF 305, if applicable.

Any organic label claim by a company that wishes to use the third-party certifying organization's seal, name, or trademark to sell, label, or represent its products must be certified according to this Standard.

A.2.2 Identification of organic production

The manufacturer should inform the certifying organization of its choice of which organic production criteria it wishes to use for the conformity assessment of the manufacturer's product. The certifying organization should obtain the most recent version of the specified criteria to use as the basis of the product conformity assessment.

A.2.3 Conformity assessment to organic production

The certifying organization should perform the necessary functions to determine whether the manufacturer's product conforms to the specified organic production criteria. This may involve activities such as an audit of the manufacturing facility; review of the product formulation; testing,

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or review of testing documentation, for compliance with the specified product attributes, and review of product labeling and literature.

A.2.4 Issuance of product certification

If the product has been demonstrated to meet the specifications of the organic production criteria, and any issues of noncompliance have been addressed, the certifying organization should provide a product certification to the manufacturer. This may include documentation of certification of the product, as well as inclusion of the product on any publicly available lists of certified products maintained by the certifying organization. The certifying organization should instruct the manufacturer regarding appropriate use of the registered certification mark of the certifying organization.

A.2.5 Monitoring of product compliance

At intervals determined by the certifying organization, the continued conformance of the certified product to the specified criteria should be monitored using periodic facility audits.

A.2.6 Organic personal care production and handling management plan

An organic personal care operation intending to sell, label, or represent products or ingredients using any organic label claim may develop an organic production or handling management plan. This plan should be agreed on by the certifying organization. An organic personal care production or handling management plan may include:

- A description of procedures to be performed and maintained;
- A list of all substance to be used as ingredient or processing aid, indicating their compositions, sources, processing facilities where each will be used, and documentation of commercial availability, as applicable;
- A description of the monitoring procedures to verify that the plan is effectively implemented;
- A description of the record-keeping system in use that complies with the certifying organization's Standard;
- A description of the management practices and physical barriers established to prevent commingling of organic and non-organic products on a split operation and to prevent contact of organic products with prohibited substances; and
- Additional information deemed necessary by the certifying organization to evaluate compliance with this Standard.

A.3 Suggested requirements for certifying organizations

A certifying organization offering a certification program for organic personal care should comply with the requirements of ISO/IEC Guide 65 *General requirements for bodies operating product certification systems*².

² International Organization for Standardization (ISO), 1 Rue de Varembé, Case postale 56, CH-1211 Geneva 20, Switzerland

A.3.1 Marking of certified product

The certifying organization should specify requirements for marking of certified products. At a minimum, the requirements for product marking should include the following:

- certified products should bear a registered certification mark and/or the name of the certifying organization;
- each product should have a unique formulation designation; and
- each product should bear a statement of organic production and content claims verified through the certifying organization's auditing process and, when appropriate, substantiated by test data.

A.3.2 Listing certified companies

The certifying organization should maintain a published listing of all certified operations and/or products. At a minimum, the listing should include the following information:

- company name and address;
- type of operation and/or product description;
- trademark / formulation designation; and
- each claim that has been successfully evaluated and is supported by data.

A.3.3 Audits

The certifying organization should conduct annual physical audits of all facilities and production locations of the certified company as specified in the certifying organization's certification policies, as applicable.

A.3.4 Formulation evaluation

Formulation information for each ingredient used in the certified product should be provided to and maintained on file by the certifying organization. At a minimum, the formulation information should include:

- the complete identity or proportion by weight of each ingredient; and
- each ingredient's sources of supply.

A.3.5 Corrective action

The certifying organization should document corrective action for all items of nonconformance found during audits and re-evaluation, including:

- provisions for review and authorization for modifications to formulations;
- modifications to certified product formulations; and
- documentation and authorization of the modification maintained on file.

A.3.6 Enforcement

To preserve the integrity of the registered certification mark of the certifying organization, enforcement action should be taken by the certifying organization for the following:

- use of the registered trademark of the certifying organization on a non-certified product;

- general nonconformance;
- unauthorized change to a certified product; and
- unauthorized shipment or disposal of product placed on hold.

A.3.7 Appeals

The certifying organization should have provisions for a process by which any party directly affected by a decision, action, or inaction of the certifying organization may appeal that decision.

A.3.8 Complaints

The certifying organization should have provisions in its policies for the following:

- investigation of complaints related to certified products;
- misuse of the registered trademark of the certifying organization by a certified company;
- use/misuse of the registered trademark of the certifying organization by a non-certified company; and
- certified company retention and disclosure of complaint records and remedial actions for certified products.

A.3.9 Advertising

The certifying organization should provide guidance to certified manufacturers regarding proper use of the organization's registered trademark in sales literature, technical publications, promotional materials, packaging, catalogs, and advertising.

A.3.10 Records

The certifying organization should have provisions for verification of complete certified company records, including:

- purchased materials and ingredients;
- production, shipment, and inventory; and
- handling of organic personal care products or ingredients that are sold or that are intended to be sold, labeled, or represented using any organic label claim.

Such records should:

- be adapted to the particular business that the certified operation is conducting;
- fully disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited;
- be maintained for a period of time specified by the certifying organization;
- be sufficient to demonstrate compliance with this Standard and with applicable federal and state regulations; and

- be available for inspection and verification during normal business hours by authorized representatives of the certifying organization.

A.3.11 Public notice

The certifying organization should have provisions for issuing a public notice for nonconformance to any requirement of certification.

A.3.12 Confidentiality

The certifying organization should have a documented policy of non-disclosure of any confidential information supplied to the certifying organization by the company regarding the product, including formulations, components, processes, ingredients, and the identities of the company's suppliers and distributors.

Annex B³
(informative)

**Tools to assist in the evaluation, inspection, and
certification of a personal care product**

B.1 Scope

The purpose of this annex is to assist the certification agency and the inspector in conducting inspections and issuing certification to NSF 305.

B.2 Background

While it is assumed that any personal care product that is made with 100% certified organic ingredients could be certified to the NOP standard and use the USDA seal, there may also be companies that would also want to be certified to NSF 305 as well as or instead of the NOP standard. For “organic” products or products that are “made with organic ingredients,” this Standard may be used. Therefore, NSF 305 encompasses a three-tiered approach to conformance.

The granting of certification to this Standard may resemble the process of granting certification to the NOP standard or to any other certification standard. The process of certification should occur as follows:

- An operation obtains an application to be certified;
- The operation returns the application to the certifying organization;

NOTE – For example, in the case of the NOP, a manufacturer would submit the required Organic System Plan (OSP).
- The certifying organization reviews the application and system plan; and
- Based on the written system plan, the certifying organization conducts an on-site inspection to verify documented proof of implementation.

This Standard includes allowances and restrictions on production practices that may determine the label claim allowed. There are several charts or graphs within the Standard that should make it easier for certifying organizations to determine the restrictions.

B.3 Labeling

Labeling and/or representation of products to be used as ingredients in multi-ingredient personal care products may use the following methods.

B.3.1 Wholesale ingredients

All suppliers for each ingredient should provide the following to the certifying organization:

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- 1) A complete compositional analysis, including percentages of all materials used in the manufacture of the product;
- 2) The process(es) used to manufacture the product; and
- 3) The organic content, calculated as organic material in the product less the non-organic materials that stay in the end product and minus water and salt.

NOTE – Manufacturers making their own ingredients should disclose all the same information as above.

B.3.2 Wholesale ingredients described for sale to a manufacturer

The organic content of each ingredient, as verified by the certifying organization, should be available to the manufacturers for the purpose of further calculations and for use in establishing a system plan.

NOTE – Certifying organizations should clarify that information is not required for sale to the end user in situations where the materials are certified to the Standard. However, certifying organizations may request files to verify compliance if they have additional standards or policies that require such files.

B.3.3 Ingredient descriptions on finished product labels

The modifier “organic” or “made with organic” may be used when approved by the certifying organization to describe materials required in the ingredient declaration. The organic content claim, as verified by the certifying organization, may be made in accordance with the certifying organization’s policies. This may include requirements or limitations on the front label subject to labeling laws in the specified market.

B.3.4 Other considerations in labeling

B.3.4.1 Use of the word “organic” to modify product identification

Third-party certifying organizations should have clear policies with regard to labeling. These policies should include labeling requirements on active or primary ingredients. For instance, third-party certifying organizations should question label claims for a product labeled as “organic mint shampoo” if the mint is not organic. Third-party certifying organizations should encourage truth in labeling, so that the product’s label should instead say “organic shampoo with mint.”

Third-party certifying organizations should identify any restrictions on the size of label claims. This may include the word “organic.”

On labels for “made with” consumer-packaged products, the front panel should not list more than three ingredients, or categories of ingredients, as specified by the certifying organization’s certification policies. In order to prevent consumer confusion, all “made with” products should disclose the exact percentage of organic ingredients within the product, rounded down to the nearest whole number.

B.3.4.2 Use of the word organic to modify a “brand name” or company name

Certifying organizations should attempt to prevent manufacturers from making a product appear to be more organic than it really is. In an effort to achieve this, third party certifying organizations may place restrictions on the size of the word or label. For instance, a certifying organization may require that the word “organic” not be more than 50% larger than the largest type size on the front

display panel of a "made with" product. Certifying organizations may choose not to place type-size restrictions on organic and 100% organic products.

Certifying organizations may encourage manufacturers not to use the word "organic"/"organics" at more than 50% of the largest type size on the front display panel of a "made with" product, and to ensure that "organic"/"organics" does not immediately precede the primary product descriptor on the label. There should be no type size or placement restrictions on organic and 100% organic products.

B.3.4.3 Labeling requirements on the ingredients list

Certifying organizations should encourage manufacturers to list ingredients in order of percent content. Therefore, the first item on the ingredient list should be considered the primary ingredient.

Certifying organizations should also encourage the use of the INCI name in listing ingredients. The INCI name is the common nomenclature for ingredient labeling on the packaging of personal care products.

B.3.4.4 Shelf-life stability and expiration dates

For personal care products that do not contain some form of preservative or anti-microbial or anti-bacterial growth agent, certifying organizations may require manufacturers to address shelf-life stability and to include an expiration date or storage requirements such as refrigeration after opening.

B.4 Calculating organic percentages

When calculating percent of organic content, an operation may not end up with more organic content in the processed product than what the plant could reasonably contribute to the product. For instance, if an operation begins with 100 lbs of plant material by weight and separates the moisture from the dry matter, the separate combined weight cannot be more than 100 lbs (e. g., 80 lbs of liquid and 20 lbs of dry plant matter). In both cases, the extracted products can each be considered 100% organic. When an operation uses a solvent to separate parts of the plant, other methods may be used to calculate organic content.

B.4.1 Example calculation for a complex product

For a final product that is made with some organic ingredients, calculation of organic percentage may be made as shown in the following example. In this example, the ingredients come from four different suppliers. Assume full disclosure from each supplier as follows:

Supplier 1 provides a product that will serve as a component to an end product. Specific organic identity and water content are provided for each ingredient of the component. Assume that this portion is 100% organic. Exact weights and volumes of the ingredients should be obtained.

Supplier 2 provides a product that will serve as a component to an end product. This product contains four ingredients in equal amounts and equal weights. Three are identified as being 100% organic, one as non-organic. The resulting component will be 75% organic. Exact weights and volumes should be obtained.

Supplier 3 provides a product that will serve as a component to an end product. One component of this product is 100% organic; the other is not. The product uses twice as much of the non-organic component (and therefore twice the weight) of the organic component. The resulting component will be 33% organic. Exact weights and volumes should be obtained.

Supplier 4 provides a product that will serve as a component to an end product. All ingredients of the component are organic except the salt and water. Exact ingredients and organic percentages are supplied.

The manufacturer obtains documentation that all the ingredients, organic and non-organic, were properly handled and processed. The certifying organization confirms the exact ingredients in terms of how much each sub-category supplies to the finished product, and confirms the organic percentage claim for the label.

A certifier of a hydrosol/water extract manufacturer should verify the organic water/volatile content of a given plant material through a random microwave drying test.

Annex C⁴
(informative)

Example screening protocol for all non-organic materials

C.1 General

This annex contains reference information regarding one screening protocol suggested for application to all non-organic materials.

C.2 Definitions

C.2.1 base ingredient: A plant, animal or mineral derivation.

C.2.2 catalyst: A non-agricultural processing material that is used in small quantities to modify or increase the rate of chemical change in an agricultural material, but which does not itself become consumed in the process or incorporated into the modified material/ingredient.

C.2.3 processing aid: A substance intentionally used in the processing of raw materials or their ingredients to fulfill a certain technological purpose during treatment or processing, which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect on the finished product.

C.2.4 reagent: A non-agricultural material that is added to an agricultural material in a processing step in order to change its chemical structure into a more useful form. The reagent is incorporated into the agricultural material in the process and becomes part of the new material/ingredient.

C.3 Screens

C.3.1 First suggested screening method

Non-organic materials for “made with” products should be supplied with:

- an affidavit that a product is not from a GE (genetically engineered)/GMO (genetically modified organism) source or process;
- an affidavit that no base ingredient was grown with sewer sludge;
- an affidavit that no base ingredients were irradiated; and
- an affidavit of no formaldehyde or formaldehyde donors.

C.3.2 Second suggested screening method

Non-organic materials for “organic” products should be supplied with:

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- an affidavit that the product does not contain synthetic solvents, processing aids, catalysts; or reagents; and
- confirmation of the non-organic materials “Allowed”.

Annex D⁵
(informative)

**Tools to assist in the evaluation, inspection, and
certification of a personal care product**

Materials Affidavit And Checklist

- To used for non-organic ingredients and all other additives.
- To be filled out by a principal or authorized representative of your supplier(s).

Supplier /Manufacturer Name: _____

Date: _____

Ingredient Name <i>(Please indicate both brand and generic material identification.)</i>	Non-Irradiated	Not grown using sewer sludge	Non-GMO Source	Non-Formaldehyde or F. Donor	Initials of responsible party

By checking the boxes above and initialing, I state that, to the best of my knowledge, the above listed product(s) were not produced using and do not contain the prohibited materials listed.

Print Name _____ Position _____

Address _____ Phone _____

Signature _____ Date _____

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Annex E⁶
(informative)

Identification of chemical processes

E.1 Definitions

E.1.1 alkylation: The formation of a carbon-carbon bond.

E.1.2 esterification: The reaction of a carboxylic acid and an alcohol in the presence of an acidic substance.

E.1.3 hydrogenation: The saturation of a double or triple bond with elemental hydrogen in the presence of a catalyst.

E.1.4 hydrogenolysis: The cleaving of a heteroatom and its reduction to a base alkane.

E.1.5 hydrolysis: The use of a catalyst to hydrolyze complex proteins and carbohydrates into individual amino acids and sugars, respectively.

E.1.6 saponification: The creation of an alcohol and an acid salt from an ester in the presence of an alkaline substance.

E.1.7 steam fractionation: The cracking or splitting of a substance under heat and/or pressure, with or without steam, and in the presence of a catalyst, to form a new substance or substances.

E.1.8 transesterification: The reaction of an ester and an alcohol in the presence of an acidic substance.

E.2 Chemical processes

Saponification of oils with alkali to make soap

Non-Agricultural Reagents: Alkali (**KOH or NaOH made from salt water**)

Non-Agricultural Catalysts: None

Does Other Process Under Consideration Generate Inputs? No

Agricultural Inputs: Triglyceride fats and oils

Reaction Conditions: 25 psi, 150 C max

Use in Personal Care: As hand soap and bodywash; sometimes as shampoo.

EWG Human/Env. Toxicity Concern of Representative Finished Ingredients: **Low**

See Saponified Coconut Oil:

<http://www.ewg.org/reports/skindeep2/report.php?type=INGREDIENT&id=3633>

Soil Association: **Allowed**

BDIH: **Allowed**

Ecocert: **Allowed**

Additional Notes: Already allowed under the NOP for O95 products and lower (alkali NOP allowed).

Saponification is actually a specific type of hydrolysis. An alkaline material (such as sodium hydroxide, which is called lye), and water are mixed with a vegetable oil, such as coconut oil or palm oil. The lye

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combines with the oil to hydrolyze the fatty acids from the glycerin, producing soap and releasing the glycerin. Any vegetable oil or animal fat can be used. The foaming ability and conditioning of the soap depend on the oils used. Soap bars made in the 1950s and 1960s were 80% tallow and 20% coconut oil, saponified with lye. Because the industry has moved away from animal ingredients, vegetable soaps are now commonly made with 80% palm and 20% coconut oil, with minor additions of olive, sunflower, or castor oil, or many other vegetable oils. If the saponified oil (soap) is subsequently neutralized with an acid, such as hydrochloric or acetic acid, the fatty acids are released. They can then be used as personal care ingredients themselves, or can be used to make other ingredients, such as esters.

When fatty acids are neutralized with an alkali to make soap, the process is often referred to as saponification as well, though it is really neutralization.

Saponification does not use a catalyst. It does require a reagent, usually sodium hydroxide or potassium hydroxide, which is also called caustic potash.

Enzyme-catalyzed or alkali-catalyzed hydrolysis

Non-Agricultural Reagents: None

Non-Agricultural Catalysts: Enzymes or Alkali (**KOH or NaOH made from salt water**)

Does Other Process Under Consideration Generate Inputs? No

Agricultural Inputs: Proteins, Carbohydrates, Sugars

Reaction Conditions: 50 psi, 150 C max

Use in Personal Care: Hydrolyzed proteins used as an emollient substantive ingredient in conditioners and lotions.

EWG Human/Env. Toxicity Concern of Representative Finished Ingredients: **Low**

See Hydrolyzed Soy Protein:

<http://www.ewg.org/reports/skindeep2/report.php?type=INGREDIENT&id=1013115>

Soil Association: **Allowed**

BDIH: **Allowed**

Ecocert: **Allowed**

Additional Notes: Already allowed under the NOP for O95 products and lower (alkali and non-GMO enzymes NOP allowed)

The following ecological ag-based oleochemical processes employ catalysts and/or reagent ingredients that are not currently allowed under the NOP for processing ingredients, or that utilize an ingredient as an input made by one of these processes. The catalysts and reagents involved in each process are allowed only within the context of that process under this Standard. The relevant information is included for each process, including the Environmental Working Group's³ judgment on representative ingredients, and the Soil Association⁴, Ecocert⁵ and BDIH⁶ positions as well.

For these processes, which involve somewhat more complicated production than most organic inspectors are used to, a single organic content value has been assigned in conjunction with the calculations committee. This is to avoid erroneous and inconsistent organic content values being assigned, even in good faith, by different companies/inspectors/certifiers for the same process/ingredient. With the exception of glycerin, all ingredients produced by these processes are restricted to O70 products under this standard.

Hydrolysis in general, particularly fat-splitting of oils to produce glycerin and fatty acids

³ Environmental Working Group 1436 U St. N.W., Suite 100 Washington, DC 20009, <http://www.ewg.org/>

⁴ Soil Association, South Plaza, Marlborough Street, Bristol BS1 3NX, <http://www.soilassociation.org/>

⁵ ECOCERT INTERNATIONAL, Gueterbahnhofstr. 10, D-37154 NORTHEIM, GERMANY, <http://www.ecocert.com>

⁶ BDIH, L11, 20-22, D-68161 Mannheim, Germany, <http://www.kontrollierte-naturkosmetik.de>

Non-Agricultural Reagents: Water (high-pressure steam)

Non-Agricultural Catalysts: Metal/Metal Compound Catalysts (**Zinc Oxide, Nickel, Palladium, Platinum from Mined Sources**)

Does Other Process Under Consideration Generate Inputs? No

Agricultural Inputs: Triglyceride fats and oils; Carbohydrates, Sugars

Reaction Conditions: 350 psi/250 C Max

Use in Personal Care: Emollient ingredients in shampoos, conditioners, lotions, etc. Often are sub-ingredients to make more complicated ingredients (see below).

EWG Human/Env. Toxicity Concern of Representative Finished Ingredients: **Low**

See Glycerin: <http://www.ewg.org/reports/skindeep2/report.php?type=INGREDIENT&id=11465>)

See Oleic Acid: <http://www.ewg.org/reports/skindeep2/report.php?type=INGREDIENT&id=1185>)

Soil Association: **Allowed**

BDIH: **Allowed**

Ecocert: **Allowed**

Additional Notes: Conventional glycerin allowed in O95 products under NOP

Hydrolysis occurs when a compound is combined with water, producing a new compound. Examples of hydrolysis are the conversion of starches to sugars, the conversion of proteins into amino acids or peptides if partially hydrolyzed, and the conversion of fats or oils into glycerin and fatty acids. Enzymes or steam can be used to hydrolyze proteins, fats, oils, and carbohydrates.

In living tissues, proteins are very large molecules that are bound up in the structure of a plant or animal. Keratin and collagen are two of the structural proteins that hold a plant or animal together. Hydrolysis can make structural proteins more useful for personal care products. Hydrolysis makes structural proteins more water-soluble by breaking them down with water, a process that is made more efficient by adding enzymes, acids, or bases. Structural proteins will then be very good moisturizers and conditioners when added to hair or skin care products.

Carbohydrates can also be modified by hydrolysis to make them more useful in personal care products. Starch, found in grains, potatoes, and many agricultural products, can be hydrolyzed to create modified starches, sugar complexes such as maltodextrin, or simple sugars such as glucose. These starches and sugars can be used in personal care products, alone or combined with other ingredients, to make new functional materials. For instance, combining glucose with coconut alcohol makes coco glucoside, a mild foamer and cleansing agent.

Hydrolyzation can use several types of catalysts: enzymes, strong acids such as sulfuric acid, or strong alkalis such as sodium hydroxide or potassium hydroxide. Zinc oxide is often used to promote steam splitting of fats. Some specific hydrolysis processes, such as steam splitting a fat into fatty acids and glycerin, can be done without the use of catalysts.

Etherification of glycerin and glycerin making polyglycerols

Non-Agricultural Reagents: None

Non-Agricultural Catalysts: Alkali (**NaOH or KOH from Salt Water**)

Does Other Process Under Consideration Generate Inputs? Yes, Fat-Splitting Producing Glycerin

Agricultural Inputs: Glycerin (product of fat-splitting)

Reaction Conditions: vacuum; 250 C Max

Use in Personal Care: Emollient ingredient and used to make esters.

EWG Human/Env. Toxicity Concern of Representative Finished Ingredients: **Low**

Polyglyceryl Oleate (Etherification of Glycerin & Esterification)

<http://www.ewg.org/reports/skindeep2/report.php?type=INGREDIENT&id=3560>

Soil Association: **Allowed**

BDIH: **Allowed**

Ecocert: **Allowed**

Additional Notes: None

Natural glycerin from the splitting of natural vegetable oils can be polymerized to a "polyglycerol" with the liberation of water if it is heated with an alkaline material. The amount of glycerin that can be polymerized depends on the degree of heating. Common glycerin oligomers are Polyglyceryl-3, -6, and -10, where the number represents the number of glycerin molecules strung together into a short polymer or oligomer. Polyglycerol esters are made by combining fatty acids with polyglyceryl and heating them to make esters as previously described. Like the alkyl polyglucosides above, polyglycerol esters are completely derived from renewable resources.

Non-catalyzed or alkali-catalyzed transesterification of organic oils and alcohols to make esters (i.e. organic sucrose & coconut oil are heated with potassium carbonate to make sucrose cocoate)

Non-Agricultural Reagents: None

Non-Agricultural Catalysts: None or Alkali (**KCO₃ or NaCO₃; NaOH or KOH made form salt water**)

Does Other Process Under Consideration Generate Inputs? No

Agricultural Inputs: Triglyceride fat and alcohol

Reaction Conditions: 60 psi, 200 C max

Use in Personal Care: Depending, esters are used as emulsifiers in lotions and/or as emollient ingredients in their own right. Some esters have preservative qualities.

EWG Human/Env. Toxicity Concern of Representative Finished Ingredients: **Low**

See Sucrose Cocoate

<http://www.ewg.org/reports/skindeep2/report.php?type=INGREDIENT&id=1212>

Soil Association: **Allowed**

BDIH: **Allowed**

Ecocert: **Allowed**

Additional Notes: Already allowed under the NOP for O95 products and lower

Transesterification is a special type of esterification. It is an exchange of one alcohol or acid for another. Vegetable oils are made of acids, called fatty acids, as esters with glycerin, which is a type of alcohol. Transesterification occurs, for instance, when ethanol is added to soybean oil along with a small amount of lye or alkali like sodium hydroxide, and the mixture is heated. At this point, the fatty acids from the vegetable oil are transferred from the glycerin and combine with the ethanol to make a new ester: soybean oil ethyl ester or "ethyl soyate." Transesterification is used to create "biodiesel" fuel from methanol and vegetable oils. The glycerin released by the process is easily extracted, leaving an inexpensive and sustainable fuel. Ethanol can also be used in this process.

Transesterification can also be done with vegetable oils and glycerin. For example, mixing one part of coconut oil with two parts glycerin and adding a small amount of lye or acid with heat will produce glyceryl monococoate, a very effective personal care emulsifier. If transesterification is carried out using a lye catalyst and vegetable oils with different compositions, interesterification occurs, and the result is a modified oil with a different composition from either of the original oils. The melting point, skin feel, and other attributes of a substance can be altered in this manner.

An alkali like sodium hydroxide, or a strong acid like sulfuric acid, will catalyze the transesterification process. Sodium methylate, made by combining sodium metal with methanol, is commonly used for this purpose. Sodium ethylate, made by combining alkali with ethanol, also works as a transesterification catalyst. Some transesterification processes, using more alcohol and less oil, can be carried out without a catalyst. Solid fixed bed catalysts are also used.

Mineral acid-catalyzed esterification or transesterification to produce various esters

Non-Agricultural Reagents: None

Non-Agricultural Catalysts: **Sulfuric or Phosphoric Acid made from Coal/Gas/Petroleum**

Does Other Process Under Consideration Generate Inputs? Potentially Yes; Fat-Splitting making Glycerin/Fatty Acids, or Hydrogenolysis making Fatty Alcohols

Agricultural Inputs: Acid and Alcohol, sometime Fatty Alcohol made by hydrogenolysis or Triglyceride fat and alcohol

Reaction Conditions: 60 psi; 200 C Max

Use in Personal Care: Depending, esters are used as emulsifiers in lotions and/or as emollient ingredients in their own right. Some esters have preservative qualities.

EWG Human/Env. Toxicity Concern of Representative Finished Ingredients: **Low**

See Glyceryl Stearate

<http://www.ewg.org/reports/skindeep2/report.php?type=INGREDIENT&id=2939>

Soil Association: **Allowed**

BDIH: **Allowed**

Ecocert: **Allowed**

Additional Notes: None

Esterification is the process of combining two ingredients, an organic acid and an alcohol, to make a new ingredient. For example, amyl alcohol, derived from grains, can be mixed with acetic acid from vinegar, a dilute solution of acetic acid. If heat and vacuum are applied, these two materials combine to make amyl acetate, an aroma compound. The combination of an acid and an alcohol can be performed to make an ingredient that has different properties from the two original ingredients, as with the previous example. It can also be done to make an ingredient more stable. For instance, tocopherol, vitamin E, tends to break down fairly quickly. Combining it with acetic acid and esterifying it makes tocopheryl acetate, a product stable enough to use in personal care products.

The personal care and food industries use a wide range of esters for many different functions. For instance, glycerin, derived from vegetable oils, can be combined with stearic acid, or with derived vegetable oils like palm oil, to make the emulsifier glyceryl stearate for creams and lotions. Glyceryl caprate, another vegetable-derived ester, helps to preserve products against microbiological contamination. There are thousands of esters, many of them petrochemical-free, used in personal care products.

No reagents or catalysts are required for esterification, but many are used in the personal care ingredient industry. Some of those used are mineral acids like hydrochloric and sulfuric acids; some are mined, like sodium carbonate; others are called Lewis acids, like zinc oxide.

Hydrogenation of oils

Non-Agricultural Reagents: **Hydrogen from Natural Gas**

Nn-Agricultural Catalysts: **Nickel, Platinum or Palladium from Mining**

Does Other Process Under Consideration Generate Inputs? No

Agricultural Inputs: Triglyceride fat/oil usually

Reaction Conditions: 200 psi; 200 C Max

Use in Personal Care: Hydrogenated oils and fats are used for their shelf-stability and “waxy” feel in lotions and conditioners.

EWG Human/Env. Toxicity Concern of Representative Finished Ingredients: **Low**

See Hydrogenated Soybean Oil

<http://www.ewg.org/reports/skindeep2/report.php?type=INGREDIENT&id=1925>

Soil Association: **Prohibited**

BDIH: **Allowed**

Ecocert: **Allowed?**

Additional Notes: None

Hydrogen is the required reagent for hydrogenation. Nickel or platinum is usually used as a catalyst.

The term “trans fat” is used in the food industry to refer to a form of fat that is not desirable from a nutritional standpoint. The terms “cis” and “trans” refer to the physical orientation of a double bond, or

the point of unsaturation, in a fatty acid. A completely saturated fatty chain is all in a straight line. If there is a double bond, or an unsaturation point, the chain bends at that point. If the two parts of the chain on either side of the double bond bend towards each other, like the letter C, that is a cis orientation. If the two parts bend in opposite directions, like the letter Z, that is a trans orientation. Most natural unsaturated fats have a combination of saturated and cis fatty acids in their make up but not trans fatty acids. Most of the catalysts used for hydrogenation cause some "isomerization" or conversion of some cis double bonds into trans double bonds and thus the formation of some "trans fatty acids." This means that most partially-hydrogenated vegetable oils, such as those used in most margarines, will have some content of trans fatty acids. If the oil is completely hydrogenated, however, there will be no cis or trans unsaturation left and thus no trans fatty acids.

The term "hydrogenation" is used loosely in the personal care industry to describe two different processes, which result in two different types of ingredients. Vegetable oils contain many different types of fatty acids, usually as esters, some saturated and some unsaturated. A saturated oil is composed of esters of fatty acids that have all single carbon-carbon bonds, no double bonds between carbons. An unsaturated fat has one or more double bonds in the fatty acid chains. Nutritionists refer to vegetable oils as primarily saturated, mono-unsaturated or polyunsaturated. Different levels of saturation change the properties of an oil in terms of its melt point, viscosity, etc. However, oils that are less saturated also oxidize and turn rancid more quickly. This reduces the long-term stability required for personal care products. Using the process of hydrogenation, a vegetable oil can be made more saturated, which makes it more stable in a personal care product. Hydrogenation can also be used to make a liquid oil into a solid wax. Castor oil is used in many personal care products because of its unique feel. If castor oil is made more saturated by hydrogenation, it becomes a wax, which has properties significantly different from those of the original oil.

In addition to vegetable oils, other unsaturated species in natural products can be hydrogenated. For example, the phenyl ring of an essential oil may be hydrogenated to make it a cyclohexyl structure. In other cases, the double bonds of a natural product may be eliminated by hydrogenation. This elimination often gives better oxidative stability to the product and thus lends stability to a personal care product made from it.

Hydrogenolysis of methyl or ethyl esters of an oil with hydrogen to make fatty alcohols

Non-Agricultural Reagents: **Hydrogen from Natural Gas**

Non-Agricultural Catalysts: **Methanol from Natural Gas; Nickel, Platinum, Palladium from Mining**

Does Other Process Under Consideration Generate Inputs? Yes, Transesterification makes Methyl Esters

Agricultural Inputs: Methyl or Ethyl Ester of Triglyceride fat/oil (fat/oil original ag input)

Reaction Conditions: 300 psi/3000 C Max

Use in Personal Care: In themselves, fatty alcohols are used as emollient/conditioning ingredients in lotions, conditioners and shampoos. Fatty alcohols are also important sub-ingredients in the manufacture of many surfactants (see Glucosidation and Sulfation below).

EWG Human/Env. Toxicity Concern of Representative Finished Ingredients: **Low**

See Cetearyl Alcohol

<http://www.ewg.org/reports/skindeep2/report.php?type=INGREDIENT&id=45>

Soil Association: **Allowed**

BDIH: **Allowed**

Ecocert: **Allowed**

Additional Notes: Transesterification First of Organic Oil with Methanol Makes Methyl Esters; No Methanol Remains in the Fatty Alcohol.

Another application of hydrogenation is the formation of fatty alcohols from esters and from fatty acids directly. If the process of applying hydrogen to a fatty material is done with higher temperatures and pressures and the right catalyst, a vegetable oil can be converted into a fatty alcohol. This process is really a combination of hydrogenation and hydrogenolysis, but is loosely referred to in the personal

care industry as "hydrogenation." In a fatty acid, the end carbon is attached to two oxygen atoms, one via a single bond and the other through a double bond. Combining the fatty acid with hydrogen removes one of the oxygen atoms, which leaves the carbon attached to one oxygen atom via a single bond. The product of hydrogenation of a fatty acid is a fatty alcohol. If an ester is used, two alcohols are produced. For example, if ethyl palmitate is hydrogenated, under these conditions, ethyl alcohol and cetyl alcohol are produced.

The commercial process of converting an oil into an alcohol can start with an unprocessed vegetable oil, a fatty acid, or an ester. There are various advantages to each of these, depending on the required equipment and the desired finished product. If a whole oil, such as coconut oil, is being converted to a whole fatty alcohol, the conversion can be achieved directly or by first converting the oil to a fatty acid. If the desired finished materials are the separate chain lengths of alcohol (lauryl, myristyl, cetyl, stearyl, etc.), the separation is most easily performed by converting the oil to a methyl ester, distilling the methyl ester to achieve the desired separation, and then converting the separate esters to fatty alcohols. Methanol is usually used, along with sodium methylate or sodium hydroxide as a catalyst, to convert the oil into the methyl ester. Adding hydrogen along with a catalyst, such as copper chromate, under high temperature and pressure, converts the methyl ester into the fatty alcohol. Using copper chromate as the catalyst achieves the desired reduction of the fatty acid to the fatty alcohol, without affecting the unsaturated double bonds in the fatty acid chains. Thus, the formation of trans-fats, which are present in partially hydrogenated vegetable oils, is avoided. If desired, the fatty alcohol can then be further distilled with heat and vacuum, for further separation or purification.

Glucosidation

Non-Agricultural Reagents: None

Non-Agricultural Catalysts: **Toluene Sulfonic Acid made from Petroleum**

Does Other Process Under Consideration Generate Inputs? Yes. Hydrogenolysis producing Fatty Alcohol.

Agricultural Inputs: Glucose and Fatty Alcohol

Reaction Conditions: Atmosphere; 150 C Max

Use in Personal Care: Surfactant in Shampoos and Bodywashes.

EWG Human/Env. Toxicity Concern of Representative Finished Ingredients: **Low**

See Lauryl Glucoside

<http://www.ewg.org/reports/skindeep2/report.php?type=INGREDIENT&id=1914>

Soil Association: **Allowed**

BDIH: **Allowed**

Ecocert: **Allowed**

Additional Notes: None

Alkyl polyglucosides, made by combining a fatty alcohol with between one and two molecules of glucose, have become significant raw materials for the formulation of personal care products. They are low in toxicity and readily biodegradable. They are not made with any petrochemicals and are completely derived from renewable resources. They are usually made by direct glycosidation of fatty alcohol, like coco fatty alcohol from coconut oil, with glucose using a very small amount of an acid to help the reaction. Alkyl polyglucosides are less frequently made via "transglycosidation," also called transacetalization. In that process, a smaller alcohol, like butanol, is used to make an alkyl polyglucoside. The polyglucoside, which has a lower molecular weight, is then combined with fatty alcohol to make an alkyl polyglucoside surfactant, and the smaller alcohol is recovered for reuse.

Sulfation

Non-Agricultural Reagents: Sulfate/SO₃ made from Petroleum/Gas and NaOH

Non-Agricultural Catalysts: None

Does Other Process Under Consideration Generate Inputs? Yes. Hydrogenolysis producing Fatty Alcohol.

Agricultural Inputs: Fatty Alcohol

Reaction Conditions: Atmosphere; 25 C Max

Use in Personal Care: Sulfated surfactants are used in many shampoos and bodywashes.

EWG Human/Env. Toxicity Concern of Representative Finished Ingredients: **Low**

See Sodium Lauryl Sulfate

<http://www.ewg.org/reports/skindeep2/report.php?type=INGREDIENT&id=1171>

Soil Association: **Prohibited**

BDIH: **Allowed.**

Ecocert: **Prohibited.**

Additional Notes: SLS is controversial.

Sulfation is the process of heating sulfur to oxidize a fatty alcohol, such as coconut alcohol, to sulfur dioxide (SO₂). The SO₂ is then further oxidized with oxygen from the air to sulfur trioxide (SO₃), which is then combined with the fatty alcohol to form a sulfate half ester. The resulting sulfate ester is neutralized with an alkali like sodium hydroxide to form sodium coco-sulfate. If the alcohol used is lauryl alcohol, which is produced from coconut oil, the ingredient is called sodium lauryl sulfate. This material has been used as the foaming ingredient in toothpaste for over fifty years.

This process uses two reagents, sodium hydroxide and sulfur / sulfur dioxide / sulfur trioxide. The conversion of SO₂ to SO₃ is accomplished using a vanadium or platinum catalyst.

This process is distinct from "sulfonation," which results in an SO₃ group attached to a carbon atom.

Protein fragment (non-petroleum) acylation

Non-Agricultural Reagents: **KOH or NaOH made from Salt Water**

Non-Agricultural Catalysts: **Phosphorous Trichloride or Thionyl Chloride**

Does Other Process Under Consideration Generate Inputs? Yes. Fat-Splitting making Fatty Acid.

Agricultural Inputs: Fatty Acid and Protein Fragment

Reaction Conditions: Atmosphere; 25 C Max

Use in Personal Care: Surfactants in shampoos and bodywashes.

EWG Human/Env. Toxicity Concern of Representative Finished Ingredients: **Low**

See Sodium Cocoyl Glutamate

<http://www.ewg.org/reports/skindeep2/report.php?type=INGREDIENT&id=2878>

Soil Association: **Allowed**

BDIH: **Allowed**

Ecocert: **Allowed**

Additional Notes: Fatty Acid is halogenated as an intermediate step to attach to protein fragment; No halogen remains in final ingredient.

Acylation is the addition of a fatty acid to a nitrogen-containing compound. For example, the addition of coconut fatty acid to glutamic acid, followed by neutralization, yields sodium cocoyl glutamate. Fatty acids may be added to other amino acids and to partially hydrolyzed proteins to produce useful personal care ingredients.

Usually, fatty acid chlorides are used for this reaction. They are made from fatty acids and phosphorus trichloride. Typically, a fatty acid is converted into an acid chloride, which can then be mixed with the amino acid or hydrolyzed protein to form a personal care ingredient.

In some instances, fatty acid chlorides are used to produce esters of hydroxyl-functional compounds via acylation. If fatty acid chloride is mixed with sorbitol, a sorbitol ester is formed.

Acylation may also be accomplished with organic acid anhydrides. For example, acetic anhydride may be added to ethanolamine to produce acetamide MEA.

Annex F⁷
(informative)

Tools to assist with Good Manufacturing Practices

F.1 Written procedures

Written procedures should be established and followed for the maintenance of Good Manufacturing Practices as applicable.

F.2 Commingling and contact with prohibited substances

Manufacturers should implement measures necessary to prevent the commingling of organic and non-organic products and to protect organic products from contact with prohibited substances. Measures implemented to prevent the commingling of organic and non-organic products should include, but are not limited to:

- Packaging materials, storage containers, or bins that contain any substance or residual substance specified in 5.2; and
- The use or reuse of any bag or container that has been in contact with any substance in such a manner as to compromise the organic integrity of any organically produced product or ingredient placed in the containers, unless the container has been thoroughly cleaned and poses no risk of contact of the organic ingredient or product with the substance.

F.3 Record retention

Written procedures should be established and followed for recordkeeping.

Records of inspections should be kept on file with documented corrective action.

Records of testing, production, control, distribution, and documentation of each batch, as required for Good Manufacturing Practices, should be retained for at least one year after the expiration or shelf life date of the batch.

Raw materials records should be maintained for at least one year after the expiration or shelf life date of the last batch of product incorporating the raw material.

All records relating to the manufacture of a product (e. g., records of maintenance, cleaning, and calibration of equipment) should be maintained for at least one year after the expiration or shelf life date of the last batch of product manufactured.

F.3.1 Master production and control records

A master production and control record (including, for example, manufacturing formula, raw materials specifications, component specifications, and/or finished product specifications) should

⁷ The information contained in this Annex is not part of this American National Standard (ANS) and has not been processed in accordance with ANSI's requirements for an ANS. As such, this Annex may contain material that has not been subjected to public review or a consensus process. In addition, it does not contain requirements necessary for conformance to the Standard.

be prepared for the manufacture of each product and should be reviewed and approved by the quality control unit.

Master production and control records should include:

- a complete list of raw materials used in the manufacture of the product, designated by names or codes sufficiently specific to indicate any special quality characteristic(s) and other specifications;
- the amount of each raw material used;
- a description of the product container(s), closures(s), and label(s), including positive identification of all labeling used; and
- manufacturing and process control instructions.

Written procedures should be established and followed.

F.3.2 Batch production and control records

Batch production and control records should be prepared and followed for each batch of product. These records should include information relating to the production and control of each batch. The records should be an accurate reproduction of the appropriate master production and control record and should include documentation that each significant step in the manufacturing process was accomplished, including:

- dates;
- identities of individual lines and major pieces of equipment used;
- specific identification, including lot number, of each raw material or in-process material used;
- weight or measure of each raw material used in the course of processing;
- if applicable, in-process testing results;
- quality control results;
- details and results of packaging and labeling area inspections;
- a statement of the actual yield at the conclusion of each critical process step of the manufacture and a statement of the percentage of theoretical yield, as appropriate;
- label control records, including specimens, copies, or records of all labels used;
- a description of product containers and closures used;
- special notes of any investigations or deviations from the described process; and
- identification of the persons performing and directly supervising the process.

Any deviations from written and approved specifications, standards, and test methods should be recorded on the batch record and justified.

Written procedures should be established and followed.

F.3.3 Complaint files

Written procedures should be established and followed for the handling of all written and oral product complaints. Such procedures should provide for review by the quality control unit and determination of the need for an investigation.

A written record of each complaint should be maintained for at least one year after the expiration or shelf life date of the product, or one year after the date that the complaint was received, whichever is longer. The written record should include, where known, the name and description of the product; the product lot number; the source and nature of the complaint; and the response, if any. When an investigation is conducted, the written record should include the findings of the investigation and follow-up action taken.

F.4 Handling and storage of raw materials, in-process materials, and rework

Raw materials, in-process materials, and rework should be inspected and segregated or otherwise handled as necessary to verify that they are clean and suitable for processing. They should be stored and transported under conditions that protect against adulteration and minimize deterioration.

Containers of raw materials should be inspected upon receipt to ensure that their condition has not contributed to the adulteration or deterioration of the contents.

Raw agricultural materials that contain soil or other extraneous material should be washed or cleaned, as necessary.

Raw materials, in-process materials, and rework should be held in bulk or in containers and under conditions of temperature and humidity that prevent the materials from becoming adulterated or contaminated.

Written procedures should be established and followed for the receipt, identification, examination, handling, sampling, testing, and approval or rejection of raw materials.

Written procedures should be established and followed for the receiving, processing, storage, and final delivery of product requiring temperature control.

Each lot of raw material should be identified with a distinctive lot number and shall be controlled according to its status (e. g., quarantined, approved, or rejected).

Each lot of raw material, in-process material, and rework that is liable to adulteration with filth, insect infestation, or other visually evident extraneous materials should be examined against established specifications.

Each lot of raw material, in-process material, and rework that is liable to microbiological contamination that is objectionable in view of its intended use should be subjected to microbiological tests before use.

Written procedures should be established and followed to verify the identity of each lot of raw material.

Approved raw materials should be rotated so that the oldest approved stock is used first.

Raw materials should be retested or reexamined after a specified time in storage or after exposure to conditions that are likely to have an adverse effect on the purity, quality, or composition of the raw material.

Rejected raw materials should be identified and controlled under a system that prevents their use in manufacturing or processing operations, and they should be stored in separate storage facilities.

Written procedures should be established and followed.

F.5 Manufacturing operations

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of personal care products should be conducted in accordance with sanitation principles in a manner that protects against adulteration from chemical, microbiological, and other extraneous sources.

Written procedures should be established and followed for all inspection, manufacturing, packaging, and storage operations.

Effective measures should be taken to segregate raw materials, packaging materials, in-process materials, rework, and finished products.

All containers, processing lines, and major equipment used during the production of a batch should be identified at all times to indicate their contents.

Effective measures should be taken for the identification, storage, and disposal of rejected and/or adulterated products.

Written procedures should be established and followed to test the purity, compositions, and quality of the finished product.

Written procedures should be established and followed prescribing the method for reprocessing batches that do not conform to finished goods standards or specifications.

F.6 Packaging and labeling operations

Filling, assembling, packaging, and other operations should be performed in such a way that products are protected against adulteration.

Written procedures should be established and followed for the receipt, storage, and examination of packaging materials.

Labels for each different product type, strength, or quantity of contents should be stored separately and controlled in a manner consistent with Good Manufacturing Practices.

Obsolete labels, labeling, and other packaging materials should be destroyed and such destruction documented in writing.

Written procedures should be established and followed to ensure that the correct labels, labeling, and packaging materials are issued and used.

Each package should be identified with a lot number that permits determination of the history of the manufacture and control of the batch.

Packaging should be examined to ensure that the containers and packages in the lot have the correct labels and lot numbers.

F.7 Warehousing, distribution, and post-distribution processes

F.7.1 Storage and distribution

Storage and transportation of finished product should be conducted under conditions that protect the product against physical, chemical, and microbial adulteration, as well as against deterioration of the product and container.

Distribution records should be maintained and retained for at least one year beyond the product's expiration date or shelf life.

Written procedures should be established and followed.

F.7.2 Written recall procedures

Written procedures should be established and followed that regulate the recall of product(s) should it become necessary.

F.7.3 Cleaning and sanitizing agents

Cleaning and sanitizing agents, pesticide chemicals, and fungicides should be safe and effective for their intended use.

Cleaning and sanitizing agents, pesticide chemicals, and fungicides should be identified, used, held, and stored in a manner that protects against adulteration of raw materials and in-process or finished products, and against contamination of processing equipment, utensils, and packaging materials.

Written procedures should be established and followed.

F.7.4 Pest control

Effective means should be taken to exclude pests from the entire plant. The use of insecticides or rodenticides is permitted only with precautions and restrictions that protect against adulteration of raw materials, products, equipment, or packaging materials.

No evidence of pests should be present on product or packaging or in the vicinity of the plant.

Pest control inspections should be performed routinely.

Written procedures should be established and followed.

F.7.5 Water supply

Potable water, as a minimum quality water, at designated temperature and pressure where appropriate, should be provided in all areas where it is required for processing and cleaning or for employee sanitary facilities. Water shall meet or exceed the standards prescribed in the USEPA National Primary Drinking Water Regulations (40 CFR part 141)⁵ or the WHO Guidelines for Drinking-Water Quality⁶.

Written procedures shall be established and followed.

Annex G
Tables

Table G.1 – Illustrative list of ingredients for personal care produced by NOP-allowed processes

Available in Organic Form	Not Commercially Available
Glucose	Dextrin
Potassium Cocoate (“Saponified Coconut Oil”)	Glyceryl Cocoate
Potassium Oliviate (“Saponified Olive Oil”)	Glycerin
Potassium Palmkernelate (“Saponified Palm Kernal Oil”)	Hydrolyzed Collagen
Sodium Cocoate (“Saponified Coconut Oil”)	Hydrolyzed Gelatin
Sodium Oliviate (“Saponified Olive Oil”)	Hydrolyzed Keratin
Sodium Palmkernelate (“Saponified Palm Kernal Oil”)	Maltodextrin
Fructose	Maltose
Potassium Castorate (“Saponified Castor Oil”)	Mannose
Potassium Hempate (“Saponified Hemp Oil”)	Polyglycerin
Potassium Palmate (“Saponified Palm Oil”)	Sucrose Cocoate (purified)
Sodium Castorate (“Saponified Castor Oil”)	
Sodium Hempate (“Saponified Hemp Oil”)	
Sodium Palmate (“Saponified Palm Oil”)	
Soy Protein	
Sucrose Cocoate (unpurified)	

Table G.2 – Illustrative list of ecological agricultural-based botano-chemical ingredients made by processes in Table 5.1 permitted under this standard for “Made with” products

Ingredients available in organic form ¹	Ingredients temporarily permitted in conventional form ²	Ingredients currently not available in organic form, and not allowed in conventional form, but allowed once organic form is available ³	
Soy Wax	Stearic Acid	Hydrolyzed Wheat Starch	Cysteine
Hydrolyzed Soy Protein	Coconut Acid	Cystine	Soy Amino Acids
	Oleic Acid	Wheat Amino Acids	Hydrolyzed Vegetable Protein
	Lauric Acid	Vegetable Amino Acids	Hydrolyzed Silk Protein
	Olive Acid	Jojoba Wax	Olive Wax
	Palm Acids	Jojoba Esters (uses hydrogenated jojoba oil so O70 only)	Olive Alcohol
	Soy Acid	Palm Kernel Alcohol	Babassu Alcohol
	Hydrolyzed Wheat Protein	Jojoba Alcohol	Lauryl Alcohol
	Coconut Alcohol	Disodium Coco-Glucoside Citrate	Disodium Coco-Glucoside Tartrate
	Palm Alcohol	Polyglyceryl-3 Beeswax	Polyglyceryl-3 Cocoate
	Cetearyl Alcohol	Cocoyl Glutamic Acid	Cocoyl Hydrolyzed Collagen
	Cetyl Alcohol	Cocoyl Hydrolyzed Soy Protein	Decyl Glucoside
	Stearyl Alcohol	Disodium Coco-Glucoside Citrate	Disodium Coco-Glucoside Tartrate
	Glyceryl Cocoate	Disodium Cocoyl Glutamate	Lauryl Glucoside
	Glyceryl Stearate	Potassium Cocoyl Glutamate	Potassium Cocoyl Glycinate
	Sodium Lauroyl Lactylate	Sodium Babassu Sulfate	Sodium Cocomonoglyceride Sulfate
	Tocopheryl Acetate	Sodium Cocoyl Hydrolyzed Collagen	Sodium Cocoyl Hydrolyzed Soy Protein
	Retinyl Palmitate	Sodium Olivoyl Glutamate	Sodium Palm Kernel Sulfate
	Polyglycerin	Sodium Palm Sulfate	
	Coco-Glucoside		
	Sodium Coco Sulfate		
	Sodium Cocoyl Glutamate		

¹ Shall only be used in organic form

²Ingredients currently not available in organic form that are temporarily allowed in the conventional form until organic form is available

³ No allowance for conventional forms of these ingredients

Table G.3 – Illustrative list of prohibited common ingredient types/classes

Synthetic Preservatives not otherwise specifically allowed
Compounds with “ethoxylate”, “PEG” or the suffix “-eth” in the ingredient name
Compounds with “Betaine” in the ingredient name
Compounds with “quaternary” or the suffix “-onium” in the ingredient name
Compounds with “sarcosinate” in the ingredient name
Compounds with “MEA”, “DEA” or “TEA” in the ingredient name
Compounds with “taurate” in the ingredient name
Compounds with “sultaine” in the ingredient name
Compounds with Sulfosuccinate in the ingredient name
Compounds with “PPG” in the ingredient name

Table G.4 – Illustrative list of prohibited ingredients

Ammonium Lauryl Sulfate	Amodimethicone
Behentrimonium Chloride	Behentrimonium Methosulfate
Butylene glycol	Carbomer
Cetareth-20	Cetrimonium Chloride
Coco Betaine	Coco DEA
Cocoamidopropyl Betaine	Cyclopentasiloxane
Diazolidinyl Urea	Dimethicone
Disodium Cocoamphodiacetate	EDTA
EthylHexylGlycerin	Glycereth-7 Cocoate
Guar Hydroxypropyltrimonium Chloride	Isoceteth 20
Isopropyl Palmitate	Lauramide MEA
Lauryl DEA	Methoxycinnamate
Olefin Sulfonate	Oleyl Betaine
Parabens (methyl, propyl, butyl, etc.)	PEG-150 Distearate
PEG-7 Glyceryl Cocoate	Phenoxyethanol
Polyquaternium 10	Propylene Glycol
Sodium Cocoyl Sarcosinate	Sodium Hydroxymethylglycinate
Sodium Hydroxymethylglycinate	Sodium Laureth Sulfate
Sodium Lauroyl Sarcosinate	Sodium Lauryl Carboxylate
Sodium Lauryl Sulfoacetate	Sodium Myreth Sulfate
Sodium PCA or Na PCA	Soyamidopropalkonium Chloride
Stearalkonium Chloride	Stearamidopropyl Dimethyl Amine
Synthetic fragrances	