

Bio&Natural Cosmetic Standards

1. Scope

The present standard is voluntary; the products covered by the standard are: body care products (skin and external parts) destined to improve the look as defined in Law 719/86 (and following modifications and integrations) like cosmetics, perfumes, soaps and others (as in Annex 1 L 719/86) that are produced with ingredients from natural origin and that contain indications referring to the natural origin and to the organic production process of the ingredients.

The present standard clarifies the definitions “natural ingredient” and “ingredient of natural origin” concerning cosmetic products. In order to be in line with the present standard, the origin of the ingredients and their characteristics should be controlled, in particular the production method adopted (i.e. from organic farming, spontaneous harvesting, physical extraction etc.).

2. Kinds of Organic and Natural Cosmetics

The present standard includes two categories of cosmetic products:

1) **Natural Cosmetic** in which the ingredients are “natural” and/or “of natural origin” (see following definition), excluding a derogation for a maximum of 5% of products of synthetic origin allowed (see Annex II);

2) **Bio & Natural Cosmetic**: the ingredients are of “natural origin” and the ingredients of agricultural origin or from spontaneous harvesting should be certified organic (on the basis of Official Regulations for Organic Farming such as EU regulation 843 /97 and followings, NOP, JAS or others included in IFOAM Regulations).

The Operator should respect all relevant laws and regulations relating to manufacturing, composition, grade, quality, quantity, product descriptions, labelling and other aspects with reference to national and European legislation (Directive 76/768/CEE of 27 July 1976, Law n. 713 of 11/10/1986 and following modifications and integrations), and industry codes of good practice (GMP).

Some chemical processes are allowed, but they should guarantee minimum pollution of the environment and safety for the consumer.

The active and functional ingredients are processed using physical processes (see following pages). The entire chain should be controlled and guaranteed by the operator.

3. Characteristics and definitions of “Natural Ingredients” and “Ingredients of Natural Origin”

“Natural ingredients” or “raw materials” are: vegetal, animal (see restrictions in the following pages) or mineral product coming from agricultural production, harvest or extraction, not processed or handled only by physical processes. The water added is allowed but it is not included in the percentage calculation of the ingredients (the calculation is done considering all the ingredients except water).

“Ingredient of natural origin” are: vegetal, animal or mineral products (see restrictions), processed by chemical processes allowed (see Positive List).

“Ingredients from bio technologies” are: vegetal, animal, micro-organic preparations obtained by micro-organisms fermentation, in Vitro cells or cells and clones cultivations, without neither the use of genetically modified organisms nor processes that are not allowed by this standard.

4. Composition and Percentages

- 1) **“Natural Cosmetic”**: it is composed by ingredients of “Natural Origin” or by “Natural Ingredients”, on the basis of the definitions written above; a maximum of 5% of ingredients of synthetic origin is allowed; this derogation regards only chemical substances that are included in the list of the allowed additives. In the

finished product the ingredients should be natural, processed only by physical means, and minimum 15% on the total ingredients (minimum 20% for Conformity to Natrue and Cosmos standards), and of natural origin. Natural plus natural origin ingredients, excluded water, should reach 95% in weight. In this case the product can be labelled as "NATURAL COSMETIC (with Natural Cosmetic trademark, Agricert control).

- 2) **"Bio & Natural Cosmetic"**: it is composed by ingredients of natural origin, agricultural production or spontaneous harvesting ingredients, but also certified as "organic"; a maximum of 5% of synthetic ingredients is allowed (this derogation regards only chemical substances that are included in the list of the allowed additives). The 95% Natural ingredients, from botanic, agriculture or natural harvesting should be certified on the basis of the Official Regulations for Organic Farming such as EU regulation 843 /07 and followings, NOP, JAS or others included in IFOAM Regulations, directly or after processing; under derogation the 5% of the ingredients can be not organic. On the total ingredients in weight, minimum the 15% must be certified organic. In this case the product can be labelled as Bio&Natural Cosmetic (with Bio&Natural Cosmetic Logo).

It is allowed up to a minimum of 70% of organic ingredients on the total of ingredients that can be certified as "organic", but in this case, the percentage of such organic ingredients must be specified on the label; in order to use the Logo, on the total ingredients in weight, minimum 10% should be organic. The percentage of ingredients from farming or spontaneous harvesting, allowed under derogation as not organic, is calculated in this category of ingredients. Water is excluded from calculation. The weight of vegetal/plant extracts is calculated using the proportion of plant used to make the extract.

5. Raw Materials and ingredients

Raw materials are the substances used for the production of the ingredients that are used for the production of the finished cosmetic.

Ingredients are the products that are used for the production of the finished cosmetic.

The main active ingredients are obtained from vegetal raw materials or raw materials of vegetal origin. 95% of all ingredients should come from agricultural raw materials or raw materials from spontaneous harvesting and the active and functional ingredients should be certified "organic" in the case of "Bio&Natural Cosmetic" or they should be "natural" in line with the present norm, this means processed only by physical processes, in case of "Natural Cosmetic". The use of additives that are not mentioned in the present standard is prohibited.

5.1 Extraction: physical processes

It is the extraction of molecules with bio-active properties, with minimal interference.

It is requested to identify these molecules and to define the standards for their identification and to provide the extraction ratio.

Solvents allowed (in case of "Bio&Natural Cosmetic" Certification):

- a) Organic alcohol.
- b) Organic glycerine.
- c) Organic oils.
- d) Purified water.
- e) Organic honey.
- f) Organic sugar.
- g) Organic vinegar.
- h) Organic lactose.

i) Other solvents certified organic.

Liquid CO₂ for extraction with supercritical fluid [liquid CO₂, supercritical fluid extraction (SCFE)]. In case of "Natural Cosmetic" certification, such solvents can be not organic.

5.2 Extraction methods

- a) Maceration.
- b) Juicing.
- c) Solar extraction.
- d) Cold extraction.
- e) Pressing.
- f) Vacuum.
- g) Decoction (hot or cold).
- h) Infusions (hot or cold).
- i) Microbial digestion/fermentation.
- j) Other physical processes allowed (see paragraph 7).

5.3 Restrictions

Solvents:

- a) Glycerine (from vegetable origin not organic - where organic is not available).

5.4 Post extraction

- a) Rectification.
- b) Post Packaging sterilisation.
- c) Pasteurisation.
- d) Preservatives and anti oxidant allowed. The justification can be demonstrated with the necessity of stability of the finished product.

5.5 Prohibited

Solvents:

- a) Mineral oils.
- b) Benzene.
- c) Hexane.
- d) Propylene glycol.
- e) Butylene glycol.
- f) Use of other solvents that are non organic and not allowed (for Bio&Natural Cosmetic).
- g) Animal non organic Glycerine (for Bio&Natural Cosmetic).
- h) Solvents coming from petrol.

Post extraction:

- a) Aroma enhancers.
- b) Ionising radiation.
- c) Irradiations with electrons.

5.6 Mineral Ingredients

It is allowed the use of inorganic salts and mineral ingredients as:

magnesium sulphate , sodium chloride etc., excluded the exceptions (see Annex II).

Mined minerals:

- ✓ Montmorillonite and kaolin clays.
- ✓ Limestone.
- ✓ Sand.
- ✓ Salt.
- ✓ Pumice.

If used as a whole and unmodified: washing, ultra heat treatment, mechanical cleaning, drying methods are allowed.

- ✓ Other ingredient of mineral origin as in the Annex II.

5.7 Ingredients of Sea Origin

Ingredients of Sea Origin are allowed as Carrageenan, Algine, Potassium Arginate etc. (see Annex II).

5.7.1 Ingredients of Animal origin

The parts of animal body or the organs are not allowed. The use of products from animal vertebrates origin (as for example animal fats, animal fresh cells turtle oil, mink oil, marmot oil, animal collagen, spermaceti) is not allowed. Ingredient derived from animal productions as lactose, lanoline, beeswax etc. are allowed (see Annex II).

5.7.2 Animal Testing

Testing on animals in the production or in the product development is forbidden.

5.8 Water

Purified water is allowed (water deionised through ionic exchange resins or through inverse osmosis) and it is excluded from the percentage calculation of the ingredients.

5.9 Surfactant & Emulsifiers

Surfactant are detergents, emulsifiers, dispersant, solubilizers and wetting agents. Detergents are used for skin and hair-cleaning and as emulsifiers in cosmetics.

Raw materials origin: it should be natural. Petrochemical products can be used only as reagents. Mined minerals can be also used.

The ingredients for natural cosmetics used as emulsifying agents and surfactants may be used if they come from the following allowed raw materials of origin:

- ✓ Fats,
- ✓ oils and waxes,
- ✓ lecithin,
- ✓ lanolin,
- ✓ monosaccharide.

Other allowed substances are:

- ✓ Oligosaccharides and polysaccharides,
- ✓ proteins and lipoproteins.

For the manipulation of raw materials, the processes allowed must be used (see following pages).

6. Finished Ingredients

Other characteristics that are considered relate to: toxicity, biodegradability, biocompatibility. These aspects are considered for the choice of raw materials of natural origin and for the related processing processes allowed. See Annex III for specific parameters.

EXAMPLES	
Ingredient category	Examples
a) Soaps:	Sodium Palm Kernalate Sodium Olivete (organic origin only)
b) Glyceryl Esters of Fatty Acids	
c) Alkylglucosides	
e) Alkylbetaines	Coco Betaine Lauryl Betaine
g) Fatty Acids & Alcohols:	Cetyl Alcohol

Specify the activity level of the surfactants (i.e. 25% active in 75% water).

Viscosity exalter:

Additives as in Annex VI Reg. CEE 2092/91; plant rubbers.

Anti-oxidants:

Plant derived anti-oxidants. Ascorbic acid, tocopherol and other as in EU Reg. CEE 889/2008 Annex VIII.

Fragrances and colour components must be organic or of natural origin.

7. Allowed processing processes

Principles

Minimise environmental impact and value bio compatibility, saving functionality.

Recommendations

Physical, mechanical, thermal and biological processing (Fermentation, use of micro-organisms non GMO).

Allowed

Traditional saponification of organic raw materials using sodium hydroxide or potassium hydroxide.

Chemical processing of raw materials to produce functional ingredients using petrochemical and synthetic products only as reagents.

7.1 Allowed physical processes

- ✓ ABSORPTION (on an inert support, conform to the Standards),
- ✓ BLEACHING - DEODORISATION (on an inert support conform to these Standards),
- ✓ CENTRIFUGING (Solid / liquid separation (spin-drying)),
- ✓ SETTLING AND DECANTING,
- ✓ DESICCATION - DRYING (Progressive or not by evaporation / natural under sun),
- ✓ DETERPENATION (if fractionated distillation with steam),
- ✓ DISTILLATION or EXTRACTION (steam),
- ✓ EXPRESSION,

- ✓ EXTRACTIONS (with any forms of water or with a third allowed solvent: ethyl alcohol-organic glycerine-organic oils -CO₂),
- ✓ FILTRATION and PURIFICATION (ultra filtration, dialysis, electrolysis),
- ✓ LYOPHILIZATION,
- ✓ BLENDING,
- ✓ PERCOLATION,
- ✓ COLD PRESSURE,
- ✓ HOT PRESSURE (depends on the fluidity of the fatty acids to be extracted),
- ✓ STERILIZATION WITH THERMAL TREATMENTS (according to a temperature respectful of the active substances),
- ✓ SIFTING.

7.2 Allowed chemical processes

- ✓ ALKYLATION,
- ✓ AMIDATION and CALCINATION of plants residues,
- ✓ CARBONIZATION (resins, fatty organic oils),
- ✓ CONDENSATION / ADDITION,
- ✓ ESTERIFICATION AND TRANS-ESTERIFICATION,
- ✓ ETHERIFICATION,
- ✓ FERMENTATION (natural / biotechnological),
- ✓ HYDRATATION,
- ✓ HYDROGENATION,
- ✓ HYDROLYSIS,
- ✓ NEUTRALIZATION (to obtain Na, Ca, Mg, K salts),
- ✓ OXYDIZATION / REDUCTION,
- ✓ PROCESSES FOR THE MANUFACTURE OF AMPHOTERICs,
- ✓ SAPONIFICATION,
- ✓ STARCHING,
- ✓ QUATERNIZATION,
- ✓ SULPHATION¹,
- ✓ ROASTING/ TORREFACTION.

8. Preservatives & Preservation methods

The following preserving processes are allowed: air drying, natural air or artificial air, freezing/quick freezing, nitrogen flushing, modified atmosphere for packaging. All other preservation methods, if physical based, could be valued if a request with a complete dossier is presented.

Natural preservation systems and natural preservatives are recommended when possible.

The following preservatives/ anti microbial agents are allowed (conforming also to Natrue):

- ✓ **Benzoic acid**
- ✓ **Sorbic acid** (they occur in nature), their salts and ethyl esters
- ✓ **Salicylic acid** and its salts
- ✓ **Benzyl alcohol**
- ✓ **Formic acid** and its sodium salt
- ✓ **Propionic acid** and its salts

¹ In particular for products for detergency. See paragraph 9 of the present Standard.

- ✓ Ascorbic acid and its salts
- ✓ Dehydroacetic acid and its salts (conforming only to Cosmos)

8.1 Restrictions

The following preservatives can be used with the ingredients. They should not exceed 0.5 % (weight), in the finished product (Conforming only to Soil Association).

- ✓ Phenoxy-2-ethanol
- ✓ Lactoperoxidase.
- ✓ Phenylethyl Alcohol

OTHER STANDARDS COMPARATION

<u>NATRUE</u>	<u>COSMOS</u>	<u>SOIL ASSOCIATION</u>
Benzoic acid	Benzoic acid and its salts	Benzoic acid and its salts
Benzyl alcohol	Benzyl alcohol	Benzyl alcohol
Formic acid		
Propionic acid		
Salicylic acid and its salts	Salicylic acid and its salts	
Sorbic acid and its salts	Sorbic acid and its salts	Sorbic acid and its salts
	Dehydroacetic acid and its salts	Dehydroacetic acid Sodium dehydro acetate
	Denatonium Benzoate Denaturing agent for alcohol	Agricultural raw materials or extracts
		Phenoxyethanol Lactoperoxidase Phenylethyl alcohol

8.2 Other synthetic additives allowed

On the total ingredients in weight, maximum 5% of few additives are allowed on the basis of proved safety and simple composition (ex. Salification, see Annex II).

8.3 Prohibited

- ✓ Sterilisation of natural ingredients and of their finished cosmetic products through radioactive treatment or irradiation is not allowed.
- ✓ Petrochemicals and synthetic substances as ingredients.
- ✓ Non-organic products of animal origin (for Bio& Natural Cosmetic)
- ✓ Talc.
- ✓ Fragrances and colour components of synthetic origin.
- ✓ All other anti-microbial agents not listed
- ✓ Chelating agents based on EDTA and its salts.
- ✓ Fats of petrochemical origin.
- ✓ All other ingredient or additives above not indicated as allowed or belonging to a list of allowed categories.

8.4 Prohibited Processes

All the processes above not indicated as allowed; for example: sulphonation, ethoxylation and propoxylation (PEG and others), irradiation, treatments with ethylene oxide, mercury and with genetic manipulation techniques (dioxane is present in ethoxylates).

8.5 Surfactants Prohibited

Examples (detergents/emulsifiers) prohibited processes:

Ingredient category	Examples
a) Alkyl Sulphates:	Sodium Lauryl Sulphate Sodium Coco Sulphate Ammonium Lauryl Sulphate
b) Alkyl Ether Sulphates:	Sodium Laureth Sulphate Ammonium Laureth Sulphate
c) Polysorbates:	Polysorbate 20
d) Ethanolamides:	Cocamide DEA Cocamide MEA

8.6 Prohibited Ingredients

- ✓ Authorised ingredient but treated with forbidden processes
- ✓ Synthetic fragrances
[The criteria for allowed fragrances are in the ISO Norm 9235]
- ✓ Synthetic colouring agents
- ✓ Ethoxylated ingredients
- ✓ Silicones
- ✓ Products coming from petrol and paraffin

9. Detergency Products

Detergency products such as: soaps for dish-washing, for floors or other surfaces, bathroom and for cloth follow the present Standard.

For Detergency Products please refer to Natural Cosmetic Norms plus point 1 of Annex III.

For the use of particular adjuvant, ingredients, raw materials used in order to give peculiar functionalities, specific authorizations can be requested applying the criteria described in Annex I, II and in particular in Annex III.

10. Certification Procedures

See annex I.

11. Labelling

11.1 Principles

Labelling should be clear, accurate and should satisfy all the law requirements. Ingredient should be indicated in INCI, (INCI – International Nomenclature of Cosmetic Ingredients) following a decreasing % order.

“Bio&Natural Cosmetic”

Labelling should comply with the labelling regulations for organic products, in case of Bio&Natural Cosmetic.

- 1) not less than 95% of ingredients from agricultural or spontaneous harvesting raw materials are allowed. They should also be certified organic and natural in line with the present Standard and/or certified in line with the official standards for organic farming (suitable ingredients for food use such as oils or pure vegetal extracts). Water is excluded. Such percentage is calculated on the basis of ingredients classifiable as “natural” (in other words the ones from farming or spontaneous harvesting). The % will be calculated on the ‘finished product’. Water is excluded from the % calculation.
- 2) It is used X% of organic ingredients, certified as above described, with a minimum of 70% of ingredients as in point 1) produced in line with the norms for organic farming.

Label should also indicate:

- a) Ingredients classification in descending order on the basis of weight
- b) Rates between vegetal elements/ solvents of each extracted material
- c) Percentage of organic content for each functional ingredient
- d) Processing Adjuvant
- e) Sell before/ Best before (write dates)
- f) A writing that clarifies that “Organic” refers to the farming production methods of ingredients
- g) All the writings and indications foreseen by the law

11.3 “Natural Cosmetic”

The product can be certified as “Natural Cosmetic” and have the trademark “Natural Cosmetic” Agricert Control, when in the finished product the 95% of ingredients are natural or of natural origin as defined by the present norm. The 5% of derogation concerns only the chemical substances included in the list of the allowed additives. It should also contain the writings indicated above, except point c).

12. Environment Health

Production methods should respect environment as much as possible; packaging should be biodegradable, recyclable and nature- friendly.

13. Social Responsibility

Ingredients from fair trade and third world projects are recommended and also from Companies that work in the Social Account Ability.

14. Logo