

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

Version 3.9

NATRUE

Version 3.9 – 01.01.2021

NATRUE



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1. Introduction

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

Complete background information (certification process, fact sheets and position papers, FAQs, etc.) concerning the NATRUE Label is publicly available for consumers and manufacturers at www.natrue.org.

1.1 Background

Recent developments in various industries, and particularly in the food sector, show the growing importance of the "natural" and "organic" qualities for consumers, who increasingly look for these not only in food, but also in cosmetics. However, the criteria to assess the natural or organic quality of food are not directly comparable with the ones applied to cosmetics. While there are well-established regulations that guarantee the organic quality of food, to date there is no definition of the parameters that define a "natural" or an "organic" cosmetic product. As a result, various definitions and corresponding labels for natural and organic cosmetics have been created at national and international level in the past years in order to address the lack of an international, harmonised definition for natural and organic cosmetics.

The production of natural cosmetics poses numerous challenges due to the complexity of this type of products and to essential aspects linked to the sourcing and production of natural ingredients (environmental protection, sustainability development, biodiversity promotion, etc.). Apart from aspects linked to the production, the formulation of natural cosmetics involves complex processes in which the number of modifications and chemical processes that raw materials are subjected to directly influence the natural and organic qualities of the final ingredients. In its belief that the formulation of natural and organic products should be based on commitments and not derogations, NATRUE's criteria go further than other definitions of "natural cosmetics" so far established in Europe by establishing that only natural, certain nature-identical and derived natural raw materials can be used in the formulation of natural and organic cosmetics in compliance with the requirements listed in this standard.

The NATRUE Label, which was created in 2008, is a guarantee for consumers and producers because it sets a high standard that ensures that only high-quality natural and organic cosmetics with the highest levels of natural and organic ingredients can be NATRUE certified. While our seal guides and reassures consumers that look for authentic natural and organic cosmetics, our strict criteria guarantees that producers who certify their products under the NATRUE scheme formulate them in accordance to one of the highest benchmarks for natural and organic cosmetics at international level. Transparency and product information, which also define the NATRUE Label, are actively supported through NATRUE's online products database, an online tool that provides details about NATRUE certified products and raw materials, as well as about their brands and producers.

1.2 Scope

The NATRUE Standard is applicable to raw materials and finished products intended for cosmetic use. The NATRUE Standard may be used for the purposes of independent third-party certification of finished cosmetic products, as well as the certification and approval of raw materials used in cosmetic products.



A Certificate of Compliance to the verifiable requirements of the NATRUE Label criteria laid out in the Standard is awarded after a successful <u>Certification Process</u> delivered by an independent <u>NATRUE Approved Certifier</u>.

For finished products, NATRUE establishes two levels of certification: natural and organic.

1.2.1 Raw Materials

Compliant raw materials include those containing only substances <u>classifiable</u> as natural, nature-identical and derived natural as defined in Sections 2 and 3 below. For additional details, please refer to the Substances Classification Decision Tree available for download here.

Starting January 2020, NATRUE implemented a scheme to allow both the approval and certification of raw materials. All raw materials presently used in NATRUE certified finished products will have a transitional period of 24 months (until 31st January 2022) to be either certified or approved (subject to their qualities).

For details regarding the approval and certification processes, please refer to Annex 3.2 (Raw Material Approval Scheme: decision tree) available for download here.

1.2.2 Finished Products

To certify a cosmetic product under the NATRUE criteria, the sections listed below cover a set of requirements which comprise:

- Descriptions of permitted origin and manufacturing processes in order to classify substances as natural, nature-identical or derived natural;
- Organic proportion requirements in order to be certified as an organic cosmetic;
- Product formulation requirements for minimum levels of natural substances and maximum levels of derived natural substances according to the product category;
- Open lists of derived natural substances and nature-identical substances approved for use in natural cosmetics (Annexes);
- Criteria for packaging, packaging and carrier materials;
- Environmental and ethical criteria as listed in Section 5.

Producers of finished products have until 31st January 2024 to formulate their products using NATRUE approved or NATRUE certified raw materials.

2. Regulations (EU and international standards)

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.

2.2 Organic production and labelling of organic products

Under NATRUE's Criteria, organic certified natural substances (Section 3.1) and derived natural substances (Section 3.2) 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.

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

In terms of GMO, finished products, starting materials and 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 non-feed substances). For reference, please find an example of a 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 (<u>Directive 2009/41/EC</u>), including any post-production treatments required according to its assigned containment level and protective measures.

2.4 Aromatic natural raw materials: ISO standard 9235

In natural cosmetics, natural fragrances (for example, essential oils) which correspond to ISOstandard 9235:2013 may be used. These include isolates of essential oils and essential oils reconstructed from them. Synthetic nature-identical fragrances may not be used in the formulation of natural cosmetics under NATRUE's criteria. The natural fragrance material must also comply with all other requirements of the NATRUE Label criteria (Section 3.1). Please refer here for NATRUE's perfume guidelines and for an example of an ISO 9235 certificate.

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.

3. Definition of permitted ingredients and processes

Apart from water, which is the basis and therefore often the ingredient that represents the highest content percentage in cosmetic formulations, chemically unmodified natural ingredients (natural substances, e.g. fatty oils, hydro-alcoholic plant extracts, etc.) 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 further reference, please find the NATRUE guide to substance classification here.

A Raw Material Documentation File (RMDF) is provided to facilitate the categorisation of raw materials. For completion purposes, please find an explanation of the RMDF and a RMDF for perfume raw materials here.

3.1 Natural substances

Natural cosmetics are products which (subject to Section 3.2 and 3.3) 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 from these 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 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).

3.1.1 *Water*

The origin of the water used in natural cosmetics is arbitrary. When calculating the portion of natural substances in the finished product (Section 4), water is in either case only considered in the calculation percentage of natural substances 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).

3.2 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 in:

- Annex 2: Nature-identical inorganic pigments and minerals
- Annex 4a: Nature-identical preservatives (Section 3.4)

Only those natural-identical substances listed may be used in natural cosmetics. Annex 2 and 4a positive lists of substances listed by INCI will be updated regularly.

3.3 Derived natural substances

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

Derived natural substances also include further substances (besides those mentioned in Section 3.2) which do occur naturally but cannot be recovered in sufficient amounts from their natural sources using state-of-the-art technology.

Derived natural substances (e.g. fats, oils, waxes, lecithins, mono-, oligo- and polysaccharides, proteins and lipoproteins) are always recovered from natural substances (Section 3.1) 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 keeping the number of chemical conversion steps to a minimum.

Only the following chemical reactions are permitted:

- Acylation
- Amidation

^{*} Examples for the calculation of plant extracts and hydrolates/floral waters are provided in Annex 6.



- Condensation (with elimination of water)
- Dehydrogenation
- Dimerization
- Esterification
- Glycosidation
- Hydrogenation
- Hydrogenolysis
- Hydrolysis (including saponification)
- Neutralisation
- Oxidation (with oxygen, ozone and peroxides or electrochemically)
- Phosphorylation
- Pyrolysis
- Sulphatation
- Transesterification

All necessary auxiliary materials and catalysts (including enzymes and microorganisms) not explicitly defined in the NATRUE Criteria may be used in the context of:

- improving sustainability to have a better adapted energy efficiency or
- due to current technical unavoidability or alternatives.

The substance is classified as derived natural in all cases where:

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

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

Annex 3 contains an open list of approved derived natural substances (listed by INCI) whose origin and manufacture must conform with the above-mentioned requirements in order to comply for end use in products. This list will be updated regularly.

3.3.1 Preservatives

For the preservation of natural cosmetics, only the preservatives classified as nature-identical or derived natural as listed by INCI in Annex 4 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 described in Section 3.3.

Annex 4 positive lists will be regularly updated.

4. Requirements for the formulation of products

Please refer to **Table 1** (Section 9) for the percentages corresponding to the minimum levels of natural substances and maximum levels of derived natural substances allowed for each product category and certification level under NATRUE's Criteria.



4.1 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).

4.2 Organic cosmetics

In addition to the basic requirements laid down in Section 4.1, the following additional requirements have to be met.

4.2.1 Additional requirements

At least **95%** of the natural substances of plant and animal origin and of derived natural substances (if applicable, as per the details below) 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.

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.

4.3 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.

5. NATRUE Principles

5.1 Animal testing

Animal testing is fundamentally against NATRUE's underlying values and ethics, as explained in detail in NATRUE's statement on animal testing. NATRUE's criteria extends the animal testing ban on finished cosmetic products (as regulated by Regulation (EC) No 1223/2009) to third countries outside the EU.

5.2 Environmental considerations

5.2.1 Surfactants for cleaning purposes

The environmental compatibility of derived natural substances that are surfactants intended to be used for cleansing purposes must be evaluated separately to ensure they can be returned to the natural circle without causing any problems. These substances must meet particularly strict requirements regarding their biodegradability (Section 2.5; Regulation (EC) No 648/2004).

5.3 Biodiversity protection

As indicated in the RMDF, a certificate of nature preservation authority is required for a natural substance (Section 3.1) 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).



5.4 Sustainability

5.4.1 Palm oil

NATRUE requires that, wherever possible and available, natural or derived natural raw materials from palm oil and palm kernel oil must come from RSPO or other certified sustainable supply chains and mass balance (MB) quality as a minimum requirement, and ideally Segregated and Identity Preserved qualities. Qualities that are not available as certified RSPO or other certified sustainable supply chains (minimum MB) are allowed unless there is indication on Annex 3 that there is supply in MB quality.

Derived natural substances with INCIs available in MB quality or greater are listed in Annex 3 for ease of reference. Annex 3 contains an open list of approved derived natural substances (listed by INCI) whose availability has been identified to conform with the above-mentioned requirements in order to comply for end use in products. This list will be updated regularly.

Only certified organic quality is a derogation to the RSPO certification requirement.

5.4.2 UN Sustainable Development Goals



The basis for the NATRUE standard reflects the legal requirements of Regulation (EC) No 1223/2009, particularly with regard to the cosmetic's composition, safety, efficacy and labelling requirements. Independent of the certified formulation of a natural or organic cosmetic product, all cosmetic products must comply first and foremost with the law in the market which they are to be placed.



The NATRUE standard promotes natural and organic cosmetic products, establishing an internationally applicable framework:

- to foster green and sustainable innovation using renewable raw materials extracted and processed with methods aligned with the principles of green chemistry, and to facilitate their procurement;
- to promote the use of non-GMO natural and organic grade raw materials;
- to avoid arbitrary exceptions* for non-renewable raw materials either synthetic or semi-synthetic substances;
- to distinguish greenwashed and nature-inspired formulations from authentic natural and organic cosmetic products and their brands;
- to reassure the consumer and facilitate transparency and informed decision-making.

All products certified under the NATRUE label contain exclusively 100% natural, derived natural or nature-identical ingredients.

• (*The NATRUE Label criteria permits one derogation at this time: a select exhaustive list of nature-identical substances, listed in Annex 4a).

During 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.





Natural and organic cosmetics are to be made from formulations containing exclusively or predominately renewable resources without arbitrary exceptions or derogations. Use of renewable raw materials in finished products goes handin-hand with an accountability to responsible sourcing, process and manufacture with reduced environmental impact and waste.

NATRUE requires the use of raw materials to be produced from renewable natural, non-GMO and certified organic agriculture meeting a standard or regulation approved in the IFOAM Family of Standards.

NATRUE sets requirements for packaging, packaging materials and carrier materials for cosmetic products. Packaging must be kept to a minimum, designed for multiple uses, and use recyclable packaging materials (if possible, made of renewable raw materials). Halogenated plastics may not be used. For carrier materials (e.g. wipes or pads), these must be made from natural and/or derived natural substances recovered from renewable raw materials.



Focusing on the use of renewable natural or organic raw materials in cosmetics helps to reduce the dependence on fossil fuel consumption, and contributes to reducing the product's carbon footprint. Furthermore, isolation, extraction, production and modification of natural substances using reusable, efficient and sustainable methods built upon the principles of green chemistry (such as the use of enzymes), also facilitate and help to improve the overall environmental impact and footprint of natural and organic cosmetics. Responsible sourcing of natural materials is integral to the ethics and values of natural and organic cosmetics (for example, sourcing of certified sustainable palm (kernel) oil).



In respect of biodegradability, the environmental compatibility of derived natural substances that are surfactants intended to be used for cleansing purposes must be evaluated separately to ensure they can be returned to the natural circle without causing any problems. These substances must meet particularly strict requirements regarding their biodegradability (i.e. detergents, (Regulation (EC) No 648/2004).

The use of microplastics, which come predominantly from fossil fuel origin such as synthetic plastic polymers manufactured from mineral oil, is inconsistent with the requirements laid out in the NATRUE Standard and with the formulation of authentic natural and organic cosmetics. Only cosmetic substances conforming with one of NATRUE's three permitted classifications (natural, nature-identical or derived natural) may be used in certified finished products carrying the NATRUE seal.



NATRUE promotes and supports certified organic agricultural practices and the protection of biodiversity. In respect of biodiversity, NATRUE requires that a certificate of nature preservation authority is presented for any natural substance when that 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).



6. NATRUE Label usage

The certification of products on the basis of NATRUE Criteria requirements for natural and organic cosmetics is possible independent of membership of NATRUE AISBL 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) is eligible to achieve the NATRUE Certification. Further details concerning the NATRUE Label Usage (Annex C and agreements) for finished products can be found here.

If a given company produces products that are currently certified to another natural and organic cosmetics standard*, the calculation of the 75% threshold, required in order to obtain the NATRUE Certification, shall take into account those products certified to another natural and organic cosmetics standard as well, but only during the <u>first two years</u> 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 only to the NATRUE Label criteria. Double labelling is permitted as long as the above requirements are met.

The requirements listed above do not apply for cosmetic raw materials. For further details about the NATRUE certification and approval of raw materials, please refer to the documents listed here.

*Other certified natural and organic cosmetic standards are those where verification and control has been carried out by an authorised certification body according to that standard.

7. Requirements for carrier materials and packaging

7.1 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.

7.2 Packaging and packaging materials

- Packaging must be kept to a minimum.
- If possible, products should be designed for multiple uses (except for sample packs).
- 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] and PP [Polypropylene]); if feasible, these should be made of renewable raw materials.
- 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.

8. Labelling

Labelling, claims and communication about the natural and organic qualities of a product must be clear so as not to mislead or confuse consumers. The NATRUE Label Use Guide (Annex C – available for download here) sets the requirements for the use of the NATRUE Label. It is mandated in this standard for verification, and included within the NATRUE Agreements on the Usage of the NATRUE Label.



9. Requirements to be met by products certified to NATRUE criteria per category (Table 1)

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	Cleansing products containing surfactants	Oral care	Decorative cosmetics, water- free	Soaps and water-free cleaning products containing surfactants	Waters
cs	80	60	30	10	10	10	10	3	3	2	1	1	0.1
Natural Cosmetics (Level 1)	20	10	30	30	30	25	55	40	85	70	50	99	10
metics	90*	60*	30*	15*	15*	15*	15*	15*	15*	15*	15*	1*	15*
Organic Cosmetics (Level 2)	10**	10**	20**	20**	15**	20**	30**	15**	25**	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 (Section 4.2).
- ** Production of derived natural substances made of organic starting material in (Section 4.2).
- *** Water-free product contains up to 5% added water.
- # For Category 12 products in Section 4.2, the minimum organic requirement (respectively ≥95% content as in * and **) refers both to the natural <u>and</u> derived natural portions to be added.

Important: As of 01.01.2021, NATRUE new certified finished cosmetic products will be certified either as "natural" or "organic". Products already certified under the phased-out certification level "natural with organic portion" can still be identified as such in the market and in NATRUE's database until the product's certificate expires. Upon recertification, a product meeting the requirements of level "natural with organic portion" will be recertified either as "natural" or "organic", subject to its compliance with the set requirements for each category.

10. Annexes

The Annexes to the NATRUE criteria with further specifications about the approved agents, inorganic pigments and minerals, as well as the substances approved for the production of natural cosmetics are available for download here.