



Certech Registration Inc.



International Organic Standard – Natural and Natural Organic Cosmetic Production Certification

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1 INTRODUCTION

2 SCOPE AND REFERENCES

2.1 SCOPE

2.1.1 This document defines the criteria for organizations seeking to obtain Certech's Natural, or Natural Organics Cosmetic Production approval.

2.2 REFERENCES

The requirements specified within the following documents have been used to develop this standard. Reference to these documents does not indicate automatic conformance or compliance with all requirements specified within the referenced documents.

- 2.2.1 Consumer Packaging and Labelling Act
- 2.2.2 Canadian Food and Drugs Act
- 2.2.3 US Code of Federal Regulations (CFR). Title 7 Part 205 Natural Organic Program
- 2.2.4 FDA/CFSAN Cosmetics Good Manufacturing Practice guideline
- 2.2.5 CAN/CGSB-32.310-2006 Organic Production Systems General Principles and Management Standards
- 2.2.6 EEC Regulation number 2092/91
- 2.2.7 California Health and Safety Code, Article 7 "The California Organic Products Act of 2003"
- 2.2.8 ISO 9001 - Quality Management System – Requirements
- 2.2.9 ISO 14001 – Environmental Management Systems - Requirements

3.0 DEFINITIONS

Batch	A defined quantity of semi-finished or finished products, manufactured during the same series of operations of production, made from the same ingredients, stored at the same time, in the same conditions.
Contaminant	A substance not naturally present in the raw material or in ratios superior to those existing naturally and leading to a pollution (persistence, residues), and possibly to toxicity risks, i.e. heavy metals, hydrocarbons, pesticides, dioxins, radioactivity, GMO, mycotoxins, medicinal residues, nitrates, nitrosamines
Ingredients	All substances used in the preparation of the product (intentional or residual from processing).
Ingredient certified as Organic	Any product, coming from a plant or animal production, complying with the CAN/CGSB-32.310-2006 Organic Production Systems General Principles and Management Standards. The water added during the manufacturing of the finished product is deemed a natural ingredient.
Ingredient of natural origin	All natural ingredients processed following the permitted chemical processes as listed in this Standard and meeting the quality criteria also defined in this Standard
Natural	Existing in, or formed by nature; not artificial
Natural Cosmetic	All cosmetic products made out of natural ingredients (≥ 95%)
Natural ingredient/Raw Material	Any plant, animal or mineral product, directly coming from agricultural production, from harvest or from working, unprocessed or extracted by the exclusive means of the physical processes listed in Addendum 3, and meeting the quality criteria as defined in this Standard. Water added during the manufacturing of the finished product is deemed to be a natural ingredient.

Organic	Grown, cultivated and stored without the use of chemical fertilizers, herbicides, pesticides, fumigants and other toxins
Primary packaging	The products' original package, with its seal
Production	Group of operations carried out in the factory or the laboratory, for obtaining, conditioning and labeling the products targeted by these Standards
Range of products	Group of products, possessing common or similar characteristics, and which can be grouped together for planning and/or marketing purposes.
Secondary packaging	Any other container different from the original one

4 ORGANICS MANAGEMENT SYSTEM

4.1 GENERAL REQUIREMENTS

4.1.1 The organization shall establish, document, implement, and maintain effective control of its natural/organic cosmetic production in accordance with the requirements of this Standard.

4.2 DOCUMENTATION REQUIREMENTS

4.2.1 The organic management system documentation shall include:

- a) A description of the main elements of the organic management system
- b) Documents, including records, required by this Standard, and
- c) Documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of production that relate to its organic products

4.3 DOCUMENT CONTROL

4.3.1 Documents required by the organic management system and by this Standard shall be controlled. The organization shall establish, implement and maintain procedures to:

- a) Approve documents prior to use,
- b) Review, revise as necessary and re-approve documents,
- c) Ensure that changes and the current revision status of documents are identified,
- d) Ensure that applicable versions of documents are available where needed,
- e) Ensure that documents remain legible,
- f) Ensure that documents of external origin are identified and their distribution controlled, and
- g) Prevent the unintentional use of obsolete documents and apply suitable identification to them if they are retained for any reason.

4.4 CONTROL OF RECORDS

4.4.1 The organization shall maintain records to demonstrate conformity to the requirements of its organic management system, applicable legislation, and this Standard, and the results achieved. The organization shall have processes for the identification, storage, protection, retrieval, retention and disposal of records. Records shall be and remain legible, identifiable and traceable.

4.4.2 Records shall as a minimum be retained for:

- a) Raw materials, primary packaging materials, each lot/batch (quantity, type, processing, handling, transferring, holding, filling, sampling, controlling, adjusting, and reworking, disposition of rejection)

- b) Certification marks for finished goods
- c) Test results
- d) Sampling, controlling and adjusting
- e) Finished product sampling, lab controls, test results and control status
- f) Distribution records

As a minimum, required records will be retained for expected product life, plus 3 years or any applicable time lines dictated by local / government authorities

4.5 MANAGEMENT RESPONSIBILITY

- 4.5.1 Management shall ensure the availability of resources necessary to establish, implement, and maintain the natural/organic cosmetics production. Resources include human resources, specialized skills, organizational infrastructure, technology and financial resources. Roles, responsibilities and authorities shall be defined, documented and communicated in order to facilitate effective management.
- 4.5.2 A member of management shall be appointed to communicate with Certech Registration regarding certification and any changes in processes

4.6 PLANNING

- 4.6.1 The organization shall plan and develop the processes needed for natural/organic cosmetics production. In planning natural/organic cosmetics production, the organization shall determine the following, as appropriate:
 - a) The need to establish processes, documents, and provide resources specific to the product;
 - b) Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;
 - c) Records needed to provide evidence that the natural/organic cosmetics production processes and resulting product meet requirements.

4.7 PERSONNEL REQUIREMENTS

- 4.7.1 The organization shall ensure that any person performing tasks for it or on its behalf that have the potential to adversely affect the product are competent on the basis of appropriate training, education, or experience, and shall retain related records. The organization shall identify training needs associated with its natural/organic production. It shall provide training or take other action to meet these needs, and shall retain associated records. The organization shall ensure persons working for it or on its behalf are knowledgeable of
 - a) The importance of conformity with the natural/organic program and with the requirements of the management system,
 - b) The potential impact on product conformity associated with their work, and the benefits of improved personal performance,
 - c) Their responsibilities in achieving conformity with the requirements of the natural/organic management system, and
 - d) The potential effects of departure from procedures.

4.8 INFRASTRUCTURE AND WORK ENVIRONMENT

4.8.1 The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable. At minimum the following will be considered:

- a) Unobstructed placement of equipment
- b) Orderly storage of materials
- c) Cleaning and maintenance
- d) Surfaces kept clean and in good repair
- e) Floors, walls and ceiling smooth and easy to clean
- f) Fixtures, ducts and pipes – not contaminating product
- g) Sufficient lighting
- h) Suitable sanitary facilities
- i) Equipment and utensils – material & workmanship prevent build-up and corrosion
- j) Equipment stored in condition to prevent contamination
- k) Equipment cleaned and sanitized

4.9 VERIFICATION OF PURCHASED PRODUCT

4.9.1 All purchased product shall be subjected to verification activities prior to being used on any certified products

4.10 PROCESSING CONTROL

4.10.1 Production control shall ensure as a minimum:

- a) Documented instructions/requirements/methods
- b) Document formulations
- c) Approved ingredients and materials
- d) Second check for ingredient/measure
- e) Process status
- f) Equipment clean and in good repair
- g) Use of acceptable cleaning/sanitizing agents
- h) Weighing and measuring of raw materials checked by second person
- i) Suitable identification on containers
- j) Batch/lot controls and identification
- k) Wearing suitable clean/non contamination clothing
- l) No food, drink or alcohol

4.11 PRESERVATION OF PRODUCT

4.11.1 Measure to preserve product shall include:

- a) Procedures to prevent contamination, mixing, and deterioration
- b) Containers closed and bagged or boxed
- c) Product and ingredients shall be stored off the floor
- d) Storage shall include correct conditions (Temp, light, etc.)
- e) Shelf life controls shall be auditable
- f) Product shall be periodically tested for contamination filth/microorganisms

4.12 CALIBRATION

4.12.1 The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to

determined requirements (see 7.2.1).

4.12.2 The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

4.12.3 Where necessary to ensure valid results, measuring equipment shall

- a) Be calibrated/verified at documented intervals, or prior to use, against standards traceable to national or international standards; where no such standards exist, an acceptable scientific basis shall be used for calibration or verification.
- b) Be adjusted or re-adjusted as necessary;
- c) Be traceable to enable the calibration status to be determined;
- d) Be protected from adjustments that would invalidate the measurement result;
- e) Be protected from damage during handling, maintenance and storage.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected (including recall). When computer software is used to verify processes or product its ability to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

4.13 MONITORING AND MEASUREMENT OF PRODUCT

4.13.1 Monitoring and measurement shall include:

- a) Samples – adequacy of mixing, absence (non presence) of hazardous organisms and chemical contamination
- b) Confirmation of conformance to specification
- c) Retained samples – defined period
- d) Water supply tested to ensure non presence of unacceptable ingredients (Herbicides and Pesticides) and harmful bacteria
- e) Fresh as well as retained samples tested for adequacy of preservation against microbiological contamination
- f) Checks to ensure that only approved ingredients and materials are used
- g) Second checks to verify ingredient measure
- h) Weighing and measuring of raw materials checked by second person
- i) Final product or its ingredients shall not be tested on animals

ADDENDUM 1 – ACCEPTABLE PROCESSES

Physical
Absorption
Bleaching - Deodorization
Grinding
Centrifuging (Solid / liquid separation (spin-drying)
Settling and Decanting
Desiccation - Drying (Progressive or not by evaporation / natural under sun)
Deterpenation (if fractionated distillation with steam)
Distillation or Extraction (steam)
Expression

Extractions (with water or a third solvent : ethyl alcohol-organic glycerin-organic oils - CO2)
Filtration and Purification (ultra filtration, dialysis, electrolysis)
Lyophilization
Blending
Percolation
Cold Pressure
Hot Pressure
Sterilization with thermal treatments
Sifting
Chemical
Alkylation
Amidation
Calcination of Plants Residues
Carbonization (Resins, Fatty Organic Oils)
Condensation / Addition
Esterification
Etherification
Fermentation (Natural / Biotechnological)
Hydratation
Hydrogenation
Hydrolysis
Neutralization (To Obtain Na, Ca, Mg, K Salts)
Oxidization / Reduction
Processes For The Manufacture Of Amphoterics
Saponification
Sulphatation
Roasting

ADDENDUM 2 – UNACCEPTABLE PROCESSES

Bleaching - Deodorization (on a support of animal origin)
Deterpenation (other than with beam)
Ethoxylation (PEG,)
Irradiation
Sulphonation (As main reaction)
Techniques using Genetic Engineering
Treatments with Ethylene Oxide
Treatments using Mercury (Mercurial Soda)