



कृषि और प्रसंस्कृत खाद्य उत्पाद
निर्यात विकास प्राधिकरण
(वाणिज्य एवं उद्योग मंत्रालय, भारत सरकार)

**Agricultural and Processed Food Products
Export Development Authority**
(Ministry of Commerce & Industry, Govt. of India)

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NOTICE

**Draft Traceability Standards for Chain of Custody (Traceability) for
Organic Cosmetics, Personal Care Products and derivatives**

Agricultural and Processed Food Products Export Development Authority (APEDA), Ministry of Commerce and Industry, Government of India propose to launch certification system under National Programme for Organic Production (NPOP) for organic cosmetics and personal care products. For the purpose standards have been drafted and are being released.

Necessary comments/feedback and suggestions are invited from stakeholders value chain Processors, Certification Bodies and Regulatory and Government Department.

Comments/suggestions should reach this office within 30 days of the release of these standards on APEDA website through e-mail: advisor.organic@apeda.gov.in


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Organic Cosmetics and Personal Care Products

1. Scope

Organic Cosmetics and Personal Care Products Standard prescribed under these rules refer to all cosmetics, cosmetic products, ingredients used in the manufacturing of organic cosmetics, personal care products and ingredients used in making of personal care products.

2. General Principles

Organic cosmetics and personal care products shall primarily consists of ingredients derived from plant, animal or microbial origin, produced, processed and handled in compliance of the standards under these rules. Natural and mineral ingredients as allowed under these rules shall be used. Synthetic ingredients (from petrochemical sources or synthetically produced through chemical reactions) shall not be used unless allowed under these standards as exceptions.

As a general rule following ingredients and processes shall be prohibited:

- i. Ingredients or raw materials produced using genetically modified organisms or their by-products, derivatives or catalysts
- ii. All forms of irradiation including gamma irradiation, X-rays etc
- iii. Testing of cosmetics products or their ingredients on animals by manufacturer or any third party associated with the manufacturing and processing of products or its ingredients
- iv. Nano-materials or ingredients made through nano-technology, except in cases where their inclusion is necessary to meet certain technological requirement, to be demonstrated by the producer and shall be subject to evaluation by accredited certification body
- v. Ingredients from sources using applications of sewage sludge

3. Organic Management Plan

The producer, processor or handler of organic cosmetics and personal care products shall submit an annual organic system plan (OSP). The OSP shall be updated annually. The OSP shall include following:

- i. Detailed description of products, processes, processing and handling facilities, equipments, machines, storages, warehouse etc
- ii. Full list of ingredients, process recipes, sources of raw materials and organic status of each and every ingredient
- iii. Detailed description of up-keep, hygiene and sanitary practices, products used in sanitation and hygiene practices

- iv. Detailed description of monitoring practices and process flow charts
- v. Detailed description of contamination control procedures
- vi. Details of record keeping to demonstrate compliance of standards and end-to-end traceability
- vii. Any other information as sought by the accredited certification body
- viii. In case if there is need to change or modify the OSP, the operator shall inform the ACB and obtain its approval before implementing the modified system plan.

4. Allowed Ingredients

- i. **Water** – The water used in the process shall be of potable quality. Water obtained from distillation, reverse osmosis, natural springs or natural sea water can also be used.
- ii. **Minerals** – Naturally mined minerals can be used subject to following conditions:
 - a. Mineral ingredients are used in their original form and shall not be subjected to chemical transformation
 - b. Mineral ingredients may be treated/ concentrated, extracted or modified with the physical processes listed in Annexure 1.
 - c. List of minerals allowed for use in organic cosmetics is given in Annex 2.
- iii. **Plant Products** – Plants, plant products, processed plant products; certified organic in compliance of standards, as follows:
 - a. All plants and raw plant products certified organic in compliance of standards prescribed at Appendix 1, 7 and 8 of these rules.
 - b. All processed plant products certified organic in compliance of standards prescribed at Appendix 5 of these rules
 - c. Plant products not listed at iii(a) and iii(b) above but produced using the methods and processes listed in Annex 1 of this standard, provided the 95% raw material used are from certified organic sources
- iv. **Animal/ livestock products** – Animal/ livestock products produced and processed subject to following conditions:
 - a. Animal/ livestock products certified organic in compliance of the standards prescribed at Appendix 2 and 3 of these rules
 - b. Animal/ livestock product produced using the methods allowed under Annex 1 of these standards, provided the 95% of the raw material was from certified organic sources
 - c. In cases where the animal product is from animals other than covered under Appendix 2 and 3 of these rules, then it is produced by the animal but not part of the animal and did not entail the death of animal concerned

- v. **Microbial products** – Products of microbial fermentation or microbial processing are allowed provided the raw material used in fermentation comprise of plant/ animal/ mineral source and have been processed by the methods prescribed in Annex 1 of these standards
- vi. **Marine products** – Plant products of marine origin such as sea weeds or algae etc, certified as organic in compliance of standards prescribed at Appendix 8 of these rules and their processed products produced by the methods prescribed at Annex 1 of these standards.
- vii. **Synthetic products** – Exempted list of synthetic ingredients as preservatives, chelating agents or denaturing agents is given in Annex 4. Accredited certification bodies may allow use of certain synthetic solvents for extraction of some ingredients for which no organically acceptable alternatives are available. But in all such cases it has to be ensured that, synthetic solvents are completely removed or removed to the technologically unavoidable and technically ineffective concentrations in the finished products

5. Processing

Processing of organic cosmetic and personal care products should be done in natural ways using physical, mechanical and biological processes in the first stage and permitted chemical processes as listed in Annexure 3.

All ingredients, processing aids and preservatives shall be of organic origin, unless otherwise mentioned at 4 (i) to 4(vii) above

List of permitted physical processes is given at Annexure 2.

List of permitted and prohibited chemical processes is given in Annexure 3

6. Composition of final product and labelling claims

For a cosmetic and personal care product to be claimed as organic, made with organic or contains organic ingredients following composition norms shall apply:

- i. As water, salt mined minerals including allowed processed mineral ingredients, are considered neutral ingredients, they shall be excluded from the calculation of organic ingredients
- ii. Single ingredient product shall be labelled as organic
- iii. Where not all ingredients are of organic origin and or are not in the list of allowed ingredients under these standards, following criteria shall apply:
 - a. Where a minimum of 95% of ingredients are of certified organic/ allowed substance origin, the product may be labelled as “ORGANIC”
 - b. Where less than 95% but not less than 70% of the ingredients are from certified organic/ allowed substances the product may not be labelled as organic but may use the term “MADE WITH ORGANIC

INGREDIENTS x%”, where x denotes the percentage of organic ingredients in the final product

- c. Where less than 70% of the ingredients are of certified organic , the indication that an ingredient is organic may appear in the list of ingredients and the product cannot be labelled as organic.

7. Storage and Transport

- i. Organic products and ingredients shall be stored in a way that there is complete integrity of the product with documented traceability. Organic products shall be protected from co-mingling with non-organic products and from contact with materials and substances not permitted under these standards
- ii. Storage areas and transport containers should be cleaned using methods and substances listed in Annex 5 of these standards
- iii. Bulk stores for organic products and ingredients should be separate from non-organic ingredients and clearly labelled.

8. Cleaning and Disinfection

- i. Entire processing and handling area including all machines and tools should be maintained at high level of cleanliness
- ii. All measures should be in place to ensure the integrity of organic products during the entire process and there are no chances for co-mingling with non-organic product/ ingredients and there are no chances of contamination through contact with non-organic or prohibited substances.
- iii. All machinery/ tools coming in contact with organic products should be cleaned, disinfected and rinsed with rinsing agent before and after the production of products covered under these standards.
- iv. List of cleaning and disinfection agents permitted under these standards is given in Annex 5.

Annex 1.

**List permitted mineral ingredients/ additives for organic cosmetics
and personal care products**

CAS No	Chemical name	Limitation of use
21645-51-2	Aluminium Hydroxide	
	Silica Aluminum Silicates Ceramics	
1344-28-1	Aluminum Oxide	
10043-01-3	Aluminum Sulphate	
7783-20-2	Ammonium Sulphate	
7727-43-7	Barium Sulphate	Only as coating agent
65997-17-3	Calcium Aluminum Borosilicate	
471-34-1	Calcium Carbonate	
10043-52-4	Calcium Chloride	
7789-75-5	Calcium Fluoride	Only in oral cavity hygiene product
1305-62-0	Calcium Hydroxide	
65997-17-3	Calcium Sodium Borosilicate	
7778-18-9	Calcium Sulphate	
1306-38-3	Ceric Oxide	
7787-59-9	Bismuth Oxychloride	
CI 77288	Chromic Oxide	
12182-82-0	Chromic Oxide hydrated	
CI 77489	Iron Oxides	
CI 77491		
CI 77492		
CI 77499		
14038-43-8	Prussian Blue	
10101-66-3	Manganese Violet	
14154-09-7	Trimanganese Bis(orthophosphate)	
7440-50-8	Copper	
1317-38-0	Copper Oxide	

7758-98-7	Copper Sulphate	
68855-54-9	Diatomaceous Earth Calcined	
7789-77-7	Calcium Hydrogen-orthophosphate	Only in oral cavity hygiene product
7782-63-0	Iron Sulphate	
7440-57-5	Gold	
112926-00-8	Silicic Acid or Hydrated Silica	
1306-06-5	Hydroxyapatite	Only in oral cavity hygiene product
Iron Hydroxide	Iron Hydroxide Oxide	
1327-43-1	Silicic Acid, Aluminium Magnesium Salt, Magnesium Aluminum Silicate	
546-93-0 ,	Magnesium Carbonate	
39409-82-0	Magnesium Carbonate Hydroxide	
7786-30-3	Magnesium Chloride	
1309-42-8	Magnesium Hydroxide	
1309-48-4	Magnesium Oxide, CI 77711	
7757-87-1	Magnesium Phosphate	Only in association with Zinc Oxide
1343-88-0	Silicic Acid, Magnesium Salt	
7487-88	Magnesium Sulphate	
12001-26	Mica, CI 77019	
10043-67	Alum, Potassium Alum	
584-08	Potassium Carbonate	
7440-09	Potassium Chloride	
1310-58-3	Potassium Hydroxide	
7681-11	Potassium Iodide	
7778-80-5	Potassium Sulphate	
333-20-0	Potassium Thiocyanate	Only as additive for preservative/ anti-oxidant systems, maximum concentration 1%
7631-86-9	Silica	
7440-22-4	Silver	
7783-90-6	Silver Chloride	

20667-12-3	Silver Oxide	
10294-26-5	Silver Sulphate	
144-55-8	Sodium Bicarbonate	
1303-96	Sodium Borate	
497-19-8	Sodium Carbonate	
7647-14-5	Sodium Chloride	
7681-49-4	Sodium Fluoride	Only in oral cavity hygiene product
1310-73-2	Sodium Hydroxide	
101659-01-2	Sodium Magnesium Silicate	
6834-92-0	Disodium Metasilicate	
7631-97-2	Disodium Fluorophosphate	Only in oral cavity hygiene product
1344-09-8.	Silicic Acid, Sodium Salt	
7757-82-6	Sodium Sulphate	
7772-98-7	Sodium Thiosulphate	Only in soaps
13463-67-7	Titanium Dioxide	
18282-10-5	Tin Oxide, CI 77861	
1302-83-6	Ultramarines	
3486-35-9	Zinc Carbonate, CI 77950	
1314-13-2	Zinc Oxide	
7733-02-0	Zinc sulphate	

List of Permitted Physical Processes in Processing of Organic Cosmetic and Personal Care Products

A. Physical Processes

1. Mixing, blending, grinding
2. Infusion
3. Heating, boiling
4. Desiccation (by evaporation), drying
5. Roasting
6. Freezing, freeze drying, Lyophilization
7. Decanting, sedimentation
8. Centrifugation
9. Squeezing, maceration, crushing and extraction of decoction through filtration/ decanting
10. Degumming, de-oiling and pressure expellers for oil extraction

B. Filtration

11. Filtration and purification through simple filtering, centrifugation, ultra filtration, dialysis, crystallization, ion exchange
12. Filtration, absorption, adsorption on an inert support conforming to these standards

C. Extraction

13. All solvent extractions should be done using natural materials. Permitted solvents are:
 - a. Ethyl alcohol
 - b. Glycerine
 - c. Vegetable oils
 - d. Honey
 - e. Super critical carbon dioxide

D. Sterilization

14. Hot air sterilization
15. Steam sterilization
16. UV, IR and microwave sterilization
17. Gas sterilization using oxygen, nitrogen, argon, helium, ozone and carbon dioxide

E. Other physical treatments such as:

18. Decolouration – Allowed decolourizing agents are bentonite, activated charcoal, bleaching earth, hydrogen peroxide, ozone.
19. Distillation – including fractionated distillation by steam, condensation
20. Microwave, Ultrasound
21. Pressure/ vacuum treatment

List of Permitted and Prohibited Chemical Processes in Processing of Organic Cosmetic and Personal Care Products

Permitted processes	Permitted processes
Alkylation	Neutralization
Calcinations, Carbonation	Ionic exchange
Oxidation, reduction	Hydrolysis
Amidation	Hydration
De-methylation	Hydrogenation
Esterification, transesterification, interesterification, etherification	Phosphorylation
Saponification	Ozonolization/ ozonolyze
Sulphatation/ Sulphation	Biotechnological process, fermentation
Complexation	

Use of petroleum solvents

Keeping in view of technological limitations, certification bodies may allow use of petroleum based solvents, in cases where no natural alternatives are available. But in all such cases it must be ensured that such solvents are completely eliminated at the end of process and are recycled.

Use of mineral acids

Use of aqueous solutions of mineral acids such as hydrochloric acid, sulphuric acid, phosphoric acid is allowed as processing aids/ auxillary for neutralization, purification and extraction. But such acids should not be the part of ingredients or raw materials.

Prohibited chemical processes

Animal support for bleaching and deodorization

Irradiation\

Sulphonation

Treatments using mercury, ethylene oxide, formaldehyde

Deterpenation, other than steam

Halogenation

Alkoxylation including ethoxylation and propoxylation using ethylene oxide, propylene oxide or other alkylene oxides

Annex 4**Permitted preservatives and denaturing agents from petrochemical origin (non - natural ingredients – NNI)**

Ingredient	Restrictions
Benzoic Acid and its salts	
Benzyl Alcohol	
Salicylic Acid and its salts	
Sorbic Acid and its salts	
Dehydroacetic Acid and its salts	
Denatonium Benzoate and Tertiary Butyl Alcohol and other denaturing agents for alcohol (excluding phthalates)	Only as denaturing agent for ethanol – where required by law

Permitted extraction of agro- ingredients using petrochemical solvents

Ingredient	Restrictions
Betaine	
Carrageenan	
Lecithin and lecithin derivatives	
Tocopherol/ Tocotrienol	
Oryzanol	
Annatto	
Carotenoids/ Xanthophylls	
Absolutes, Concretes, Resinoids	
Lanolin	
Phytosterol	
Glycosphingolipids and Glycolipids	

Use of aromatic, alkoxyated, halogenated, nitrogen- or sulphur-based solvents is prohibited. The solvents used must be completely removed or removed to technologically unavoidable and technologically ineffective concentrations in the finished product and must be recycled.

Permitted list of disinfectants and sanitizers

S. No.	Permitted disinfectant/ sanitizer	Conditions for use
1	Plant derived products such as ethyl alcohol, vinegar	
2	Plant based Decyl glucoside	
3	Lactic acid	
4	Isopropyl alcohol	
5	Hydrogen peroxide	
6	Mineral acids and alkali	
7	Per acetic acid and stabilizing agents	
8	Formic acid	
9	Ozone	
10	Any certified organic plant ingredient used in cosmetics	Completely biodegradable and have low aquatic toxicity (LC50> 1mg/l)
11	Plant based surfactants	