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American National Standard

NSF/ANSI 305 - 2016

Personal Care Products
Containing Organic Ingredients



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NSF International Standard/
American National Standard
for Organic Personal Care Products —

Personal Care Products Containing Organic Ingredients

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Foreword²

This American National Standard, NSF/ANSI 305 Personal Care Products Containing Organic Ingredients, has been developed as part of the ongoing efforts of a number of interested parties to encourage participation in the manufacturing of personal care products using organically grown ingredients within the supply chain and to address issues on chemical processes, terminology, commercial availability, product composition, calculations, and labeling. Stakeholders involved in developing the Standard included regulatory/public health, industry, trade associations, ingredient suppliers, general interest and product certifiers. The scope of this Standard includes, but is not limited to, rinse-off/leave-on personal care products, cosmetic products, oral care and personal hygiene products.

The National Organic Program (NOP) Regulations (Standards) & Guidelines established requirements for the production and handling of organically produced products, specifically food products. The NOP helps to assure consumers that food labeled 'organic' is truly organically produced and processed. Organic personal care companies have sought voluntary validation of organic claims, but have had to work within the limitations of the NOP standards.

NSF/ANSI 305 – *Personal care products containing organic ingredients*, allows personal care companies the option to use this Standard to make organic label and marketing claims, while meeting the strict requirements of this Standard, which includes the proper organic levels for personal care products.

By January 2015, the allowance of plant-based materials certified to EC 834/2007 and EC 889/2008 will be revisited by the Joint Committee on Organic Personal Care, given the cooperative efforts of the USDA National Organic Program with international governments in regard to their organic regulations.

This edition of the Standard (NSF/ANSI 305-2016) includes the following revisions:

Issue 26: This revision provided clarification on how non-retail containers are labeled for shipping and storage.

Issue 28: Normative references were updated.

This Standard emphasizes open disclosure of impacts and benefits, and does not compromise proprietary, patented, or trade secret information. These requirements are intended to form the basis of conformity assessment programs, such as third-party certification or registration.

Suggestions for improvement of this Standard are welcome. This Standard is maintained on a Continuous Maintenance schedule and can be opened for comment at any time. Comments on this Standard should be sent to Chair, Joint Committee on Organic Personal Care Products at standards@nsf.org or c/o NSF International, Standards Department, P.O. Box 130140, Ann Arbor, Michigan 48113-0140, USA or to standards@nsf.org.

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NSF/ANSI Standard for Personal Care Products

Personal Care Products Containing Organic Ingredients

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. Production practices implemented in accordance with this Standard shall maintain or improve the natural resources of the operation, including soil and water quality. This Standard is to be used voluntarily by companies that may not be able to meet the current USDA organic food regulations.

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. This Standard intends to address products with a minimum organic content of 70% (O70).

Products intended to be labeled with organic processing claims currently defined under the USDA National Organic Program (NOP), including "100% Organic", "Organic", and "Made with Organic", are not covered by this Standard.

Items covered by this Standard include, but are not limited to: cosmetic products; rinse-off and leave-on personal care products; oral care products; and personal hygiene products. These products may be applied to or used externally on any part of the body (e.g., hair, face, hands, and feet). 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 Program³ (NOP) regulations, this Standard includes allowances and restrictions on processes, agricultural 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.

Product compliance with this Standard does not ensure compliance with all regulatory requirements.

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 Reference documents

2.1 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. The most recent published edition of the document shall be used for undated references.

7 CFR Part 205, *National Organic Program*³

40 CFR Part 141, *National Primary Drinking Water Regulations*³

Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control⁴

Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91⁵

IASC, *Aloe Vera Quality Standard*⁶

International Cosmetic Ingredient Dictionary and Handbook (INCI), 13th edition, 2010⁷

WHO, *Guidelines for Drinking-Water Quality*⁸

2.2 Informational references

The following documents are references that provide supplemental information to the provisions of this Standard. At the time this Standard was written, the editions indicated were valid. All documents are subject to revision, and parties are encouraged to investigate the possibility of applying the most recent edition of the document indicated below. The most recent published edition of the document shall be used for undated references.

21 CFR Chapter 9, *Federal Food, Drug and Cosmetic Act (FD&C Act)*⁹

CDFA, *California Organic Products Act of 2003* (Food and Agricultural Code Sections 46000-46029, Health and Safety Code Sections 110810-110959)¹⁰

Food and Drugs Act (R.S.C., 1985, c. F-27)¹¹

³ U.S. Government Printing Office, 732 N. Capitol Street, NW, Washington, DC 20401 <www.gpo.gov>.

⁴ European Commission, Rue de la Loi 200, 1049 Brussels, Belgium <www.ec.europa.eu/index_en.htm>.

⁵ European Council, Rue de la Loi 175, B-1048 Brussels, Belgium <www.consilium.europa.eu/>.

⁶ International Aloe Science Council, 8630 Fenton St., Suite 918, Silver Spring, MD 20910 <www.iasc.org>.

⁷ Personal Care Products Council, 1101 17th Street, NW, Suite 300, Washington DC 20036-4702 <www.ctfa.org>.

⁸ World Health Organization, 1211 Geneva 27, Switzerland <www.who.int/en/>.

⁹ Food and Drug Administration, 10903 New Hampshire Ave., Silver Springs, MD 20903-0002, <www.fda.gov>.

¹⁰ Department of Food and Agriculture, 1220 N Street, Sacramento, CA 95814 <www.cdfa.ca.gov>.

¹¹ Department of Justice, 248 Wellington St., Ottawa, Ontario K1A 0H8 <laws-lois.justice.gc.ca/eng/>.

*Cosmetic Regulations (C.R.C., c. 869)*¹¹

US FDA, *Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist*⁹

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 botano-chemical: An ingredient made with non-petroleum, agricultural-based material that has been reacted during processing with one or more permitted reagents.

3.3 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.

3.4 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.

3.5 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 product production or handling.

3.6 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.

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

3.8 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 (Federal Food, Drug, and Cosmetic Act⁹, 21 U.S.C. 321(i)).

3.9 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.

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

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

3.12 extract: Soluble material of plant origin that is dissolved out of the plant material by soaking the plant in a solvent, such as water or alcohol.

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

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

3.15 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.

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

3.17 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.

3.18 ingredient: A substance used in the preparation of a personal care product that is still present in the final commercial product.

3.19 ionizing radiation: Electromagnetic radiation of sufficient energy to overcome the binding energy of electrons in atoms or molecules causing them to be ionized (i.e. charged).

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

3.21 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.

3.22 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.

3.23 lot number: A distinctive combination of letters, numbers, or symbols, or any combination thereof from which one can track the product through the stages of the manufacturing, processing, packaging, holding, and distribution of a lot covered by this Standard.

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

3.25 National List: A list of allowed and prohibited substances as provided for in National Organic Program, 7 CFR 205³. 605-606.

3.26 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 205³.

3.27 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 Act³ (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 Act³. (National Organic Program, 7 CFR Part 205)³.

3.28 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.

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

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

3.31 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 includes written plans

concerning all aspects of agricultural production or handling described in this Standard or the NOP regulations.

3.32 personal care product: A consumable cosmetic product (as defined above) or soap product (as defined below). 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.

3.33 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.

3.34 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.

3.35 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.

3.36 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.

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

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

3.39 salt: Sodium chloride, only containing any additives or flow agents specifically allowed on the NOP National List.

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

3.41 sewage sludge: A solid, semisolid, or liquid residue generated during the treatment of domestic waste 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.

3.42 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.

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

3.44 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.

3.45 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.

3.46 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 of weight is considered the volatile content; similar to moisture content.

3.47 water: Water that meets or exceeds safe drinking water standards [USEPA National Primary Drinking Water Regulations (40 CFR part 141)³ or WHO Guidelines for Drinking-Water Quality⁸].

4 General requirements

4.1 Scope

A personal care product using any “contains organic ingredients” 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.

4.2.2 Prohibited labeling practices

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

- ingredients or catalyst and reagent 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;
- ingredients with petroleum compounds, except as specifically allowed in this Standard; or
- substances not on the NOP National List³ 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 is prohibited.

4.2.2.3 Labeling as “contains organic ingredients” of any product containing both organic and non-organic forms of the same ingredient specified as “organic” on the label is prohibited.

5 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 “contains organic ingredients” shall conform to the applicable provisions of this Standard.

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 “contains organic ingredients” 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 demonstrate compliance with this Standard;
- a description of the management activities and practices and the physical barriers established to prevent commingling of organic and non-organic ingredients 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 NOP³ are allowed under this Standard to produce ingredients such as vegetable oils, non-synthetic waxes and essential oils. These ingredients may be used in conventional form.

Of particular relevance are the following NOP-allowed processes:

- cooking vegetable oils or animal fats with NOP-allowed alkali to make soap (saponification);
- 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 (transesterification).

Ingredients produced from saponification, transesterification, and hydrolysis shall be used in organic form if commercially available.

NOTE — Refer to Annex G, Table G.1, for an illustrative list of ingredients made by the above processes, and to see availability of these ingredients in organic versus conventional form. Ingredients produced by the above processes shall be used in organic form as commercially available.

5.3.1 Ecological agricultural-based botano-chemical processes

Table 5.1 specifies Ecological agricultural-based botano-chemical processes that make ingredients that are not permitted under the NOP³ but are allowed for “contains organic ingredients” 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 “contains organic ingredients” products, if commercially available.

Table 5.1 – Ecological agricultural-based botano-chemical processes

Process to produce ingredient	Organic percentage of ingredient
Hydrolysis in general, particularly fat-splitting of oils to produce glycerin and fatty acids ¹	98%
Esterification of glycerin and glycerin making polyglycerols	98%
Mineral Acid-catalyzed hydrolysis, esterification or 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 and glycerin ¹	98%
Glucosidation	98%
Sulfation	60%
Protein fragment (non-petroleum) acylation	85%
¹ Glycerin made by fat-splitting oils is a NOP National List allowed substance. NOTE 1 — See Annex E, Section E.2 for details on ecological agricultural-based botano-chemical processes in Table 5.1. The allowed reagents and catalysts (individually or in combination) enabling these processes in Table 5.1 include: - Potassium/Sodium Hydroxide; - Metal Catalysts (Nickel, Platinum, Palladium); - Copper Chromite; - Zinc Oxide; - Strong Mineral Acids (Sulfuric, Phosphoric, HCl); - Strong Hybrid ChlorSulfonic Acid; - Methanol; - Phosphorous Trichloride or Thionyl Chloride; - Hydrogen; and - Sulfur/Sulfur Trioxide Any catalyst meeting the chemical definition of catalyst (see above) shall be allowed. NOTE 2 — See Annex G for clarification of ecological agricultural-based botano-chemical processes and ingredients available in organic form.	

5.3.2 Preservatives

Table 5.2 – Preservative ingredients allowed in “Contains Organic” products

Benzoic Acid and its salts and esters (non-petroleum feedstock when commercially available)
Sodium Benzoate derived from partial petroleum feedstock (until non-petroleum derived feedstock is commercially available)
Grapefruit Seed Extract
Potassium Lactate
Salicylic Acid, its salts and esters
Sorbic Acid, and its salts and esters (non-petroleum feedstock when commercially available)
Potassium Sorbate derived from partial petroleum feedstock (until non-petroleum derived feedstock is commercially available)
Benzyl Alcohol (non-petroleum feedstock only)
Glucose, Glucose Oxidase, Lactoperoxidase

Other ingredients with antimicrobial properties produced by an allowed process in 5.3 include but are not limited to: Ethanol, Glyceryl Caprate, Capryloyl Glycine, Glyceryl Caprylate, Glyceryl Laurate, Lauroyl Lysine, Undecylenoyl Glycine.

NOTE – Preservative ingredients listed in Table 5.2 should be verified free of unauthorized ingredients via signed affidavit from the source supplier/compounder/manufacture.

5.3.3 Mined ingredients

Table 5.3 – Allowed mineral ingredients

Chalk
Clays
Pumice

Table 5.4 – Allowed processed mineral ingredients

Iron oxides
Titanium Dioxide
Zinc Oxide

NOTE — A product meeting the requirements of NSF/ANSI 305 may not meet the minimum requirements of the California Organic Products Act of 2003¹⁰ if using mined minerals. If manufacturing personal care products containing mined minerals with intent to market in the State of California, please refer to COPA 2003¹⁰ for the applicable calculation of the percent organic contribution of mined minerals.

5.4 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.

5.5 Commercial availability

This certification program adopts the list of materials deemed commercially unavailable that appears on the NOP National List of Allowed and Prohibited Substances, 7 CFR Part 205.606³, as amended.

Commercial availability determinations under this Standard shall be made in the same manner as such determinations are made under the NOP³.

NOTE — Annex G contains illustrative lists of ingredients allowed under this Standard. Ingredients available in organic form are noted.

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 "contains organic [specified ingredients]," or as including organic ingredients shall be calculated by:

- dividing the total net weight (excluding mined minerals, water and salt) of combined organic ingredients at formulation by the total weight (excluding mined minerals, water and salt) of the combined ingredients;
- dividing the fluid volume of all organic ingredients (excluding mined minerals, water and salt) by the fluid volume of the finished product (excluding mined minerals, 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 combined ingredients; 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 mined minerals, water and salt) by the total weight (excluding mined minerals, water and salt) of the combined ingredients.

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 Mined minerals, water and salt

Mined minerals (including allowed processed mineral ingredients in 5.4), 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.

When a standard of identity exists or there is an onsite scientific method used to measure moisture removed from a plant, water, equal to the amount removed, may be added to that processed product and be considered as part of the original plant. For instance, a concentrate that fulfills the organic