

NATRUE Label: requirements to be met by natural and organic cosmetics

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Updated text passages (in comparison to Version 3.7) are highlighted in yellow.

Preface

This document represents the criteria by which cosmetics products certified to the NATRUE standard must comply.

Complete background information (criteria, lists of approved substances, a list of certified products and raw materials, FAQs) concerning the NATRUE Label is freely available on the Internet, for consumers and manufacturers, at www.natrue.org.

1.1 Background

Recent developments, particularly in the food sector but also in other industries, have highlighted the growing importance of "naturalness" for consumers. Consumers have changed their habits and are paying increasing attention to "natural" aspects when buying cosmetics, too.

However, the assessment of the "naturalness" of food on the one hand and cosmetics on the other is not directly comparable. The most important aspects of "naturalness" in food include its occurrence in nature, forms of cultivation and traceability of production, as reflected in the multitude of "natural" and "organic" labels. Natural cosmetics, by contrast, are usually complex compositions of natural, mostly processed raw materials. Hence, they have to be evaluated differently.

A number of definitions and corresponding labels for natural cosmetics have existed for some time now; both at national and international level. This raises the question: Is another definition needed? The biggest challenge facing the production of natural cosmetics, in addition to the selection of adequate raw materials, is to be able to offer consumers safe, effective, efficient and sensory appealing high-quality products. However, products of this kind cannot always be manufactured exclusively from pure natural ingredients. Aspects of sustainable development must also be taken into account along the entire value chain, under respect of biodiversity (submission of a sustainability report or an environmental impact assessment by the manufacturers).

For natural cosmetics the question arises as to which natural ingredients can be used without modification, where (physico)chemical modifications seem to be necessary within a clearly defined framework, and how substances which are "close to natural substances" are to be evaluated. Compromises of this kind are necessary to a certain extent. Consequently, care must be taken to ensure that they are transparent and comprehensible for the consumer and that the consumer is sufficiently informed. The definition of "natural cosmetics" must not be rendered implausible by a multitude of seemingly arbitrary exceptions, and any compromises should be limited to the absolutely necessary within a clearly defined framework. The proposed criteria for the NATRUE Label goes further than any definition of "natural cosmetics" so far established in Europe in terms of consistency and complete transparency. Only natural, some nature-identical and derived natural raw materials may be used in line with the requirements listed below.

1.2 Regulations (EU and International standards)

1.2.1 Cosmetics Products: Regulation (EC) No 1223/2009

Independently of the formulation of a natural cosmetic product, all products must comply first and foremost with the basic requirements of Cosmetics Regulation (EC) No 1223/2009, particularly with regard to their composition, safety, efficacy and labelling requirements. Furthermore, animal testing is fundamentally against NATRUE's underlying values and ethics.



It is for this reason that the NATRUE criteria extends the animal testing ban on finished cosmetic products as regulated by Regulation (EC) No 1223/2009 to third countries outside the EU.

1.2.2 Organic production and labelling of organic products

Organic certified natural substances (Section 2.1) and derived natural substances (Section 2.3) must come from controlled organic farming and/or wild collection, certified by a duly recognized certification body or authority to an organic standard or regulation approved in the IFOAM Family of Standards, or to this Standard.

1.2.3 Prohibition on the use of Genetically Modified Organisms (GMOs)

In terms of GMO, finished products and starting materials, as well as the used enzymes and microorganisms must comply with the criteria laid down in the EU Eco-regulation (Regulation (EC) No 834/2007). This requirement also applies to substances which are not covered by the Regulation (e.g. non-organic certified ingredients, non-food or -feed substances). For reference please find an example standardised form for non-GMO compliance here.

<u>Enzyme origin derogation:</u> Where justifiable, due to current technical unavailability of alternatives and/or for improved sustainability, isolated enzymes from recombinant microorganisms (recombinant enzymes) may be used for the manufacture or processing of a substance where the recombinant host must have been grown under regulated contained use conditions (*cf.* <u>Directive 2009/41/EC</u>), including any post-production treatments required according to its assigned containment level and protective measures.

1.2.4 Aromatic natural raw materials: ISO standard 9235

In natural cosmetics, natural fragrances (for example essential oils) which correspond to ISO standard 9235:2013 may be used. This includes isolates of essential oils and essential oils reconstructed from them. Synthetic nature-identical fragrances may not be used in natural cosmetics. The natural fragrance material must also comply with all other requirements of the NATRUE-label criteria (Section 2.1). Please refer here for NATRUE perfume guidelines and an example ISO 9235 certificate here.

1.2.5 Detergents: Regulation (EC) No 648/2004

Detergent surfactants substances used must be completely biodegradable in accordance with the EC Regulation on Detergents (Regulation (EC) No 648/2004).

In principle all legal references given in this catalogue of requirements are related to EU law in force at the moment. In non EU countries/regions these references must be adapted according to the corresponding national regulations in the countries in which the respective products will be marketed.

1.3 NATRUE Principles

A <u>Raw Material Documentation File</u> (<u>RMDF</u>) is recommended to facilitate the categorisation of raw materials. For completion purposes please find an explanation of the RMDF <u>here</u>. Please find a RMDF for perfume raw materials <u>here</u>.

1.3.1 Sustainability

As indicated in the Raw Material Documentation File (RMDF), a certificate of nature preservation authority is required for a natural substance (Section 2.1), when a starting material originates from animal and botanic species that are under the restriction of the Washington Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), (Appendix I).

1.3.2 Manufacturer requirements

The concrete requirements to be met by natural cosmetics listed below comprise:

 Open lists of derived natural substances and nature-identical substances approved for use in natural cosmetics:



- Descriptions of permitted manufacturing processes for natural cosmetics as well as for natural, derived natural and nature-identical raw materials:
- The required minimum levels of natural substances and substances of organic grade, and the maximum levels for derived natural raw materials in the three categories "natural cosmetics", "natural cosmetics with an organic portion" and "organic cosmetics";
- Criteria for packaging and certain carrier materials.

1.3.3 Requirements for NATRUE label usage

The certification of products on the basis of NATRUE criteria for natural and organic cosmetics is possible independent of membership of NATRUE or other institutions. In order to bear the NATRUE Label it is necessary that at least 75% of products of a specific brand (or sub-brand when the sub-brand is specifically developed to qualify the natural and organic cosmetic line of an already existing brand) needs to achieve NATRUE Certification. Please refer to Chapter 2 of the NATRUE Label Usage Agreement for finished products.

If the Company would produce products that are certified to another natural and organic cosmetics standard, the calculation of the 75% threshold, required in order to obtain the NATRUE Certification, takes into account those products certified to another natural and organic cosmetics standard as well, but only for a period during the first two years of the certificate in order to provide a smooth transition to the NATRUE Label. After these first two years, the threshold of 75% must be guaranteed with products certified to the NATRUE Label only. Double labelling is permitted as long as the above requirements are met. Other certified natural and organic cosmetic standards are those where verification has been carried out by an authorised control body according to that standard.

These requirements do not apply for cosmetic raw materials. Please refer to the <u>NATRUE Label Usage Agreement for raw materials</u> for further details.

2. Definition of permitted ingredients and processes

Apart from *water*, which is the basis and therefore often the largest ingredient in cosmetic formulations, chemically unmodified *natural ingredients* (*natural substances*, e.g. fatty oils, hydro-alcoholic plant extracts) usually predominate in the finished product if it is claimed to be a "natural cosmetic product". The chemically unmodified natural ingredients used should preferably be of organic grade. For reference please find the NATRUE guide to substance classification <u>here</u>.

2.1 Natural substances

Natural cosmetics are products which (subject to Sections 2.2 and 2.3) are produced exclusively from **natural substances**.

Natural substances are substances of botanic, inorganic-mineral (not organic-mineral e.g. mineral oil) or animal origin (except for dead vertebrates) and their mixtures with each other.

Only physical processes including extraction with the extraction and purifying agents listed in Annex 1a and the pH-adjusting agents listed in Annex 1b are permitted for recovery and further processing.

Enzymatic and microbiological reactions are also permitted in so far as exclusively naturally occurring microorganisms or enzymes obtained thereof are used, and the end products are identical to those which occur in nature.



For regulatory details with respect to natural fragrances (e.g. essential oils) with corresponding reference to ISO standard 9235:2013 please refer to Section 1.2.4.

Raw materials of plant or animal origin as well as finished products may not be subjected to ionizing radiation. The bleaching of natural substances is only permitted when no chlorine is used (sodium hypochlorite).

2.1.1 Water

The origin of the water used in natural cosmetics is arbitrary. When calculating the portion of natural substances in the finished product (*cf.* Section 3), water is in either case only considered as natural substance if it derives directly from a vegetable source (directly obtained vegetable juices).

Water-containing natural substances are taken into account with the following percentage by weight: *

- a) Vegetable juices: 100 % as natural substance
- b) Concentrated vegetable juices: only the 100 % concentrate (as a natural substance) but not the water used for dilution
- c) Aqueous extracts: only the plant portion
- d) Hydroalcoholic extracts: the plant and alcoholic portions (if this is a natural substance)
- * Examples for the calculation of plant extracts & hydrolates/floral waters are given in Annex 6 (Section 6).

2.2 Nature-identical Substances

Nature-identical substances may only be used when natural substances cannot be recovered from nature using reasonable technical effort.

Nature-identical ingredients are dealt with in corresponding positive lists:

- Annex 2: Nature-identical inorganic pigments and minerals
- Annex 4a: Nature-identical preservatives (Section 2.4)

Only those natural identical substances listed may be used in natural cosmetics.

Annex 2 and 4a positive lists will be updated regularly.

2.3 Derived Natural Substances

Derived natural substances are only justified if their function cannot be achieved using natural substances, and natural starting materials for derived natural raw materials should preferably be of organic grade.

Derived natural substances are always recovered from natural substances, as defined in Section 2.1 (e.g. fats, oils, waxes, lecithins, mono-, oligo- and polysaccharides, proteins and lipoproteins), and may only be used for the production of natural cosmetics if they are recovered using chemical reactions, including biotechnological processes. Derived natural substances should only be manufactured using processes which are modelled on physiological mechanisms (e.g. formation of partial glycerides by fat digestion), and number of chemical conversion steps should be kept to a minimum.

Only the following chemical reactions are permitted:

- Acylation
- Amidation,
- Condensation (with elimination of water),



- Dehydrogenation,
- Dimerization.
- Esterification,
- Glycosidation,
- Hydrogenation,
- Hydrogenolysis,
- Hydrolysis (including saponification),
- Neutralisation.
- Oxidation (with oxygen, ozone and peroxides),
- Phosphorylation,
- Pyrolysis
- Sulphatation,
- Transesterification

All necessary auxiliary materials and catalysts (including enzymes and micro-organisms) not explicitly defined in the NATRUE Criteria may be used in the context of: (a) improving sustainability to have a better adapted energy efficiency or (b) due only to current technical unavoidability of alternatives.

In all cases where:

- the catalyst used for reaction is non-enzymatic/non-microbiological
- the enzymatic/microbiological reaction produces an end product substances that is not identical to those which occur in nature
- the reactions are performed using an enzyme(s) isolated from recombinant microorganisms

that substance is classified as derived natural.

The use of recombinant microorganisms (Genetically Modified Microorganisms, GMMs), other than for the production of recombinant enzymes where justified according to Section 1.2.3, is prohibited.

In all cases, auxiliary materials and catalysts must be completely removed after use, or at least considered as technically unavoidable and technologically ineffective traces in the finished product.

The environmental compatibility of derived natural substances, which are surfactants intended to be used for cleansing purposes, must be evaluated separately to ensure they can be returned without causing any problems to the natural circle, and must meet particularly strict requirements regarding their biodegradability (Section 1.2.5; Regulation (EC) No 648/2004).

Derived natural substances also include further substances (besides those mentioned in Section 2.2) which do occur naturally but cannot be recovered in sufficient amounts from their natural sources using state-of-the-art technology.

Annex 3 contains an open list of approved derived natural substances (INCI), which may comply with the above-mentioned requirements. This list will be updated regularly.

2.4 Preservatives

For the preservation of natural cosmetics, only the nature-identical preservatives listed in Annex 4a, and derived natural preservatives listed in Annex 4b may be used (in compliance with Annex V of Regulation (EC) No 1223/2009).



Derived natural substances, which are permitted in Annex V of <u>Regulation (EC) No 1223/2009</u>, must comply with the requirements as in Section 2.3.

Annex 4 positive lists will be updated regularly.

2.5 Manufacturing, processing and filling processes

During all manufacturing, processing and filling processes it must be ensured that undesirable substances deriving from these processes, packages or storage containers materials do not migrate to the products.

3. <u>Minimum requirements to be met by levels of natural substances, natural substances of organic grade, and maximum levels of derived natural substances</u>

Please refer to Table 1 for each corresponding levels of natural substances and derived natural substances for each certification level and category respectively.

3.1 NATURAL COSMETICS

The minimum levels of natural substances and the maximum levels of derived natural raw materials (referring to the whole formulation) are presented by product group in Table 1 (Annex 5 does not apply here).

3.2 NATURAL COSMETICS WITH AN ORGANIC PORTION

Over and above the basic requirements laid down in Section 3.1, the following additional requirements have to be met.

Additional requirements:

- 3.2.1 At least 70 % of the natural substances of plant and animal origin and of derived natural substances (if applicable and as per § 3.2.2.) contained in the product must come from controlled organic farming and/or wild collection, certified by a duly recognized certification body or authority to an organic standard or regulation approved in the IFOAM Family of Standards, or to this Standard.
- 3.2.2 In case derived natural substances contained in the product have been produced out of controlled organic starting material, the organic amount as defined in Annex 5 will be considered and added to the organic total amount. This list will be updated regularly, in order to take the increasing availability of such organic based derived natural raw materials into consideration.

3.3 ORGANIC COSMETICS

Over and above the basic requirements laid down Section 3.2, the following additional requirements have to be met.

Additional requirements:

- **3.3.1** At least 95 % of the natural substances of plant and animal origin and of derived natural substances (if applicable and as per § 3.3.2.) contained in the product must come from controlled organic farming and/or wild collection, certified by a duly recognized certification body or authority to an organic standard or regulation approved in the IFOAM Family of Standards, or to this Standard.
- 3.3.2 In case derived natural substances contained in the product have been produced out of



controlled organic starting material, the organic amount as defined in Annex 5 will be considered and added to the organic total amount. This list will be updated regularly, in order to take the increasing availability of such organic based derived natural raw materials into consideration.

4. Requirements to be met by carrier materials (e.g. for wet wipes and pads)

All carrier materials of cosmetics, used for the topical application of a formulation to the skin (e.g. wipes or pads) must comply with the requirements for natural and/or derived natural substances recovered from renewable raw materials.

5. Requirements to be met by packaging and packaging materials

- 1. As far as possible packaging must be kept to a minimum.
- 2. If at all possible, products should be designed for multiple uses (except for sample packs).
- 3. If at all technically feasible and available, recyclable packaging materials are to be used (e.g. glass, aluminium, paper/cardboard and/or recyclable plastics such as PET [Polyethylene Terephthalate]; PP [Polypropylene]); if possible made of renewable raw materials.
- 4. Halogenated plastics may not be used as packaging materials (e.g. Polyvinyl chloride; chlorinated plastics)
- Pressurised gas packs only with Air, Nitrogen, Oxygen Carbon dioxide and/or Argon (but without VOC - Volatile Organic compounds) can be certified as natural or organic cosmetics according to NATRUE. Gases will not be taken into consideration for calculations as of Table 1.

6. Annexes

Please find following annexes available online in Excel file format at: "Annexes Version 3.8"

- Annex 1a: Extraction agents approved for the production of natural substances
- Annex 1b: pH-adjusting and ion exchange agents approved for the production of natural cosmetics
- Annex 2: Nature-identical inorganic pigments and minerals approved in natural cosmetics
- Annex 3: Derived natural substances approved for the production of natural cosmetics (open list of INCI designations)
- Annex 4a: Nature-identical preservatives approved for the production of natural cosmetics
- Annex 4b: Derived natural preservatives approved for the production of natural cosmetics
- Annex 5: Organic portion of derived natural substances if they have been processed from organic raw materials according to certification by a duly recognized certification body or authority to an organic standard or regulation approved in the IFOAM Family of Standards, or to this Standard.
- Annex 6: Examples for the calculation of the natural (organic) portion of plant extracts and hydrolates / floral waters



Table 1: Requirements to be met by products certified to NATRUE criteria per category

Minimum content of natural substances (%) (Green) and maximum content of derived natural substances (%) (Orange). Please note the following additional requirements laid out below.

	1***	2	3	4	5	6	7	8	9	10	11***	12#	13
Content of raw materials referred to the finished product (%)	Oils/water-free cleaning and skin care products	Parfums, Eaux de Parfum, Eaux de Toilette, Eaux de Cologne	Skin care emulsions (W/O) and Oleogels	Decorative cosmetics containing water	Deodorants and antiperspirants	Skin care emulsions (O/W) and gels	Sunscreens	Hair treatment products	Cleaning products containing surfactants	Oral care	Decorative cosmetics, water- free	Soaps	Waters
Natural Cosmetics (Level 1)	80	60	30	10	10	10	10	3	3	2	1	1	0.1
	20	10	30	30	30	<mark>25</mark>	<mark>55</mark>	40	85	70	50	99	10
Natural Cosmetics with Organic Portion (Level 2)	90*	60*	30*	15*	15*	15*	15*	15*	15*	15*	15*	1*	15*
	10**	10**	<mark>20</mark> **	15**	15**	20**	30**	15**	25 **	15**	15**	99**	5**
Organic Cosmetics (Level 3)	90*	60*	30*	20*	20*	20*	20*	20*	20*	20*	20*	1*	20*
	10**	10**	15**	15**	15**	15**	15**	15**	<mark>25</mark> **	15**	15**	99**	5**

- No specific requirement or limitation on percentage content of nature-identical substances or water except where indicated
- * Content of substances from controlled organic farming in Section 3.2 and 3.3.
- ** Production of derived natural substances made of organic starting material in Section 3.2 (Natural Cosmetics with Organic Portion) or Section 3.3 (Organic Cosmetics).
- *** Water-free product contains up to 5% added water.
- # For Category 12 products (Bar Soaps) in Section 3.2 or Section 3.3, the minimum organic requirement (respectively ≥70% or ≥95% content as in * and **) refers to both the natural and derived natural portions to be added.