



ECOCERT STANDARD

NATURAL AND ORGANIC COSMETICS

May 2012 v2

Application on the 1st of July 2012

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PREFACE



I. PREAMBLE

This standard is the result of a partnership between Ecocert, certification body in the environment field, and certain professionals of the cosmetic products sector who have been expressing for a long time the need to find a solution to the following issues:

- The absence of official standard concerning the cosmetics produced using ingredients from natural origin, and the labeling of the cosmetic products as « organic ».
- The existence of a great number of private European and extra-Community standards little known and/or not recognized by the body of the cosmetic professionals.
- The difficulty or the impossibility for the consumer to recognize products as being manufactured with significant quantities of ingredients from natural origin and organic ingredients according to environmentally friendly procedures.
- The necessity to support the cosmetic products' manufacturers who make a point of respecting the quality of ingredients from natural origin used and who respect the environment.

In other words, it is a question of acknowledging the know-how of those cosmetics manufacturers who are respectful of nature throughout the production process and of ensuring better information, to the consumer, on the composition of the products.

II. MAIN OBJECTIVES

Thanks to this standard, Ecocert Greenlife aims to answer the following objectives:

- To define a quality level superior to the one defined by the French and European legislation on cosmetic products, which will safeguard a real enhanced value of the ingredients from natural origin, a real practice of the respect of the environment, throughout the production process and a real respect of the consumer.
- To establish a link between certain cosmetic products and Organic Agriculture in promoting the use of Organic Agriculture plant products.
- To establish a link between certain cosmetic products and the respect of the environment.



III. BASIC PRINCIPLES OF THE STANDARD

The objectives for the standard find their expression in the implementation of the following principles:

- To give preference to the natural origin above any other origin.
- To give preference to the use of ingredients from organic farming, best guarantee for the respect of natural values.
- To give preference to environmentally friendly process.
- To add criteria on the environment impact (biodegradability, ecotoxicity) during the valuation of ingredients from natural origin.
- To be transparent towards the consumer by using a mode of communication and phraseology, which are not misleading.
- To enhance the willingness of the manufacturers who want to improve the quality of their supply and of their products by inscribing their research in a dynamic and progressive certification process.
- To leave a wide enough opening in order to permanently adapt to the requirements, to the technical progress and to the evolution of the legislation.
- To apply the precautionary principle on issues concerning certain questions raised by the scientific community, questioning the respect of the consumer and/or of the environment, whose answers are in progress.

To work out this standard, Ecocert:

- relied on its tried and tested areas of expertise in Organic Agriculture: respect of the environment, respect of the consumer and experience in the capacity for standards to be inspection led,
- relied on a group of professionals organized within a Technical Committee and particularly motivated in this new field of research,
- sought impartiality in inducing independent scientific expertise, and in relying on the support of a group of professionals representative of the industry,
- sought quality by being selective but not restrictive, so as to allow a sufficient variety of formulations to exist,
- tried to define a progressive system allowing the promotion of the continuous technical innovations in this area.



IV. RATIONALE OF THE STANDARD

The article I describes the scope of the standard:

I. AREA OF APPLICATION

The article II presents the starting definitions:

II. STARTING DEFINITIONS

The article III concerns the consumer. It describes the nature and the mode of communication of the information relative to the characteristics of the certified products:

III. LABELLING AND COMMUNICATION

In the articles IV à VII, the requirements regarding the production cycle are defined:

IV. RULES ON THE INGREDIENTS AND THE COMPOSITION OF THE FINISHED PRODUCT

V. CONDITIONING AND PACKAGING

VI. PRODUCTION RULES

VII. COMPANY CONTROL SYSTEM

Then in the article VIII, the overall environment management requirements are defined:

VIII. PROTECTION MEASURES - CLOSE ENVIRONMENT

The conditions of valuation of the product conformity are described in the article IX which sends back to the diagram in the Appendix II:

IX. CERTIFICATION PROCESS

A final article (article X) detailed the conditions of evolution of the standard:

X. STANDARD UPGRADE CONDITIONS



V. REGLEMENTARY FOUNDATIONS OF THE STANDARD

Every modification of a regulation mentioned in this standard will be applicable as soon as it will come into force, this even before the update of the standard.

This standard has been elaborated:

- in partnership with professionals of the cosmetics sector who are eager to promote their know-how as to the beneficial aspects of the use of substances from natural origin, the respect of the environment and of the consumer,
- in collaboration with independent experts,
- in relation with European organizations (particularly German and English), to share their thoughts and lay the foundations for a common regulation,
- in compliance with the general regulation related to cosmetic products in Europe, which describes, in particular, the requirements linked to the human health and the security of the cosmetic product.

A. The general regulation related to cosmetic products

The natural and organic cosmetics standard applies to cosmetic products.

Any applicant for certification must have read the regulations in force in the country where the certified cosmetic products are produced and/or distributed and comply with them.

In Europe, cosmetic products are defined by Directive 76/768/EEC of 27 July 1976 (amended), transposed into French law by the Decrees N° 2000-569 of 23 June 2000 (repealed on 08/02/2004) and the Orders of 23 June 2000 and 30 June 2000, amending Book V of the Health Code.

This will be replaced by Regulation (EC) N° 1223/2009 of the European Parliament and of the Council of 30 November 2009 relative to cosmetic products published in the Official Journal of the European Union from 22/12/2009 as soon as it enters into force*.

They must also comply with the following Articles of the French Public Health Code, applicable to cosmetic products, and to the Orders establishing the composition of the products:

- Articles L. 5131-1 to L. 5131-11 and R. 5131-1 to R. 5131-14 of the French Public Health Code
- Order of 06/02/2001 (amended), establishing the list of substances that may not enter into the composition of cosmetic products
- Order of 06/02/2001 (amended), establishing the list of substances that may not be used in cosmetic products over and above the restrictions and conditions set out by this list
- Order of 06/02/2011 (amended), establishing the list of preservatives that cosmetic products are permitted to contain
- Order of 06/02/2011 (amended), establishing the list of colouring agents that cosmetic products are permitted to contain
- Order of 06/02/2001 (amended), establishing the list of ultra-violet filters
- Any other applicable regulations



* Article 40 of Regulation (EC) N° 1223/2009:

Regulation (EC) N° 1223/2009 comes into force on the twentieth day following the day of publication in the Official Journal of the European Union. It applies on the 11th of July 2013, with the exception of:

- Article 15, paragraphs 1 and 2 which apply on the 1st of December 2010, together with Articles 14, 31 and 32, insofar as they are necessary for application of Article 15, Paragraphs 1 and 2, and
- Article 16, Paragraph 3, second part, which applies on the 11th of January 2013

Outside of Europe, it is up to the company to advise Ecocert Greenlife if there is a discrepancy between local regulations and this standard.

B. Regulation in Organic Agriculture

Organic Agriculture is governed by the following production regulations for plant and animal products (processed or not):

- Council Regulation (EC) N° 834/2007 of 28 June 2007 and its application regulations
- American regulation: National Organic Program (NOP)
- Japanese regulation: Japanese Agricultural Standard (JAS)
- The other regulations considered as equivalent by Ecocert Greenlife

C. Regulation relating to industrial products certification

The Ecocert Greenlife standard for natural and organic cosmetics is in line with the industrial products and services certification provided for by the article 137 of the French law N° 2008-776 of 4 August 2008 of economic modernisation.

Thus any candidate for the certification of natural and organic cosmetic products must have full knowledge of the applicable regulatory texts and of the regulations provided by the Code of Consumption concerning:

- Articles L.115-27 to L. 115-33 and R. 115-1 to R. 115-3 of the Code of Consumption,
- Notification of the National Council of the Consumption: « Notification of 17 December 2007 », « Notification of 6 July 2010 », « Notification of 15 December 2010 ».



ARTICLES OF THE STANDARD



I. AREA OF APPLICATION

A. The cosmetic products as defined by the regulation relating to the cosmetics

This standard applies to cosmetic products as they are defined by Regulation (EC) N° 1223/2009 of the European Parliament and of the Council of 30 November 2009, published in the Official Journal of the European Union on 22/12/2009 which will replace Directive 76/768/ECE of 27 July 76 (amended) as soon as it enters into force: they are all substances or mixtures intended to come into contact with the superficial parts of the human body (epidermis, down and hair systems, nails, lips and external genital organs) or with teeth and visible oral mucous membranes, solely or principally, to clean them, perfume them, modify their aspect, protect them, keep them in good condition or correct body odour (Chapter I Article 2 of Regulation (EC) N° 1223/2009).

It is up to each certification applicant to check that the submitted products comply with this definition.

B. Products intended to present some indications referring to their natural origin and to the organic production process

This standard applies to the products and their ingredients, and intended to refer to their natural origin and to the organic mode of production.

C. Standard that can be applied without prejudice to the European community provisions

This standard applies without prejudice to the Community provisions governing the manufacturing, the inspection, the packaging, the launch on the market, the labelling, the importation and the distribution of cosmetic products.



II. STARTING DEFINITIONS

For the purposes of these specifications, is meant by:

A. Contaminants

A substance not naturally present in the ingredient or in ratios superior to those existing naturally and leading to a pollution (persistence, residues), and possibly to toxicity risks (heavy metals, hydrocarbons, pesticides, dioxins, radioactivity, GMO, mycotoxins, medicinal residues, nitrates, nitrosamines).

B. Primary packaging

The products' original package, with its seal.

C. Secondary packaging

Any other container different from the original one.

D. Range of products

Category of products, possessing common or similar characteristics, and which can be grouped together for planning and/or marketing purposes. Thus, all products of a same range can be sold, at least, under the same brand name.

E. Ingredients

Without prejudice to the French and European legislation on cosmetic products, this is meant, in this standard, for all substances used in the preparation of the products targeted by the standard.

The water added during the manufacture of the finished product is thus seen as an ingredient itself.

The use of the designation « raw material » can be found, especially for organic ingredients certified according to this standard.

« Physically transformed ingredients »

A physically transformed ingredient is an ingredient that has only been subjected to physical processes, i.e. the molecular structure of the ingredient has not been modified.

The physical processes authorized by the standard are listed in the technical sheet TS033.

The ingredients concerned by this definition are the plant ingredients, the animal ingredients, the mineral ingredients and the marine ingredients as defined in article IV.A.1.

« Chemically transformed ingredients »

A chemically transformed ingredient is an ingredient that has been subjected to at least one chemical process, i.e. the molecular structure of the ingredient has been modified (e.g.: soap).

The chemical processes authorized by the standard are listed in the technical sheet TS033.

The ingredients concerned by this definition are the ingredients from plant origin, the ingredients from animal origin, the ingredients from mineral origin and the ingredients from marine origin as defined in article IV.A.1.

The term « moiety » is used to refer to a specific segment of a molecule bound after chemical transformation.



F. Batch

A defined quantity of an ingredient, raw material, packaging or product manufactured in one operation or a series, such that it can be considered as uniform.

G. Manufacturing

Group of operations carried out in the factory or the laboratory, for obtaining, conditioning and labelling the products targeted by this standard in the factory or the laboratory.



III. LABELLING AND COMMUNICATION

A. Information relating to the standard and obligatory on the labelling of a finished cosmetic product

1. Appelations allowing the identification of the standard

The products defined in this standard and which meet its conditions, are granted the obligatory indication « NATURAL COSMETIC » or « ORGANIC COSMETIC », following the rules on the ingredients and composition of the finished product set out in the article IV.

2. References to the certification body and the appellation

The references to the certification body and to the appellation (Cf. article III.A.1) must appear as a group on the products' label. Furthermore, they must be no more apparent than the trade denomination itself.

References to the certification body are: « certified by Ecocert Greenlife according to Ecocert Standard available at <http://cosmetics.ecocert.com> ».

3. Claim for the essential characteristics of the standard

Once reference has been made regarding the certification in the labelling of the product, the following characteristics should appear with the references of the certification body:

- « XX % of the total ingredients are from natural origin »
- « XX % of the total ingredients are from organic farming » (if the product is 100% organic, this statement is enough)

The appellation, the references to the certification body and the essential characteristics of the standard have to be written together.

4. Information concerning the ingredients issued from production complying with the Organic Agriculture mode of production

The ingredients issued from manufacturing complying with the Organic Agriculture mode of production must be mentioned in the list of ingredients followed by an asterisk, referring to the indication: « ingredient from organic farming ».

5. Information concerning the ingredients issued from production complying with the Organic Agriculture mode of production and chemically transformed

The ingredients issued from manufacturing complying with the Organic Agriculture mode of production and chemically transformed must be mentioned in the list of ingredients followed by a double asterisk, referring to the indication: « made using organic ingredients ».

6. Conditions for using information linked to the standard

A product complying with this standard may benefit from the indications linked to this standard if the product has been certified by means of a certification process.

B. Information relating to the standard and obligatory on the labelling of a raw material

1. References to the certification body and the appellation

The references to the certification body and the appellation are: « Raw material certified by Ecocert Greenlife according to the Ecocert Standard for Natural and Organic Cosmetics available at <http://cosmetics.ecocert.com> ».

This information must be indicated on the raw material label or on an enclosed technical data sheet. In all cases, the following must appear on the label: the name of the raw material and the name of the certification body.



2. Claim for the essential characteristics of the standard

Once reference has been made regarding the certification in the labelling of the product, the following characteristics should appear on the label of the raw material or on the technical data sheet:

- « XX % of the total ingredients are from natural origin »
- « XX % of the total ingredients are from organic farming » (if the product is 100% organic, this statement is enough)

3. Information concerning the ingredients issued from production complying with the Organic Agriculture mode of production

The ingredients issued from manufacturing complying with the Organic Agriculture mode of production must be mentioned in the list of ingredients followed by an asterisk, referring to the indication: « ingredient from organic farming ».

4. Information concerning the ingredients issued from production complying with the Organic Agriculture mode of production and chemically transformed

The ingredients issued from manufacturing complying with the Organic Agriculture mode of production and chemically transformed must be mentioned in the list of ingredients followed by a double asterisk, referring to the indication: « made using organic ingredients ».

The list of ingredients must be indicated on the raw material labels and/or the technical data sheet.

C. Transparency with respect to consumers

1. Translation of the list of ingredients

The ingredients may be translated into more commonly used names in a paragraph entitled « Composition » where the list of ingredients must be indicated exhaustively, in accordance with the INCI list.

2. Use of the word « organic » in the name of a finished product

The term « organic », in whatever language, its derivative or abbreviation, such as « org », used alone or together with other terms, must not appear in the commercial name of the product unless it is a product containing over 95% of ingredients from organic farming.

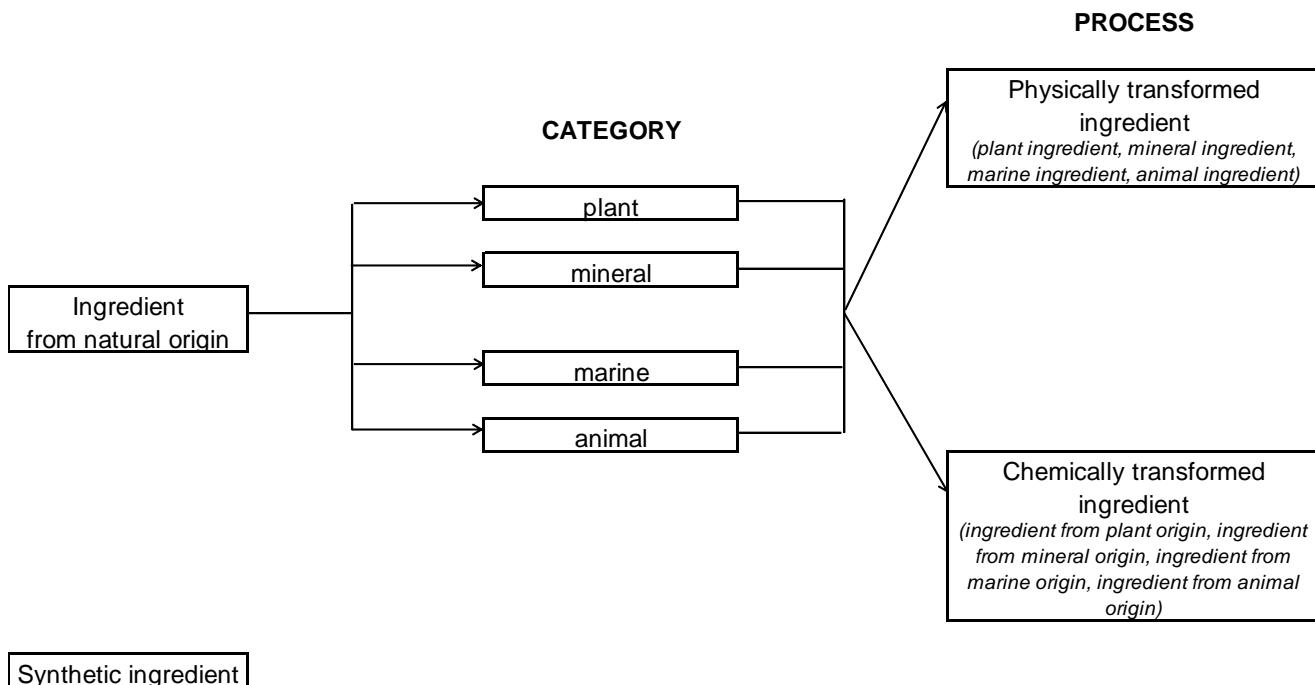
Details of labelling and translation are given in technical sheet TS005.



IV. RULES ON THE INGREDIENTS AND THE COMPOSITION OF THE FINISHED PRODUCT

All ingredients defined below must comply with the rules on composition, set out in the Orders of 6 February 2001 (cf. Reglementary foundations V.A. of the Preface) and the referential criteria, without prejudice to changes in French and European legislation.

A. Definitions and rules for the different types of ingredients



1. Ingredient from natural origin

a) *Plant ingredient or ingredient from plant origin:*

They are all permitted if their production or the harvesting of them in their natural habitat doesn't generate a degradation of the landscape and an imbalance of the ecosystems, and insofar as they don't belong to an endangered species.

They must also comply with the national and international lists of protected species (cf. the Washington Convention or the EEC Regulation 338/97; list of the protected species on the whole of the French territories: Order of 20 January 1982, amended) or must have an importation authorization and the corresponding CITES certificates.

They are not subject to a specific positive list within this standard.

They must be obtained following the physical and chemical processes permitted in the technical sheet TS033.

They have to be guaranteed not derived from GMO.

Plant ingredients can't be extracted with petrochemical solvent.

b) *Mineral ingredient or ingredient from mineral origin:*

They are permitted insofar as they are used for their intrinsic qualities, where their extraction doesn't generate a contamination and/or a degradation of the landscape.

Their process must be compliant with the positive list available in the technical sheet TS033.

Mineral ingredients, not chemically transformed, are not subject to a specific positive list. Ingredients from mineral origin are covered in a positive list in the technical sheet TS034, Table 2.

The addition of a new ingredient to this list will be in compliance with article X, relative to standard modification.



c) Marine ingredient and ingredient from marine origin:

The acceptance criteria are identical to those listed for ingredients from the plant category. Plant ingredients grown beneath sea level or in non-saline stretches of water are considered as marine.

E.g.: Algae.

d) Animal ingredient and ingredient from animal origin:

They are permitted and submitted to restrictions in accordance to the national and international lists of protected or dangerous species.

Thus, certain animal products which do not originate from species at risk (bovine, pig or sheep species...), whose sampling will not produce a negative effect on the natural balance, may be used.

They can't be a part of the animal, nor caused stress, pain or death and they must be naturally produced by them.

They must be obtained following the physical and chemical processes permitted in the technical sheet TS033.

2. Synthetic ingredients

Synthetic ingredients are considered to be any ingredient, fully or partially stemming from a petrochemical origin. They may not enter into the composition of a product covered by this standard.

However, without prejudice to French and European Law on cosmetics, preservatives compliant with the technical sheet TS034, Table 1 are authorized in ingredients or the finished product.

Also accepted are the other ingredients in Table 1 that do not have a preservative function.

B. Rules applicable to certain types of ingredients

1. Nanoparticulate ingredients

Non-soluble or bio-persistent substances, produced intentionally, characterised by one or more external dimensions or by an internal structure, on a scale of 1 to 100 nm (Definition from Regulation (EC) N° 1223/2009 of the European Parliament and of the Council of 30 November 2009 relative to cosmetics, published in the Official Journal of the European Union of 22/12/2009).

This type of ingredient is prohibited by this standard.

Ingredients in the mineral category may be concerned.

2. Ingredients certified as organic

Any ingredient complying with the definition of the regulation on organically grown products, details of which are given in the V.B Reglementary foundations of the Preface, may be used if compliant with the rules for ingredients described in this standard.

Raw material organic certified by this standard or any other equivalent cosmetics standard are also accepted.

Ingredients in plant, marine or animal categories may be concerned.

3. Extracts

a) General rules

All extracts are concerned by the following measures.

We can quote: hydrolates, decoctions, hydro alcoholics extracts, hydro glycerin extracts, aqueous extracts...

- An aqueous extract will be counted as 100% organic (or plant origin) starting from the moment that the ratio of organic dried plant (or not organic dried plant) / final extract will be > 5%.
- If the ratio organic dried plant (or not organic dried plant) / final extract is less than 5%, a proportional rule is applied: if the ratio is equal to 1%, the extract is counted at 20% organic (or plant origin).



- A mixture of organic essential oil and water will not be counted 100% organic even if it has been certified organic already: the organic percentage will be equal to the quantity of essential oil used.
- For all organic extracts, the ratio organic dried plant / final extract as well as the extract final composition must be declared by the manufacturer on the technical data sheet of the product or on an attestation.

b) Oily macerates

The organic percentage in oily macerates is calculated thanks to the quantities of organic ingredients initially introduced.

The TS012 technical sheet covers examples of the calculation of organic percentages in plant extracts.

4. Soaps and other chemically transformed ingredients from organic ingredients

Chemically transformed ingredients may be certified according to this standard, provided that one or more reagents used for their production are of organic origin.

This percentage is calculated according to the following rules:

- Case for ingredients for which the incorporated weight of reagents is known
organic % of the ingredient = weight of organic reagents / weight of all reagents
- The organic % is weighted by the organic and non-organic reagents recycled or eliminated and by the final content in terms of active substance.
- Case for ingredients for which the incorporated weight of certain reagents is not known (example: hydrogen flow)
organic % of the ingredient = molar weight of the ingredient organic moieties / molar weight of the ingredient.

The TS011 technical sheet covers examples of the calculation of organic product percentages for chemically transformed ingredients.

5. Biotechnological processed ingredient

Ingredient from the action of a bacteria or an enzyme on a substrate. This substrate must be of non-derived GMO origin and each substrate ingredient must comply with the criteria indicated above according to its origin (article IV.A.1).

The product of the biotechnological reaction must have been subjected to PCR (Polymerase Chain Reaction) analysis with a negative result proving the non contamination of the process.

Enzymes from animal origin must be compliant with the definition of the article IV.A.1.d. Nutrients, such as trace elements, salts and vitamins must be eliminated from the final environment as far as possible.

For organic ingredients obtained by fermentation, the requirements of Regulation (EC) N° 834/2007 relative to organically grown products are applicable.

If the enzymes and bacteria are directly incorporated into the formulation of a certified cosmetic, they are considered as ingredients and must follow the rules described in the article IV. They must be guaranteed not derived from GMO.

6. Water

Water is considered as being a mineral ingredient. As such, it cannot be organic.

Water must be known to be compliant for a cosmetic use and may be:

- Spring water
- Water obtained by osmosis
- Distilled water
- Sea water
- Water mains



In the case of an internal water treatment system, it must comply with the processes authorized in the technical sheet TS033 and avoid stagnation and risk of contamination. The water obtained must be of a defined quality.

The water quality must be verified by tests or by monitoring of the treatment system parameters.

The component water contained in a raw material of plant or marine origin is not concerned by this paragraph. In this case, refer to Paragraphs IV.A.1.a. or IV.A.1.c. if relevant.

7. Ingredients covered by a derogation

These ingredients are listed in the technical sheet TS035.

C. Rules on the composition of the finished product

The ratios of ingredients in the finished product defined below take into account the characteristic importance of the amount of added water used in the formulation of a cosmetic.

The calculation of the percentages described below is made with values in weight.

1. All of the ingredients are submitted to an obligation of conformity

100% of the ingredients used in a certified cosmetic product must be compliant with the European legislation for cosmetic products and to the criteria described in IV.A and IV.B.

2. The quantity of natural origin ingredients in the finished product

A minimum of 95 % of the total of the ingredients are ingredients from natural origin, meeting the definition in the article IV.A.1.

This ratio may be positively revised as the technological advances allow us to define with more exactitude the final uses of the natural substances and of the importance of respecting the environment and the consumer.

3. The quantity of ingredients issued from pure synthesis in the finished product

It concerns all the ingredients described in the article IV.A.2. They cannot represent more than 5 % maximum of the whole of the ingredients.

It concerns the synthetic molecules reputed indispensable.

They must comply with the positive list (Cf. technical sheet TS034, Table 1).

4. The proportion of plant ingredients and ingredients from plant origin issued from Organic Agriculture

Among the ingredients validated as plant (transformed or not), a minimum must be organic certified.

| APPELATIONS | % of organic plant ingredients and organic ingredients from plant origin on the total of ingredients validated as plant (Ratio: weight on weight) |
|------------------------------|--|
| NATURAL COSMETIC | 50% minimum |
| NATURAL AND ORGANIC COSMETIC | 95% minimum |

5. The proportion of ingredients issued from Organic Agriculture in the finished product

In order to avoid specific products containing only a very small proportion of ingredients issued from Organic agriculture, a minimal proportion of the total of these ingredients in the finished product is required. This minimal proportion corresponds to ingredients originating directly or after processing (following the permitted processes listed in the



technical sheet TS033), from products obtained in compliance with the rules of the Organic mode of production.

| APPELATIONS | % of certified organic ingredients on the total of the ingredients making up the finished product (Ratio: weight on weight) |
|------------------------------|--|
| NATURAL COSMETIC | 5% minimum |
| NATURAL AND ORGANIC COSMETIC | 10% minimum |

TABLE SUMMARISING THE RULES RELATED TO THE PROPORTION OF INGREDIENTS IN THE FINISHED PRODUCT:

| COMPOSITION OF A CERTIFIED PRODUCT | | |
|------------------------------------|------------------------------|--|
| General Rules | | Σ % of ingredients from natural origin > 95% That is to say Σ % of synthetic ingredients < 5% |
| Two labels | NATURAL COSMETIC | Σ % Organic of plant ingredients and ingredients from plant origin <hr/> Σ % plant of plant ingredients and ingredients from plant origin <hr/> $\frac{\Sigma \text{ % of certified organic ingredients}}{\text{Total of ingredients}} > 5\%$ |
| | | Σ % Organic of plant ingredients and ingredients from plant origin <hr/> Σ % plant of plant ingredients and ingredients from plant origin <hr/> $\frac{\Sigma \text{ % of certified organic ingredients}}{\text{Total of ingredients}} > 50\%$ |
| | | Σ % Organic of plant ingredients and ingredients from plant origin <hr/> Σ % plant of plant ingredients and ingredients from plant origin <hr/> $\frac{\Sigma \text{ % of certified organic ingredients}}{\text{Total of ingredients}} > 95\%$ |
| | NATURAL AND ORGANIC COSMETIC | Σ % Organic of plant ingredients and ingredients from plant origin <hr/> Σ % plant of plant ingredients and ingredients from plant origin <hr/> $\frac{\Sigma \text{ % of certified organic ingredients}}{\text{Total of ingredients}} > 10\%$ |
| | | Σ % Organic of plant ingredients and ingredients from plant origin <hr/> Σ % plant of plant ingredients and ingredients from plant origin <hr/> $\frac{\Sigma \text{ % of certified organic ingredients}}{\text{Total of ingredients}} > 50\%$ |
| | | Σ % Organic of plant ingredients and ingredients from plant origin <hr/> Σ % plant of plant ingredients and ingredients from plant origin <hr/> $\frac{\Sigma \text{ % of certified organic ingredients}}{\text{Total of ingredients}} > 95\%$ |

D. Quality of the ingredients and of the finished product

1. Contaminants

All ingredients and their by-products must be known to be unpolluted by contaminants.

2. Prohibited ionizing treatments

The finished product or its ingredients must not be submitted to treatments by means of ionizing ray (alpha rays, beta rays, gamma rays, X rays...).

3. Absence of nitrosamines

The ingredients and the finished products must not generate the formation of nitrosamines.

4. Prohibited genetic technology

The ingredients cannot be issued from processes using reactant that are genetically modified organisms.

5. Animal testing of the finished product

This is prohibited, in accordance with the European legislation.



V. CONDITIONING AND PACKING

A. Conditioning

Items must be conditioned with respect for the environment and therefore in recyclable forms and volumes. The level of consumed energy must be low.

As far as possible, products should be conditioned with materials for which a material recycling system is in operation (example: glass, aluminium, paper/cardboard, PP, PET, PE). Packaging from renewable resources are accepted. Packaging derived from dead animals or leading to the death of animals (leather, silk, etc.) are prohibited.

For any other material submitted, a technical file will be studied, taking one or more of the following criteria into account:

- Resources used and process
- Use: primary packaging, secondary packaging, etc.
- Technical complexity (Ecocert Greenlife assessment)
- Possible replacement by another material
- Packaging end-of-life: reuse, recycling, etc.

The use of certain materials such as vinyl polymers (e.g.: PVC) and styrene polymers (e.g.: PS) will be rejected without a technical file.

These validation rules are valid for primary and secondary packaging. A particular effort should be made to minimise secondary packaging.

Overpackaging, such as cellophane wrapping for boxes, is prohibited.

B. Propulsive gasses

Certain propulsive gasses are prohibited.

Vaporizers, atomizers or sprays using pressurized gas such as propane, n-butane, isobutane or dimethyloxide (dimethylether), representing a potential hazard, are prohibited.

We will accept for example: compressed air, N2.



VI. PRODUCTION RULES

A. Storage and transportation of ingredients and finished product

Storage conditions must ensure full traceability and set aside any risk of contamination, confusion or mix-up.

Transport conditions must enable any risk of contamination, confusion or mix-up to be set aside, products carried in bulk without packaging in particular.

B. Production operations (manufacturing, conditioning and packing)

They must be performed in complete series, separated physically or by timeframes from similar operations concerning products not covered by this standard.

They must be performed according to manufacturing processes compliant with this standard (listed in the technical sheet TS033).

Every measure must be taken to ensure batch identification and to avoid any risk of contamination, confusion or mix-up.

C. Cleaning and disinfection operations

The designation « cleaning and disinfection operation » stands for all the stages realised between two manufactures (of certified or non-certified products) allowing to:

- ensure a level of cleanliness, aspect and non-contamination of a surface/piece of equipment
- avoid contamination of the products covered by the standard by other products, including the cleaning/disinfection products used

The rinsing stage is an integral part of this operation.

Production covered by this standard must not under any circumstances generate the use of non-compliant products, the cleaning and disinfection operations **before** and **after** the production of products covered by this standard must be carried out with cleaning and disinfection products compliant to the requirements set out in Appendix III.

The aim of the cleaning/disinfection operations performed by products compliant with Appendix III **before** the production of the products covered by this standard is specifically to:

- ensure there is no contamination by a non-compliant product
- reduce the impact of production on the environment

The aim of the cleaning/disinfection operations performed by products compliant with Appendix III **after** the production of the products covered by this standard is specifically to reduce the impact of production on the environment.

Thus, surfaces in contact or liable to come into contact with ingredients (tank, conditioning line, small items of equipment, etc.), bulk, semi-finished or finished products must be cleaned/disinfected with a product compliant with Appendix III.

In addition, if ingredients or products aren't stored on a pallet or in such a way as to avoid contact with the floor (and therefore possible contamination), floor cleaning/disinfection products must also comply with the requirements of Appendix III.

Moreover, any product used during atmospheric treatment that might come into direct or indirect contact with the products covered by this standard must comply with Appendix III.



VII. COMPANY CONTROL SYSTEM

A. Ingredients

1. Compliance of ingredients

When an ingredient is received, the company must check packaging integrity and compliance of the product with the requirements of this standard.

When verification leads to uncertainty as to the origin of an ingredient or supplier, this ingredient may only be transformed once the uncertainty has been eradicated, unless the resulting product is put on the market without any indication linking it to this standard.

2. Guarantees of compliance for organic ingredients

The company must make certain of the origin of ingredients, notably by the presence of organic guarantees (reference to the appellation or, as applicable, to the standard and/or certification body) from the various documents, as follows: invoice, delivery note and label. In addition, a certificate of conformity with the organic production mode (cf. V.B. Reglementary foundations of the Preface) must be present and validated at the time of the transaction.

3. Suppliers of ingredients

If the supplier of ingredients has only a distribution activity (no re-labelling with its name) and is not certified, traceability must be maintained and checked with respect to the declared original supplier.

For all ingredients (organic or non-organic), this involves:

- no-repackaging and therefore the reference of the original supplier on the delivered product packaging
- the presentation of a transaction document (invoice, delivery note) or a declaration from the supplier providing assurance of the original one

For an organic ingredient, this more specifically involves:

- the presentation of a certificate of conformity with the organic production mode in the name of the original supplier, valid at the time of the transaction
- reference to the organic origin on the packaging as well as the transaction documents and, as applicable, on the above-mentioned certificate

B. Sub-contracting and handling

To ensure the traceability and the appellation of the sub-contracted/handled products, the transaction documents (invoices, delivery note, intermediate labels) must show guarantees of certification (reference to the appellation or the service and, as applicable, to the standard and/or certification body).

In addition, a certificate and/or attestation of conformity with this standard must be presented and be valid at the time of the transaction.

C. Marketed products

To ensure the traceability and the appellation on marketed products (finished products and certified raw materials), the transaction documents (invoices, delivery notes, intermediate labels) must show guarantees of certification (reference to the appellation and, as applicable, to the standard and/or certification body).

For the indications on the labels of finished products or certified raw materials, please refer to the article III of this standard.

In addition, a certificate of conformity with this standard must be presented and be valid at the time of the transaction.

A sample of each certified batch of finished products (including the raw material) must be kept throughout the lifetime of the product at the very least, in a sufficient quantity to be able to conduct tests to check conformity with this standard.



D. Traceability and workflow control

The traceability of ingredients up to the finished product (= internal traceability in the production unit) and finished products up to consumers (= traceability external to the production unit), together with accounting follow-up of incoming/outgoing elements within the company must be rigorously implemented, recorded and available for consultation by an auditor.

The company must keep the following documents available:

- Accounting follow-up and/or records (overall monitoring of quantities), as applicable for elements received/purchased (ingredients, raw materials and/or finished products), shipments/sales (ingredients, raw materials and/or finished products) and stocks (ingredients, raw materials and/or finished products).
- Accounting follow-up and records for ingredients, raw materials and/or semi-finished/finished products (purchase invoices, purchase summaries, delivery notes, production sheets, etc.) in order to keep track of the origin, nature and quantities of all ingredients, raw materials and/or products received, as well as their ultimate use within the company (internal traceability).
- Accounting follow-up and records for products marketed (sales invoice, delivery notes, sales summary, etc.) in order to keep track of the origin, nature, quantities and recipients of all products sold (external traceability).
- Accounting follow-up and records of stocks at regular intervals (physical and computer-generated inventories, etc.) for products marketed and for ingredients in order to ensure the compliance of material workflows within the company.
- The exact composition of the products produced.

E. Quality system

The company must have a control system which allows verification and particularly control of the conformity of:

- ingredients and suppliers
- subcontractors, handlers and related products
- products marketed and/or services provided
- production operations and cleaning and disinfection products
- production equipment and analyses
- communication documents (commercial, technical, etc.)



VIII. PROTECTION MEASURES – CLOSE ENVIRONMENT

Companies must establish a series of measures with their internal control conditions regarding the treatment of all residual products emanating from a production process, aimed at protecting the environment.

As a minimum, these measures must include:

- An environmental analysis plan which enables to identify the activities, products and services that have significant impact on the environment.
- An Environmental Management Programme enabling the environmental objectives set by the company to be defined, supervised, implemented and achieved.

These requirements only apply to companies directly committed to the certification entity which have a production process (manufacture and/or conditioning, etc.).

For example, this standard considers that an ISO 14001 approach constitutes compliance with these requirements.

A. Discharge management

All companies must develop a Plan for the improvement of the discharge management (wastes resulting from an industrial activity: gaseous, liquid or liquid solids), whose aim is the refining of any waste products on an efficient and rational basis.

B. Waste management

All companies must develop a Plan for the improvement of the waste management and at least:

- Practice of the selective sorting of cardboard, glass, paper and all other materials
- Recycle or treat every waste
- Entrust the products which have specific destruction regulations and the packagings which are not recyclable within the company itself, to an outside specialised recycling company

C. Energy management

All companies shall develop a Plan for the improvement of the energy management, whose objectives are to ensure an ever-greater use of renewable energies and an ever-greater recourse to energy-saving measures.



IX. CERTIFICATION PROCESS

The certification process is based on an annual cycle. At its end, a license and a certificate allowing the company to manufacture and sell its products with a reference to the certification and/or Ecocert are delivered to the client.

A summary diagram is available in the Appendix II.

The detailed certification process is joined with the standard for organic and natural cosmetics to any demand of information to Ecocert.

X. STANDARD UPGRADE CONDITIONS

A. Modification of the standard

Modifications are made to the standard in the context of cosmetics regulations (cf. V.A. Reglementary foundations of the Preface).

The certification standard is a technical document defining the characteristics which a cosmetic product must have and the conditions for checking of the compliance of these characteristics. Preparation of the standard and modifications are made in line with French standard NF X50-067, notably, as a minimum, with provision made for consultation with the parties involved as follows:

- the professionals who make the products
- the associations or bodies representing consumers or, as applicable, the users themselves
- the government agencies concerned.

B. Certification Committee

The Certification Committee is a commission composed of expert consultants and of representatives of the profession and of the consumers, having applied for candidature with Ecocert Greenlife. This Committee is consulted particularly for any updating of the standard.

C. Updating and information

Ecocert Greenlife will, by every possible means, keep companies committed to compliance with this standard informed of any modifications made to the standard and the conditions for implementation and will provide them with a modified version of the standard on the Ecocert web site.

This standard should be considered as an open-ended document, liable to be constantly updated and improved.

In the event of modification of the standard, Ecocert Greenlife will define and inform those concerned of a transition period. No withdrawal of products already on the market can be requested (except in the case of a regulatory requirement), provided the products comply with the previous version of the standard.



APPENDICES



APPENDIX I: Validation criteria for processes used to obtain ingredients

To comply with this standard, all new processes to obtain ingredients must comply with the criteria below, in addition to current regulations.

Authorized and forbidden physical and chemical processes are listed in the technical sheet TS033.

If the process is not present on the technical sheet TS033, a technical file must be drawn up covering all the following criteria for assessment by the Ecocert Greenlife Committees.

A. General comments

1. Reactants and ingredients from natural origin:

Reactants and ingredients must comply with article IV of this standard.

The standard gives preference to ingredients of a renewable origin.

Ingredients not obtained from petrochemical sources:

- help to preserve the earth's resources
- keep greenhouse effect gas to a minimum

In fact, the carbon footprint of ingredients of plant origin is generally lower than that of petrochemical ingredients, the availability of which is also limited in the long term.

2. Encouraging energy efficiency:

In an endeavour to protect energy resources, the processes authorized are basic processes where:

- the rise in pressure and temperature is lower
- output is optimum to keep waste and discharge to a minimum and limit the presence of non-recycled sub-products as far as possible

B. Criteria specific to physical processes

1. Application of organic production principles:

The criteria required for organically grown ingredients are applied to certain processes used to obtain and produce non-organic ingredients, as applicable. Thus,

- Plant ingredients (not chemically transformed) may only be extracted or purified by using solvents of natural origin
- Plants or substrates must be guaranteed as not being obtained from Genetically Modified Organisms

2. Integrity of plant resources:

The standard guarantees that the selected processes allow the integrity of plant resources to be achieved.

Ingredient sterilisation processes must not deteriorate the latter.

For example, ionising processes are prohibited.

C. Criteria specific to chemical processes

1. Use of green solvents:

The use of petrochemical solvents should be avoided throughout the production process, as far as possible.

2. Origin of reactants:

Plants or substrates must be guaranteed as not being obtained from Genetically Modified Organisms.



3. The biodegradability and ecotoxicity of ingredients:

The biodegradability and ecotoxicity of ingredients are indicators that enable the impact of the finished product to be limited after use/discharge into waste water. The standard therefore gives preference to:

- Processes that enable biodegradable, non-ecotoxic molecules to be formed
- Processes that enable waste and the energy used for its implementation to be properly managed
- Processes that enable ecological balance to be maintained

Criterion 1: Minimum aquatic toxicity requirement:

LC50 or EC50 or IC50 > 1 mg/l.

Criterion 2: Minimum biodegradability requirement:

Substances recognised as being bio-accumulative and non-biodegradable are prohibited.

Criterion 3: Relationship between biodegradability and aquatic toxicity:

Aquatic toxicity: LC50 or EC50 or IC50 > 10 mg/l and

Biodegradability: > 70% (or 60% for the method using the measurement: DthO or D₂CO₂) (OECD 301 in 28 days or any equivalent test)

OR

Aquatic toxicity: 1mg/L < LC50 or EC50 or IC50 < 10 mg/l and

Biodegradability: > 70% (or 60% for the method using the measurement: DthO or D₂CO₂) (OECD 301 in 14 days or any equivalent test)

4. Catalysts:

As far as possible, preference should be given to the use of catalytic reactants to minimise the use of catalysts.

If need be, the standard will give preference to the use of non-petrochemical catalysts.

5. Transportation-related risks for the environment:

Production processes and methods must minimise the transportation of hazardous substances.

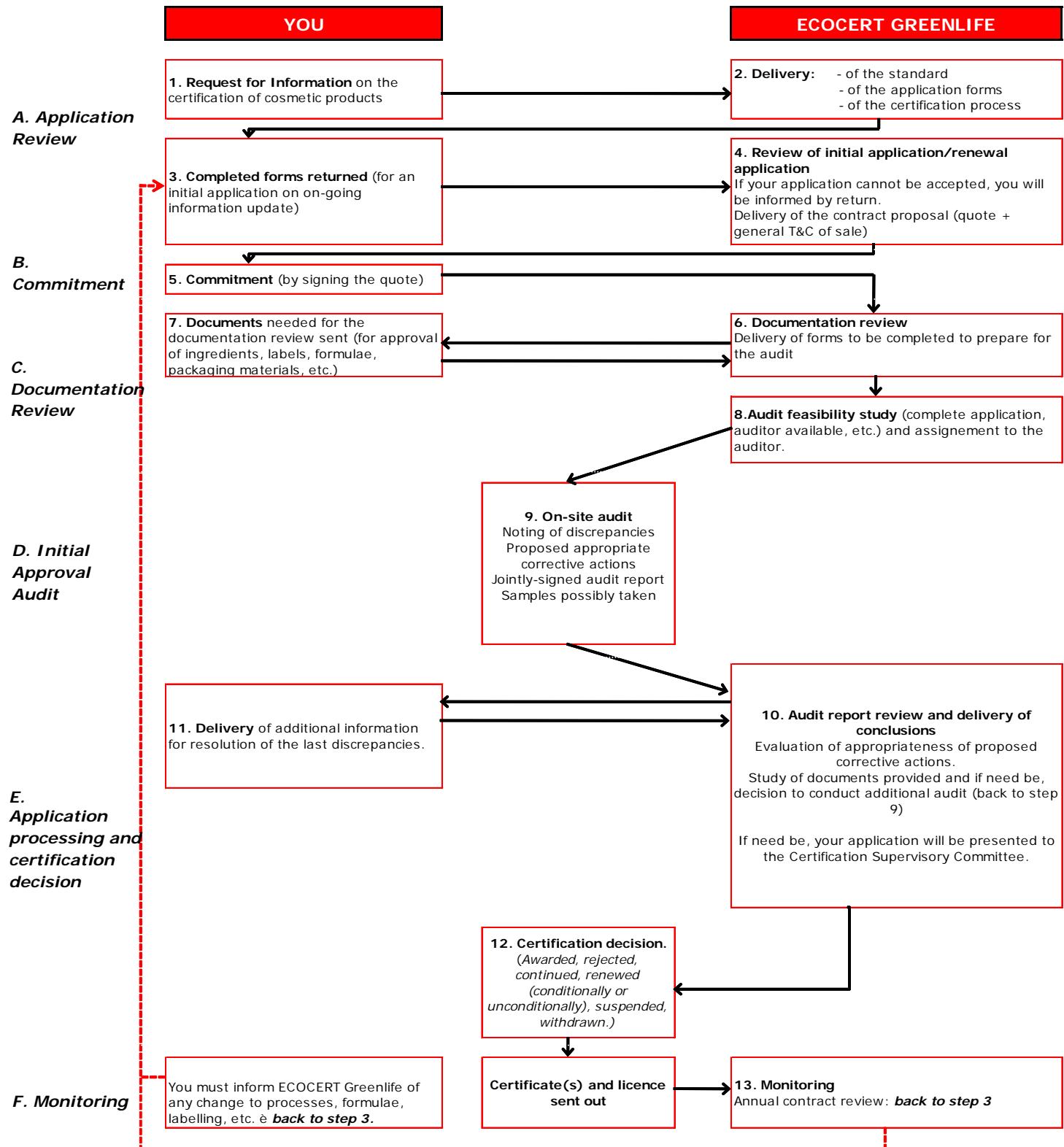
D. An open-ended standard

The standard is open-ended in terms of scientific progress in order to implement increasingly strict criteria for environmental requirements.

Ecocert Greenlife will assess the availability of new alternatives before any referential criteria are modified. Any modification concerning technical criteria will be examined by the technical committee.



APPENDIX II: Summary diagram of the certification process (cf. TS004)



APPENDIX III: Criterias regarding authorized products for cleaning and disinfection

Each cleaning product used by the company should be checked by Ecocert Greenlife in order to be sure about its conformity to this appendix.

A. Criterias concerning the composition of cleaning/disinfection products

1. Authorized substances:

All authorized organic cosmetic ingredients can be used.

Morevoer, the following disinfecting substances can be used:

- Peracetic acid, hydrogen peroxide (and their stabilizing agents)
- Lactic acid
- Alcohol (Isopropanol and natural Ethanol)

2. Restricted substances:

In conformity with the rules of this standard, the following substances and products are forbidden:

- Formaldehyde
- Ethylenediaminetetra-acetic acid (EDTA)
- Products based on genetically modified micro-organisms
- Chlorine and chlorinated-based products
- Products based on ammoniac
- Products based on phosphates et de phosphonates

3. Specific rules:

a) Surfactant:

Surfactants which are not conform to the present organic certified cosmetic standard but can be used in cleaning products must follow the criterias below:

- Must be based on renewable resources
- Low aquatic toxicity (EC50 or IC50 or LC50 > 10 mg/l or equivalent test)
- Complete, easy and quick biodegradability (OECD 301 > 70% in 28 days) under aerobic and anaerobic conditions
- Ethoxylated surfactants based on renewable resources and which respect the above criterias can be accepted if their content stay under 50% of the total surfactant mass, if they are not ethoxylated more than 8 times and if they do not contaminate the natural and organic certified cosmetics

b) Other ingredients:

The others ingredients (not concerned by the above requirements) which are refused in certified cosmetics but may be used in cleaning products for facilities should meet the previously listed criterias or should not be subject to the following risky environmental phrases as described in CLP Regulation (Regulation (EC) N° 1272/2008 of the European Parliament and the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures): H400, H410, H411, H412, H413 (or risky phrases R50 to R59 regarding Directive 2001/59/EC).

B. Controlled cleaning products

Cleaning products controlled by Ecocert Greenlife (or admitted as equivalent by Ecocert Greenlife following a technical study) will be automatically accepted.



APPENDIX IV: List of additional technical sheets

Every modification of these lists must be validated by the Ecocert Greenlife Committees.

TS033 List of authorized and forbidden processes

TS034 Positive list of authorized synthetic ingredients and ingredients from mineral origin

TS035 List of ingredients authorized by exemption



LIST OF AUTHORIZED AND FORBIDDEN PROCESSES

Changes to this document are identified by a vertical line in the margin

This technical sheet lists all the physically and chemically processes authorized by Ecocert Greenlife standard for natural and organic cosmetics. It also specifies some forbidden processes.

If a process is not mentioned in this technical sheet, a technical file must be drawn up covering all the criteria described in the Appendix I for assessment by the Ecocert Greenlife Committees.

A. Authorized physical processes

| List |
|---|
| Absorption / Adsorption (on an inert support conforming to this standard) |
| Bleaching, deodorisation (on an inert support conforming to this standard) |
| Grinding |
| Centrifuging |
| Decanting |
| Degumming / De-oiling |
| Desiccation, drying |
| Deterpenation with water steam or a natural solvent |
| Distillation (solvents from natural origin: water, CO2...) |
| Extraction (solvents from natural origin: water, glycerin, natural ethanol...) |
| Filtration (on an inert support conforming to this standard) |
| Lyophilization |
| Blending |
| Percolation |
| Pressure |
| Sterilization by heat |
| Sterilization by gas (those authorized in Organic Agriculture: O ₂ , N ₂ , Ar, He, O ₃ and CO ₂ sc) |
| Sterilization UV, IR and micro-waves |
| Sifting |

B. Authorized chemical processes

| List |
|--|
| Alkylation |
| Calcination, Carbonization |
| Condensation / Addition |
| Complexation |
| Demethylation |
| Esterification / Transesterification / Interesterification |
| Etherification |
| Biotechnology / Natural fermentation |
| Formation of amide |
| Hydratation |

| |
|---|
| Hydrogenation |
| Hydrolysis |
| Neutralization |
| Oxydation / Reduction |
| Ozonolyze |
| Processes for the manufacture of amphoteric (formation of amide and quaternisation) |
| Saponification |
| Sulphatation |
| Roasting |

C. Forbidden processes (non exhaustive list)

| List |
|--|
| Bleaching on an animal support |
| Deodorisation on an animal support |
| Irradiation (ionizing rays: alpha, gamma) |
| Sulphonation (except for the auxiliaries) |
| Treatment using mercury (mercurial soda or potash) |
| Use of ethylene oxide |
| Use of formaldehyde |

POSITIVE LIST OF AUTHORIZED SYNTHETIC INGREDIENTS AND INGREDIENTS FROM MINERAL ORIGIN

Changes to this document are identified by a vertical line in the margin

This technical sheet lists all the synthetic ingredients and ingredients from mineral origin authorized by the Ecocert Greenlife standard for natural and organic cosmetics.

Table 1 : Synthetic ingredients

| Ingredient (INCI Name) | Function |
|----------------------------------|------------------|
| Benzoic acid and its salts | Preservative |
| Benzyl alcohol | Preservative |
| Dehydroacetic acid and its salts | Preservative |
| Salicylic acid and its salts | Preservative |
| Sorbic acid and its salts | Preservative |
| Tetrasodium glutamate diacetate | Chelating agent |
| Tertiary butyl alcohol (TBA) | Denaturing agent |
| Isopropyl alcohol | Denaturing agent |
| Denatonium benzoate | Denaturing agent |

Where required by law, the use of a denaturing agent not compliant with this standard will be studied.

Table 2 : Ingredients from mineral origin

Ingredients authorized for a specific use:

| Ingredient (INCI Name) | Function |
|--|--|
| Calcium Fluoride | Agent for product for the oral cavity hygiene |
| Mono-, Di-, Tri-calcium Phosphate | Abrasive agent / Agent for product for the oral cavity hygiene |
| Potassium Phosphate | Buffer agent |
| Sodium Fluoride | Agent for product for the oral cavity hygiene |
| Sodium Glycerophosphate | Only for make-up products |
| Sodium Monofluorophosphate | Agent for product for the oral cavity hygiene |
| Mono-, Di-, Tri-sodium Phosphate | Buffer agent |
| Trimanganese bis(orthophosphate), CI 77745 | Inorganic pigment / Colorant |
| Tetrasodium pyrophosphate | Only for peel-off masks |

Ingredients authorized for any use (Usual or INCI name):

| | |
|--------------------------------|--|
| Aluminium Hydroxide | Manganese Sulfate |
| Bismuth Oxychloride, CI 77163 | Ammonium Manganese Diphosphate, CI 77742 |
| Calcium Aluminium Borosilicate | Potassium alum |
| Calcium Carbonate, CI 77220 | Potassium Carbonate |
| Calcium Hydroxide | Potassium Chloride |
| Calcium Sodium Borosilicate | Potassium Hydroxide |
| Calcium Sulfate, CI 77231 | Potassium Sulfate |

| | |
|---|----------------------------|
| Chromium Oxides : CI 77289, 77288 | Silica |
| Copper Oxide | Silver, CI 77820 |
| Copper Sulfate / Cupric Sulfate | Silver Chloride |
| Diatomeaceous Earth | Silver copper zeolite |
| Ferric Ferrocyanide - Prussian blue, CI 77510 | Silver Oxide |
| Iron Hydroxide | Silver Sulfate |
| Iron Oxides : CI 77489, 77491, 77492, 77499 | Sodium Bicarbonate |
| Iron Sulfate | Sodium Borate |
| Lazurite (Ultramarine), CI 77007 | Sodium Carbonate |
| Magnesium Aluminium Silicate | Sodium Hydroxide (Soda) |
| Magnesium Carbonate - Magnesite, CI 77713 | Sodium Magnesium Silicate |
| Magnesium Chloride | Sodium Silicate |
| Magnesium Hydroxide | Sodium Sulfate |
| Magnesium Oxide, CI 77711 | Titanium Dioxide, CI 77891 |
| Magnesium Silicate | Zinc Oxide, CI 77947 |
| Magnesium Sulfate, Magnesium sulfate heptahydrate | Zinc Sulfate |

LIST OF INGREDIENTS AUTHORIZED BY EXEMPTION

Changes to this document are identified by a vertical line in the margin

Some ingredients for which there is no alternative complying with this standard are authorized by exemption.

This appendix will be reviewed according to the availability of alternatives complying with the standard, to the evolution of the legislation, and/or to new technical or scientific data.

Ingredients authorized only for specific use:

| Ingredient (INCI Name) | Function |
|---|---------------------------------|
| Lecithin (extraction with hexane) | Emollient / Emulsifying agent |
| Tocopherol (extraction with hexane) | Antioxydant |
| Carrageenan (extraction with methanol, isopropanol) | Viscosity agent / Gelling agent |
| Alkylbetaine | Amphoteric surfactant |

Ingredients containing synthetic moieties (amphoter and moieties with C3 maximum on an oily chain or a polymer from vegetal origin) authorized:

| Ingredient (INCI Name) |
|--|
| Alkylamphoacetate |
| Alkylamphodiacetate |
| Alkylglucosidecarboxylate |
| Dicaprylyl carbonate |
| Carboxy methyl cellulose / Cellulose gum |

Ingredients containing synthetic moieties (amphoter and moieties with C3 maximum on an oily chain or a polymer from vegetal origin) authorized until the 31st of December 2016 (non exhaustive list):

| Ingredient (INCI Name) |
|---|
| Alkylcarboxylate (other than Alkylglucosidecarboxylate) |
| Alkylcarbonate (other than Dicaprylyl carbonate) |
| Acylglycinate |
| Alkylsulfosuccinate |
| Alkylsulfoacetate |
| Tocopheryl acetate |
| Isopropyl ester |

Mother-of-pearl extracted from shells obtained by:

- reuse of co-products from fish farming
- naturally-dead shells collection

Chemical UV filters are not compliant with the principles of the standard and there is no existing alternative recognized other than mineral UV filters.

Therefore, the mineral ingredients **zinc oxide** (ZnO, INCI Zinc Oxide) and **titanium dioxide** (TiO₂, INCI Titanium Dioxide) are authorized independently of the size distribution of particles, under the two following conditions:

- for use as UV filter,
- in accordance with the criteria defined in the opinions into force of the scientific committee on consumer safety.

For any other function than UV filter, these ingredients are authorized only on condition that they have mainly a non-nanoparticulate size distribution.