



# CERTIFICATION GUIDELINES FOR ORGANIC AND NATURAL HEALTH & BEAUTY PRODUCTS, AND FOR ORGANIC & NATURAL INGREDIENTS

5<sup>th</sup> Edition - 2014

IBD Certificações

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#### INDEX

1. INTRODUCTION	2
2. SCOPE	2
3. LEGISLATION	3
4. PRINCIPLES AND OBJECTIVES	3
5. ANIMAL PROTECTION AND TESTS ON ANIMALS	3
6. PROCESSES TO OBTAIN INGREDIENTS	3
7. PROHIBITED INGREDIENTS	7
8. PRODUCTION	8
9. PRODUCT CLASSIFICATION	9
10. LABELLING	.11
11. PACKAGING REQUIREMENTS	.13
12. CERTIFICATION STEP-BY-STEP	.13
ANNEX I - GLOSSARY	.15
ANNEX II- REQUIREMENTS TO BE MEET BY THE "NATURAL COSMETICS", "NATURAL COSMETICS WITH ORGANIC PORTION" AND "ORGANIC COSMETICS" CATEGORIES	.18
ANNEX III - SOME IBD PERMITTED MATERIALS USED IN NATURAL AND ORGANIC CERTIFIED COSMETIC PRODUCTION	.21
ANNEX IV - ORGANIC PORTION OF DERIVED NATURAL SUBSTANCES IF THEY HAVE BEEN PROCESSED FROM ORGANIC RAW MATERIALS	29
ANNEX V - EXAMPLES FOR THE CALCULATION OF THE NATURAL (ORGANIC) PORTION OF PLANT EXTRACTS AND HYDROLATES / FLORAL WATERS	.29

#### 1. INTRODUCTION

These guidelines have been developed by IBD Certifications as an answer to the increasing demand for organic or natural health and beauty products, certified in accordance with the internationally known and accepted system of certification by a third party, that is, an independent certification body.

This 5<sup>th</sup> Edition has been worked as to attend the alignment and harmonization agreement with NATRUE for standards and certification and has been approved by both IBD and NATRUE. IBD is thankful for this agreement and alignment.

IBD-Certifications mission is to apply these guidelines to inspection and certification within the specified procedures under ISO 65.

As there are no rules, laws, national or international guidelines for organic certification regulations established and recognized worldwide for beauty products, these guidelines should be seen as a document that will be continually improved and adapted to national and international realities, so transparent and accessible to all interested parties.

With the entry into force in Brazil's Law 10.831 and Decree 6,323 and Regulatory Instructions relating to this law, these standards have been adapted to meet the criteria of minimum concentration of organic ingredients in the ratings "ORGANIC" and "MADE WITH ORGANIC INGREDIENTS."

Until the national authority edits any regulation, these rules will be in this format. For now the policy of IBD is to promote the certification of organic cosmetics, mainly for export. For the domestic market, IBD policy is to promote the certification of NATURAL cosmetics offering the label "NATURAL INGREDIENTS" IBD to the market.

#### 2. SCOPE

These guidelines include certification for organic, natural and wild harvest ingredients, as well as certification rules for cosmetics and personal hygiene products destined to the final consumer.

This norm is compatible to any international norm for body health and beauty products. In case the certification is for raw matter or final product for a specific international market, it is recommended to consult IBD for verification and product adaptation for that market.

#### 3. LEGISLATION

Certified producers shall be in compliance and up to date with the current national laws, for health and beauty products. Whenever the object of certification is the cosmetic for the final consumer, IBD will only certify companies that are legally constituted and authorized by ANVISA.

For ingredients/ingredients, IBD will only certify companies that are legally constituted and have valid licenses issued by competent authorities regarding extraction and/or production of the respective ingredients.

#### 4. PRINCIPLES AND OBJECTIVES

In order to be certified by IBD, cosmetics must have the following characteristics:

- a) A composition with as much organic and natural ingredients as possible.
- b) To preserve as much as possible the original qualities of the ingredients, avoiding modifying the ingredients from their natural state.
- c) Their production, use and disposal shall cause the smallest possible environmental impact.
- d) To reach high quality and to be clearly labelled for consumer orientation.
- e) Not tested on animals.
- f) Harmless for human beings.

#### 5. ANIMAL PROTECTION AND TESTS ON ANIMALS

- a) Testing on animals is forbidden, either for the ingredients that will compose the formulation of the finished product as for the finished product that will be offered to the consumer.
- b) The use of ingredients obtained from vertebrate animals is not allowed if those animals have been sacrificed for the extraction of such materials.
- c) The use of ingredients originated from animals will only be allowed when those come from the collection from living beings, as in the cases of honey and derivate products, milk and derivate products, lanoline etc., and as long as the animals are managed in organic production systems.
- d) The use of genetically modified animals is not allowed.

#### 6. PROCESSES TO OBTAIN INGREDIENTS

Processes for obtaining and purifying the ingredients for organic and natural ingredients will:

6.1. <u>Natural Substances:</u> Not cause any alteration to the natural component: when ingredients are extracted and purified in a way they are not contaminated by non-allowed

chemicals. Substances obtained this way can be considered organic depending on their source – organic agriculture or certified wild harvest, which are the desirable methods for production and purification of ingredients destined to the formulations of organic and natural cosmetics.

6.2. <u>Nature-identical</u>: 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 of Annex 2\_4\_EN.

6.3. <u>Derived from Natural:</u> Cause some alteration to the natural component: when ingredients have their natural structure modified without being completely disqualified as natural products. Those are considered as derived from natural products and can be used in formulations of organic or natural cosmetics. However, depending on the alteration performed to the ingredient, it cannot be considered organic or natural.

6.4. <u>Prohibited Substances</u>: this occurs when the ingredients are obtained from non natural chemical products or from non allowed alterations of a natural substance so that this substance is disqualified for the use in organic or natural products.

- 6.1. <u>Natural Substances:</u> Processes that do not cause any alteration to the natural component
  - a) Extraction processes using cold, pressure, water or steam distillation, percolation and/or concentration through physical and mechanical methods are allowed for obtaining ingredients.
  - b) Processes using extraction solvents such as plant and animal oils, alcohol, vinegar and glycerine are also allowed, as long as the extractors are obtained organically. The use of those products in conventional form will only be allowed when it is verified that the organic form is not available.
  - c) Processes that use water, CO<sup>2</sup> and Nitrogen are also allowed.
  - d) Generally, the methods for extraction may not alter the qualitative composition of the ingredient, produce residues that are toxic for the environment or use any non-allowed synthetic resources or extractors in intermediary steps of extraction. The following is a list of some categories of ingredients for cosmetics which are obtained by extraction methods.
    - i. Vegetal fats: triglycerides (fatty esters formed by alcohol, glycerine and three vegetal fatty acids) extracted from plants rich in triglycerides formed mainly by saturated fatty acids.
    - ii. Vegetal oils: triglycerides extracted from plants rich in triglycerides formed mainly by unsaturated fatty acids.
    - iii. Lanoline: purified ingredient from sheep wool, containing cholesterol, alcohols and fatty esters. A sub-product of the raw sheep wool cleaning process. Though this ingredient is derived from animals, its obtaining does not require their sacrifice.
    - iv. Natural colour agents <u>Nature Identical</u>: soluble organic substances added to the finished product with the purpose of enhancing its appearance and meeting the consumers' requirements, having an attractive effect.

- v. Natural pigments <u>Nature Identical</u>: colouring substances which are not soluble in the medium they are applied to. Like the colouring agents, pigments have the purpose of enhancing the product's appearance and meeting the consumers' requirements, having an attractive effect
- vi. Essential oils: aromatic volatile organic compounds produced by various plants and found in different plant parts. Extracted by effleurage (oil based extraction), water vapour, solvents, pressing and carbon dioxide.
- vii. Plant extracts (glycolic, dry and tinctures): substances extracted from various plant parts by maceration, percolation, liofilization, among other methods.
- viii. For rehydrated extracts, the organic concentration will be considered the one for which occurred concentration, for example from 100 to 20%. The addition of water is not permitted to continue classifying organic extracts at 100%. In this case the organic concentration is 20%.
- 2. Minerals <u>Nature Identical</u>: extracted and purified from natural sources legalized for prospection activities.
- 3. Natural polymers: some polymers can be obtained from natural sources such as xanthan gum, alginates and starches.
- 6.1.2 Fermentation: biochemical process of transforming one substance in another using the action of specific microorganisms (bacteria or fungi) and nutrients. Fermentation can occur in an aerobic or anaerobic medium, and many cosmetic ingredients can be obtained as a result of this process

# <u>6.3</u> <u>Derived from Natural</u> : Processes that cause some alteration to the natural component

 a) Hydrolysis: defines chemical reactions that involve the participation of water. Hydrolysis reactions can start from the contact of a chemical compound with water, or from water solutions in the presence of an alkali or acid, or enzymes. Ingredients obtained by hydrolysis are allowed for organic and natural certified formulations.

- Protein hydrolysis: the hydrolysis of these macromolecules allows the obtaining of amino acids or peptides for use in various cosmetic formulations.

- Polysaccharide hydrolysis: the hydrolysis of these macromolecules allows the obtaining of sugars or oligosaccharides for use in cosmetics.

b) Hydrogenation: the process of hydrogenation consists of transforming an organic unsaturated compound into a saturated compound, by the addition of Hydrogen. In the case of natural products, it is common to perform hydrogenation on plant oils formed by triglycerides rich in unsaturated or poli-unsaturated fatty acids. Hydrogenation enhances the stability of the plant oil, modifies its texture and elevates its melting point. The hydrogenation process occurs in the presence of

hydrogen and catalysts, and the natural product suffers modifications in its structure, exchanging unsaturated for saturated connections, and therefore showing slight alterations from its natural chemical characteristics. The vegetal butters obtained from oils are typical examples of hydrogenated cosmetic ingredients.

- c) Esterification: the process of esterification consists of a condensation reaction between an alcohol and an organic or inorganic acid. In this process, one hydroxyl radical of the acid is substituted by an alcoxyl group supplied by the alcohol, with a loss of water. Alcohols and natural organic acids are commonly esterified resulting in various derivates used in cosmetic formulations. However, though the ingredients used to obtain the ester can be natural, the final product was originated from slight changes to those, and in the presence of a catalyst.
- **d**) Saponification: consists of the reaction between a natural fatty acid or triglyceride with an alkali forming an anionic surfactant (soap). If the fatty acid or the triglycerides are not from animal origin and the alkali is allowed for organic and natural products, the ingredient resulting from this process will be allowed for organic and natural products.
- e) Sulfatation: process by which sulfonic acid (-SO4H) is introduced into an organic molecule forming a sulfuric ester or an acid sulfate which can be afterwards neutralized.
- **f)** Transesterification: consists of a reaction in which a triglyceride, a fatty tri-ester, reacts with another alcohol in the presence of a catalyst, transforming into a new ester with different physical properties: one ester is transformed into another. This process is authorized, depending on the catalyst and the ingredients (natural or organic).

Obs: if the respective plants and animals have been produced organically or come from certified wild crop collection and the extraction is performed with allowed methods, the final ingredient is classified as "organic" or "made with organic ingredients". Otherwise it will be classified as natural ingredient.

- 6.2. Prohibited processes
  - a) Ethoxilation: process to obtain ingredients in which ethylene oxide molecules are introduced into compounds that have active Hydrogen atoms; reaction of addition or ethoxilation. The ethylene oxide as such is a highly toxic gas, easily burning and explosive, besides being carcinogenic, mutagenic and neurotoxic.
  - **b**) Sulfonation: process by which a sulfonic acid (-SO3H) or sulfonyl halide (-SO2X) is introduced directly into a molecule of Carbon or Nitrogen.
  - c) Phophatation: chemical reaction to obtain phosphoric esters from Phosphor oxide.
  - **d**) Proposilation: method of obtaining ingredients by introducing one or several molecules of propylene oxide into an organic molecule. The propylene oxide

as such is highly toxic, easily burning, besides being carcinogenic and mutagenic.

- e) Polymerization: consists of the formation of polymers by the union of equal or different monomers. This process of obtaining cosmetic ingredients is not allowed.
- f) <u>Alquilation: consists of processes in which an alquil group is introduced into another chemical compound, by substitution or addition, with the help of a catalyst. Alquilation can be used to form ester, ether and amide. This process is allowed, provided the two ingredients added are from natural origin.</u>

#### 7. PROHIBITED INGREDIENTS

- **a)** Synthetic colouring agents: colouring agents obtained by chemical synthesis and therefore not allowed in organic and natural formulations. Besides, some synthetic colouring agents can potentially be mutagenic, cause allergy problems and itching.
- **b**) Synthetic fragrances: obtained by the mixture of synthetic aromas or the association of such with essential oils, and therefore not allowed.
- c) Polyethylene glycol (PEGs): obtained by the polymerization of the propylene oxide and by the co-polymerization of the propylene and ethylene oxides. Therefore, no PEG can be used in organic and natural formulations, as well as ingredients derived from PEGs.
- **d**) Quaternary Ammonium: obtained by the complete alquilation of ammonia or other amines. If the amines are not natural, despite the process being allowed, the final product will not be accepted as organic or natural.
- e) Silicones: the name silicone refers to several different compounds formed by a nucleus of Silicon combined with Oxygen (-Si-O-Si-). Those are produced from sand. Though sand is a natural product, the different types of silicones are obtained by the chemical manipulation of this material, changing completely the basic ingredient. Any kind of silicone is prohibited in natural and organic products.
- **f**) Preservatives: all synthetic preservatives are prohibited for organic or natural formulations. For this kind of formulation, the preservatives used must be natural or food grade. The sterilization methods using radiation are prohibited for ingredients and for finished products.
- **g**) Diethanolamides: formulation components obtained from the condensation of babaçu or coconut fatty acid with a synthetic diethanolamide.
- **h**) Derivates of petrol: any ingredient derivate from petrol or elaborated of product derivate from petrol can not be used in organic or natural cosmetic formulations. Therefore, the following cannot be used: petrolatum, mineral oil, liquid Vaseline or paraffin.

Observation: these standards give priority to what organic agriculture worldwide was able to provide, which is the use of substances derived from life in recent geological processes, meaning derived from living processes, thus excluding the petrol derivates and those of chemical synthesis that are incorporated to the molecular structures of the ingredients. From the evolutionary point of view, the human being is not adapted to consuming petrol derivates and synthesis substances and it is not desirable for the human health to incorporate such into the consumption chain due to the risk of direct and indirect side effects to the organism and the environment.

i) Final products and/or ingredients must not contain or derive from GMOs.

#### 8. PRODUCTION

- a) Companies that produce organic and/or natural cosmetics formulations must be legalized by Agência Nacional de Vigilância Sanitária (ANVISA) and comply with the current legislation for cosmetics.
- b) IBD certified producers must take measures to prevent commingling of organic or natural ingredients and cosmetic products with conventional ones during production, transport and storage.
- c) The cleaning and sanitary measures must be described and recorded, and care measures must be taken to prevent the contamination of the equipment with cleaning products before an organic or natural processing.
- d) The measures for pest control must comply with the current legislation in order not to contaminate the organic and/or natural products.

## 9. PRODUCT CLASSIFICATION

#### 9.1. Natural

For multi ingredient products: A cosmetic can be classified as natural and be certified as such if its formulation contains a formulation composed by water and non-certified natural ingredients or ingredients allowed for natural formulations.

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

- a) <u>Vegetable juices: 100 % as natural substance</u>
- b) <u>Concentrated vegetable juices: only the 100 % concentrate (as a natural substance) but not the water used for dilution</u>
- c) <u>Aqueous extracts: only the plant portion</u>
- d) <u>Hydroalcoholic extracts: the plant and alcoholic portions (if this is a natural substance).</u>

9.1.1. For raw metrial: A raw material/ingredient can only be classified as natural and receive such certification if it is as described above, if the reaction for obtaining the product is authorized in item 6 and if the conservant used is authorized in the IBD Materials List. 9.1.2. Please check ANNEX II, Table 1 for formulation detail.

9.2. Natural cosmetics with an organic portion.

For multi ingredient products: <u>The product must contain (referred to the whole formulation) at least 15 % of chemically unmodified natural substances and maximum 15 % of derived natural substances.</u>

Additional requirements:

- At least 70 % of the natural substances of plant and animal origin and of derived natural substances (if applicable and as per § B2.2.) contained in the product must come from controlled organic farming and/or from controlled wild collection in line with the criteria laid down in the EC ecoregulations [Regulation (EC) No 834/2007, former (until 31 December 2008) Regulation (EEC) No 2092/91] or in the USDA National Organic Program (NOP) or BR 10.831.
- 2) In case derived natural substances contained in the product have been produced out of controlled organic starting material, the organic amount as defined in Annex 4 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.

9.2.1. For raw material: A raw material/ingredient can only be classified as made with organic ingredients and receive such certification if it is as described above, if the reaction for

obtaining the product is authorized in item 6 and if the conservant used is authorized in the IBD Materials List.

9.2.2. Please check ANNEX II- 2 for formulation detail.

\* Examples for the calculation of plant extracts & hydrolates/floral waters are given in Annex 5.

# For soaps: natural <u>and</u> derived natural part to be added.

#### 9.3. Organic

For multi ingredient products: <u>Over and above the basic requirements laid down under 2.</u>, the following additional requirements have to be met: The product must contain (referred to the whole formulation) at least 20 % of chemically unmodified natural substances and maximum 15 % of derived natural substances.

Additional requirements:

- At least 95 % of the natural substances of plant and animal origin and of derived natural substances contained in the product must come from controlled organic farming and/or from controlled wild collection in line with the criteria laid down in the EC eco-regulations [Regulation (EC) No 834/2007, former (until 31 December 2008) Regulation (EEC) No 2092/91] or in the USDA National Organic Program (NOP) or BR 10.831.
- 2) In case derived natural substances contained in the product have been produced out of controlled organic starting material, the organic amount as defined in Annex 4 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.

9.3.1. For raw material: A raw material/ingredient can only be classified as organic and receive such certification if it is as described above, if the reaction for obtaining the product is authorized in item 6 and if the conservant used is authorized in the IBD Materials List. 9.3.2. <u>Please check ANNEX II- 3 for formulation detail.</u>

\* Examples for the calculation of plant extracts & hydrolates/floral waters are given in Annex 5.

# For soaps: natural and derived natural part to be added.

#### 10. LABELLING

The labelling of natural or organic cosmetics or cosmetics made with organic ingredients must follow, in the first place, the Rules for Labelling and Classification of Cosmetics established by the Resolution (RDC) 211 of July 14, 2005.

The product can receive a specific label emphasizing its classification as "natural", "organic" or "made with organic ingredients". Independently of the classification, all labels must specify the total percentages of organic and natural ingredients.

10.1. Natural Product

Natural cosmetics labels shall highlight those ingredients which are natural and/ or organic and/or from certified wild crop harvest. The label can indicate that the product contains natural and/or organic ingredients.

The label can display the "IBD Natural Ingredients" seal associated to the project's number, and the indication "natural ingredients", but never the "IBD Organic" seal.

The back of the label or package must display the following sentence: "IBD certifies natural cosmetics according to international standards".

The main panel of the labels of ingredients shall display the sentence: "IBD - Natural ingredient appropriate for use in organic or natural certified products".



Project xxx IBD certifies natural cosmetics according to international standards

#### 10.2. <u>Natural cosmetics with an organic portion</u>

Cosmetics made with organic ingredients shall discriminate the organic ingredients on their labels and can use the "IBD Organic" seal, as below:



Project xxx Natural cosmetics with an organic portion

The back of the label or package must display the following sentence:





Project xxx IBD certifies <u>natural cosmetics with an organic portion</u> according to international standards.

#### 10.3. Organic

Organic cosmetics labels shall highlight the organic ingredients and can use the "IBD Organic" seal.

The back of the label or package must display the following sentence next to the "IBD Organic" seal:



Project xxx IBD certifies organic products according to international standards.

Organic ingredients shall display the following sentence on the main panel:



Project xxx IBD certifies organic products according to international standards.

#### 10.4. Organic with "IFOAM ACCREDITED"

In order to be labelled with "IBD Organic" and "IFOAM ACCREDITED" seals, a product must use only additives approved by IFOAM Standards. In this case, labelling will follow the same criteria stipulated for the use of the "IBD Organic" seal, available in the IBD Guidelines.

Also, in this case, techniques used to process organic cosmetics and their ingredients shall be biological, physical, and mechanical. Extraction can only be carried out with water, ethanol, plant and animal oils, vinegar, carbon dioxide.





Project xxx IBD certifies organic products according to international standards.

### 11. PACKAGING REQUIREMENTS

The chosen packaging material must:

- a) be produced with methods that preserve the environment;
- b) use preferably Biodegradable materials;
- c) use preferably materials that are recyclable and have less environmental impact.
- Obs.: PVC and polystyrene are forbidden.

#### 12. CERTIFICATION STEP-BY-STEP

The certification procedure is basically the same for ingredients and finished products. Any outsourced companies must also be inspected and certified.

- a) Application (cadastre information) at IBD,
- b) After application, operator receives an identification code and IBD will designate a client manager for the operator's guidance regarding the certification process.
- c) The client manager will contact the client to inform about the minimum requirements for the first inspection and request the filling out of a specific questionnaire, with the formulations of the product to be certified, as well as documents for the elaboration of a certification contract.
- d) An annual cost estimate will be sent to the operator, covering the following items of the certification process:
  - application;
  - approval of the formulations (mandatory for the validation of the rest of the process. Without this step the application is not complete);
  - pre-inspection and inspection visits (both announced and unannounced);
  - laboratorial analysis (the company must provide resources for any quantitative and qualitative analysis);
  - Inspection reports;
  - Evaluation services by IBD;

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- issuing of an Annual Certificate
- issuing of Transaction Certificates
- inclusion of the company into the list available at the IBD website www.ibd.com.br;
- use of the IBD seal on the company's promotional material
- the inspector's travel and hosting costs, if this is the operator's interest. If not, such costs will be charged separately.
- e) After approval of the cost estimate, the client manager will send the operator the certification contract. The application will be effective when the contract between certifier and client is signed.
- f) IBD technical staff will evaluate the application based on the information provided in the questionnaire, checking compliance with the standards for which certification is requested and, if necessary, determining requirements for the first inspection.
- g) IBD technical staff will perform the inspection visit, and present a report. The final product, the storage, the processing facilities and the commercialization form must be inspected.
- h) The client receives a copy of the inspection's exit interview (= results of the inspection), which must be evaluated and signed by the responsible person of the operation to show agreement with the contents. In case of disagreement, IBD should be informed in written form about the discrepancy points.
- i) The report will then be evaluated by Certification Management, producing a <u>Certification Letter</u> that will be sent to the operation. If the operator does not agree with the decision, a request may be sent to the Council of Appeals, which shall judge the case again.
- j) If the inspection verifies any Non-compliance with the Certification Guidelines that make the immediate certification of the operation impossible, IBD can recommend an independent consultant or the client can seek specialized consultancy in the market to provide necessary adjustments to the certification. As an IFOAM and ISO65 accredited certification body, IBD is not allowed to perform consultancy activities, only certification.
- k) After approval of the operation, the company is issued the Annual Certificate, bearing the IBD code of the operation, a description of the certified product(s) and their presentation.
- 1) To ensure the continuity of the certification, annual visits are necessary, which may include an unannounced inspection every year.

Important: the use of the IBD seal is strictly forbidden for marketing or sampling purposes before the certification contract has been signed and the operation has been issued an Annual Certificate.

#### ANNEX I - GLOSSARY

Organic Agriculture: process used by an agricultural system that pursues a balanced management that conserves the soil and other natural resources and promotes an harmonic relationship of all elements of the system (water, soil, plants, animals, insects...) amongst themselves as well as with human beings. The organic production follows strict certification rules which require not only the non-use of toxic substances but also basic care measures for the conservation of natural resources and adequate labour conditions.

Biodynamic Agriculture: agricultural management system based on the precepts of Rudolf Steiner (1924). All requirements for organic agriculture are also applicable to biodynamic agriculture. Biodynamic agriculture differs from organic agriculture by its concept of self-sustainable agricultural organism, the use of the knowledge about cosmic rhythms, and the use of biodynamic preparations made of medicinal herbs and natural substances and ministered in homeopathic doses to the sol and plants to contribute for a higher vitality in foods. The biodynamic quality standard is established by Demeter Standards.

Agência Nacional de Vigilância Sanitária (ANVISA): government agency that determines rules for public health protection, through sanitary control of production, trading of products and services, including facilities, processes, inputs and technology related to those. The Agency also controls ports, airports and the country's borders and works together with the Ministry of External Relations and foreign institutions on international matters of sanitary control.

Certification: process in which a certifying agent formally assures the quality of a product, by means of inspections that check the origin of the ingredients, the production facilities and processes, composition of the product, storage, transport, measures to protect the environment and labour conditions. Certification aims to identify the origin of products, from their production to the point of sales to the final consumer, thus ensuring a differentiated product. The main purpose is to verify if the product to be offered to the consumer complies with the rules of certification agents for organic and natural products.

Demeter: internationally acknowledged seal for products from biodynamic agriculture and processing. IBD is responsible for Demeter certification in Brazil.

Certified wild crop harvest: collection of raw materials form forests or natural environments according to wild crop harvest rules stipulated by certifying agents and / or the Government.

Forest Stewardship Council (FSC): international non-governmental organization that certifies forest management in all forests of the world. IBD has a partnership with IMAFLORA: certifier for wood and other forestry products, acting in Brazil.

IBD : certification body which inspects and certifies ingredients, agriculture, livestock and finished products.

International Federation of Organic Agriculture Movements (IFOAM): International Federation which acts in the universe of organic products, stipulating policies and norms for this sector, besides contributing for the divulgation of organics through several partnerships such as international fairs and meetings. Accredits and audits certification bodies for organic and natural products by its program IFOAM ACCREDITATION, this work being carried out by IOAS (International Organic Accreditation Service), seated in the USA.

Raw material/ ingredient: chemical substances that are part of a cosmetic formulation, being, generally, natural, organic, synthetic or derived from natural products.

Ingredients from animal origin: substances obtained from animals, e.g. honey, wax, lanoline. The organic certification does not allow the use of ingredients from animal origin when animals are sacrificed for obtaining these materials.

Ingredients from vegetal origin: substances obtained from various plants, which can be organic or not.

Ingredients from mineral origin: natural substances resulting from the interaction of geological processes in the geological environment.

Natural ingredients: ingredients of vegetal or mineral origin, mostly obtained conventionally and, therefore, not always in compliance with the criteria established for the production of organic products. A natural ingredient is not necessarily organic.

Organic ingredients: ingredients obtained following strict norms of production, extraction, purification and processing. Such ingredients must be obtained from certified crops or wild harvest, and it is fundamental that they are biodegradable and preserve their natural chemical characteristics as much as possible. An organic ingredient will always be also natural.

Synthetic ingredients: ingredients obtained by various chemical syntheses, from non natural components.

Ingredients derived from naturals: substances based on a natural component which has undergone chemical alterations in order to from final substances with specific wished characteristics. In short, those are natural ingredients that were chemically modified, and cannot be considered "100%" natural.

Genetically Modified Organisms (GMOs): organisms which have had their genetic material - DNA - altered by genetic engineering techniques, by which the genes of living beings are inserted in other beings from a different species.

Certified organic cosmetic products: consist of formulations elaborated with certified and allowed ingredients. Such products can be sub-divided, according to their content of organic ingredients, in "organic" and "produced with organic ingredients".

Natural cosmetic products: formulations elaborated with certified and allowed ingredients. They are different from the organic products by the content of organic ingredients in their formulations.

Organic production system: methods that adopt specific techniques to optimize the use of the available natural, social and economical resources, and to respect the cultural integrity of the producer communities, with the purpose of economical and ecological sustainability, maximization of social benefits, minimization of the dependence of non-renewable energy sources, using, whenever possible, cultural, biological and mechanical methods instead of synthetic materials, eliminating the use of genetically modified organisms and ionizing radiation in any step of production, processing, storage, distribution and commercialization, and protecting the environment.

ANNEX II- REQUIREMENTS TO BE MEET BY THE "NATURAL COSMETICS", "NATURAL COSMETICS WITH ORGANIC PORTION" AND "ORGANIC COSMETICS" CATEGORIES.

	1*** c	2 ×	3	4	5	6	7	8	9	10	11*** ຍ	12	13
Content of raw materials referred to the finished product (%)	Oils/water-free cleaning and sk care products	Parfums, Eaux de Parfum, Eau de Toilette, Eaux de Cologne	Skin care emulsions (W/O) and Oleogels	Decorative cosmetics containin water	Deodorants and antiperspirants	Skin care emulsions (O/W) and gels	Sunscreens	Hair treatment products	Cleaning products containing surfactants	Oral care	Decorative cosmetics, water-fre	Soaps	Waters
Water content (%)	Water- free	Water- free No specific requirement or limitation Water- free								No sp require or limi	ecific ement tation		
Minimum content of natural substances (%)	90	60	30	15	15	10	10	3	3	2	1	1	0.1
Content of nature- identical substances (%)	No specific requirement or limitation												
Maximum content of derived natural substances (%)	10	10	15	20	30	20	45	40	85	70	50	99	5

Table 1: Requirements to be met by the "natural cosmetics" category

\*\*\* Up to 4.4 % water contained in alcohol is excluded when considering the product category thus the product is considered water-free.

IBD Cosmetics Guidelines – 5th Edition – doc. 8\_1\_2\_C\_E - Revision August 2014

	1	2	3	4	5	6	7	8	9	10	11	12	13
Content of raw materials referred to the finished product (%)	Oils/water-free cleaning and skin care products	Parfums, Eaux de Parfum, Eaux de Toilette, Eaux de Cologne	Skin care emulsions (W/O) and Oleogels	Decorative cosmetics containing water	Deodorants and antiperspirants	Skin care emulsions (O/W) and gels	Sunscreens	Hair treatment products	Cleaning products containing surfactants	Oral care	Decorative cosmetics, water-free	Soaps #	Waters
Water content (%)	Water- free No specific requirement or limitation Water								Water- free	No sp require or limi	ecific ement tation		
Minimum content of natural substances (%)	90*	60*	30*	15*	15*	15*	15*	15*	15*	15*	15*	1*	15*
Content of nature- identical substances (%)	No specific requirement or limitation												
Maximum content of derived natural substances (%)	10**	10**	15**	15**	15**	15**	15**	15**	15**	15**	15**	99**	5**

#### Table 2: Requirements to be met by the "natural cosmetics with an organic portion" category

\* Please take notice of the additional requirements on the content of substances from controlled organic farming in section 9. 3.

\*\* Please take notice of the additional requirements with regard to the production of derived natural substances made of organic starting material in section 9. 3.

\*\*\* Up to 4.4 % water contained in alcohol is excluded when considering the product category thus the product is considered water-free.

# Please note, that the additional requirements with regard to soaps in section 9.2.

	1***	2	3	4	5	6	7	8	9	10	11***	12	13
Content of raw materials referred to the finished product (%)	Oils/water-free cleaning and skin care products	Parfums, Eaux de Parfum, Eaux de Toilette, Eaux de Cologne	Skin care emulsions (W/O) and Oleogels	Decorative cosmetics containing water	Deodorants and antiperspirants	Skin care emulsions (O/W) and gels	Sunscreens	Hair treatment products	Cleaning products containing surfactants	Oral care	Decorative cosmetics, water-free	Soaps #	Waters
Water content (%)	Water- free No specific requirement or limitation Water- free								Water- free	No sp require or limi	ecific ement itation		
Minimum content of natural substances (%)	90*	60*	30*	20*	20*	20*	20*	20*	20*	20*	20*	1*	20*
Content of nature- identical substances (%)	No specific requirement or limitation												
Maximum content of derived natural substances (%)	10**	10**	15**	15**	15**	15**	15**	15**	15**	15**	15**	99**	5**

#### Table 3: Requirements to be met by the "organic cosmetics" category

\* Please take notice of the additional requirements on the content of substances from controlled organic farming in section 9.3.

\*\* Please take notice of the additional requirements with regard to the production of derived natural substances made of organic starting material in section 9. 3.

\*\*\* Up to 4.4 % water contained in alcohol is excluded when considering the product category thus the product is considered water-free.

# Please note the additional requirements with regard to soaps in section 9.3.

ANNEX III -SOME IBD PERMITTED MATERIALS USED IN NATURAL AND ORGANIC CERTIFIED COSMETIC PRODUCTION.

For more detail consult IBD.

# A- <u>Processing aids (Preservers, pH correctors, antioxidants, chelants and colorants)</u>

- 1. Benzoic acid: Aromatic compound that is naturally present in balms and vegetal resins. It is used as a food preservative. However it acts mainly against fungi.
- 2. Natural colorants: norbixin, curcumin, luthein, carothen, anthocianin, bethain are natural chemical compounds drived respectively from bixa, curcuma, sun flower, green vegetables, grape and beetroot which give colour. These are commonly used in food.
- 3. Fitic Acid: chelant obtained from wheat.
- 4. Rosemary oil extract: with anti-oxidant and conserving action. Other essential oils also have anti-oxidant and conserving action.
- 5. Lonicera caprifolium/ Lonicera japonica (Plantaservative®): Natural preserver with with broad action spectrum.
- 6. Dehydroacetic acid and benzilic alcohol: the benzilic alcohol is an aromatic alcohol that can be found as component of essencial oils. Is biodegradable and does not cumulate in nature. Dehydroacetic alcohol is being accepted as conserving by certifiers. It is not natural but is non aromatic and non formaldeheyde liberator.
- 7. Potassium benzoate or sodium benzoate: benzoic acid potassium or sodium salts. Benzoates can be found naturally in fruits, mushrooms, cinnamon and other plants. On commercial purposes, they can be produced by chemical synthesis. Such substances are used in the food and cosmetic industry, as microbiologic preservatives.
- 8. Potassium sorbate: sorbic acid derivate, frequently used in the food industry as preservative. Same purpose in the cosmetic industry.
- 9. Talc powder: magnesium hydrated silicate mineral, extracted from natural resources. It is used in Cosmetics as opacifying, coating agent and powder formulations vehicles.

IBD Cosmetics Guidelines – 5th Edition – doc. 8\_1\_2\_C\_E - Revision August 2014

- 10. Sodium Hydroxide or Potassium Hydroxide: used for soap production as alcali for pH correction.
- **11.** Citric acid: present in many plants, it can be obtained commercially from carbohydrates fermentation processes. It is a very used processing aid in the cosmetic industry, as antioxidant and for pH adjustment.
- 12. Lactic acid: Obtained from lactose, sucrose, starch or glucose fermentation. It is used in the cosmetic industry as a processing aid for pH adjustment and as an active exfoliating agent. When neutralized, it transforms into lactate, which has moisturizing properties.
- 13. Sorbic acid: naturally present in some fruit, it is frequently used as preservative in the food processing industry. It is used with the same purposes in the cosmetic industry.
- **14.** Alfa-tocoferol (Vitamin E): natural anti-oxidant obtained from edible vegetal oils such as soybeans and sunflower, by molecular distillation techniques, either by centrifugation or gravity processes, which aims at separating complex molecules, as vitamins, from natural sources.
- 15. Ferulic Acid: present in small quantities in vast number of plants, this acid can be used in organic cosmetics as antioxidant and conservant.
- 16. Oleuropein: antioxidant extracted from olive oil leaves. Can also help in microbiological conserving of products.
- 17. Farnesol is a natural <u>organic compound</u> which is an acyclic <u>sesquiterpene</u> alcohol found as a colorless liquid. It is insoluble in water, but miscible with oils. Farnesol is the alcohol derivative of Farnesol Pyrophosphate (FPP). It is the building block of most (possibly all) acyclic sesquiterpenoids and is an important starting compound for organic synthesis. It is present in many <u>essential oils</u> such as <u>citronella</u>, <u>neroli</u>, <u>cyclamen</u>, <u>lemon grass</u>, <u>tuberose</u>, <u>rose</u>, <u>musk</u>, <u>balsam</u> and <u>tolu</u>. It is used in perfumery to emphasize the odors of sweet floral perfumes. Its method of action for enhancing perfume scent is as a co-solvent that regulates the volatility of the odorants. It is especially used in lilac perfumes.

18. Titanium dioxide: inorganic compound extracted in the form of rutile or anatase mineral or obtained synthetically. It is used in the cosmetic industry as sunblock, opacifying and coating agent.

#### B. *Emolients*

- 1. Fatty acids and its condensed forms, from agricultural origin: Raw materials produced from vegetal triglycerides (vegetal oils).
- **2.** Lanolin: extracted from wool fat, obtained from lamb wool washing: wool is used by the textile industry and sub-product (fat) is used for lanolin production, and eventually in the cosmetic and pharmaceutical industry.
- 3. Vegetal oils: triglycerides produced and stored in some plants seeds. Extracted traditionally by pressing or with the use of organic solvents or carbonic gas (CO<sub>2</sub>).
- 4. Vegetal butters: natural triglycerides mixed with high content of saturated fatty acids.
- 5. Oleil erucate: is an ester obtained from oleic alcohol and from erucic acid (omega 9), normally obtained from rape and mustard seed, two natural raw materials.

# C. Lipofilic thickeners

- 1. Cetilic alcohol: 16 carbon atoms fatty alcohol, extracted from natural oils of coconut and palm kernel, or from animal / synthetic origin.
- 2. Cetostearilic alcohol: mixture of cetilic alcohol and stearyl alcohol (in the proportion of 30/70 or 50/50, respectively), used as viscosity and opacifying agents of cosmetic formulations.
- 3. Stearyl alcohol: 18 carbon atoms fatty alcohol, extracted from natural oils of coconut and palm kernel, or from animal / synthetic origin. Such raw material is used in the cosmetic industry as a viscosity agent.
- **4.** Glycerin monostearate, glycerin stearate: it is a mixture of mono-, di- and tri-glycerin ester. Since monoester is predominant, it is often called glycerin monostearate. It is obtained by a stearication reaction, from animal or vegetal glycerin, as for example

IBD Cosmetics Guidelines – 5th Edition – doc. 8\_1\_2\_C\_E - Revision August 2014

stearic acid from animal or vegetal origin. It is used in cosmetics as thickener and formulations stabilizer.

- 5. Natural waxes: mainly composed of waxy esters, produced by plants or invertebrate animals, i.e. bee wax. Such waxes are collected in their natural habitat, purified and used in cosmetic formulations, mainly in order to increase products viscosity and to obtain framed solid formulations.
- 6. Behenyl alcohol: is a derivate of natural triglycerides (vegetal oils), therefore a product derived from vegetal oil. It cannot be considered organic raw material, as it is obtained from the processing of vegetal oil.

### D. <u>Active Ingredients</u>

- **1.** Alpha bisabolol: it is a monocycle non-saturated alcohol with anti-inflammatory and bactericidal properties. Such raw material comes from natural products and is normally extracted by direct distillation. It is used in the cosmetic industry as active agent against skin irritation and benign injuries.
- 2. Retinoids: this term refers to a large number of compounds such as A vitamin and its natural and synthetic derivates. Some plants are able to produce A vitamin derivates, which can be used in natural or organic cosmetics.
- **3.** Glycolic extracts: plant extracts, obtained from plant maceration in glycolic solvent, as for example glycerin or a mixture of solvents. In the case of glycolic extracts the origin of the extracting liquid must be observed. Propylene glycol, butylene glycol, ethylene glycol and polyethylene glycol cannot be used.
- **4.** Potassium lactate: hygroscopic salt, with high water affinity, used in the food industry as meat preservative, since it reduces water activity and interferes in microbiological metabolism. It can be used in the cosmetic industry as skin hydrating agent.
- **5.** Amino acids: basic chemical compounds used in the animal and vegetal protein formation. They can be obtained, for special use in cosmetics, from chemical or enzymatic hydrolyses, of natural proteins or by fermentation processes. They are used in skin and hair care products.

6. Hydrolyzed vegetal proteins: obtained from chemical or enzymatic hydrolyze of natural proteins. It is used in the cosmetic industry in skin and hair care products.

### E. Surfactants

- **1.** Alkyl-glycosides: raw materials extracted from natural products. Alkylglycoside is a generic term used to designate raw materials elaborated from condensation of natural carbohydrate molecules (glycosides) and natural fatty alcohols (alkyl). Some kind of alkyl glycosides can be used in emulsion or shampoos formulations.
- 2. Olivoyl hydrolyzed wheat protein, glyceryl oleate, glyceryl stearate, potassium hydroxide, cetearyl alcohol (Olivoil Emulsifier®): mixture of surfactants derived from natural raw materials (hydrolyzed wheat protein and olive oil acid) associated with lipofilic thickeners permitted for organic products.
- **3.** Lecithin: natural lipids that contain phosphate in its structure, reason why they are often called polar lipids, and have surfactant properties. They can be used in cosmetic emulsions formulations and, depending on the kind of lecithin, can have antioxidant properties. Lecithin derived from genetically modified vegetals cannot be used.
- **4.** Cetearyl wheat bran glycosides (and) cetearyl alcohol (Emuliance®): surfactant produced based on wheat bran glucose and fatty coconut acid, mixed with fatty acid cetoestearilic alcohol.
- **5.** Cetearyl wheat straw glycosides (and) cetearyl alcohol (Xyliance®): surfactant produced based on wheat straw carbohydrate and fatty coconut acid, mixed with fatty acid cetoestearilic alcohol.
- 6. Olivoyl hydrolyzed wheat protein (Olivoil surfactant®): surfactant produced based on hydrolyzed wheat protein and fatty coconut acid.
- 7. Cetearyl olivate, sorbitan olivate (Olivem® 1000): surfactant produced based on fatty acid of olive and sorbitol.
- 8. Sorbitan olivate (Olivem® 900): surfactant produced based on fatty olive acid and sorbitol. Permitted for organic products.

- 9. Disodium cocoil glutamate (Amisoft® CS22): obtained from esterification of coconut oil with salt from glutamate. Raw materials and process allowed. Glutamate exists in almost all types of proteins found in food and is used by animals for synthesis of proteins in their bodies. Glutamate can be obtained by processes of fermentation or hydrolysis of natural proteins permitted by IBD. Glutamate salt, glutamate sodium, is largely used in the food industry.
- 10. Cetearyl glucoside cetearilico (e) álcool cetearílico (Emulgade® PL 68/50): mixture of surfactant based on fatty acid of coconut and corn glucose + lipofilic thickener
- 11. Alkyl polyglucosides based on natural fatty alcohol C10-C16 (Glucopon® 425 N and 600UP): are surfactants based on natural fatty acids and carbohydrates, therefore raw materials derived from natural ones.
- 12. Lauryl glucose (Plantaren® 1200): produced from sugar (glucose) and vegetal fatty acid with carbon chain  $C_{8-16}$ , in a process known as acetalization. Although the raw materials used in the synthesis of the surfactant are natural, the process involves the addition of chemical aids for the reaction to occur, so the product is a "coconut glucoside made with fatty acid of coconut and glucose". Therefore the product is not 100% natural, but obtained from natural raw materials. Lauryl glucoside has low toxicity, is biodegradable and assimilated by aerobic and anaerobic bacteria.
- **13.** Decyl glucoside (Plantaren® 2000): is produced with sugar (glucose) and vegetal fatty acid, normally coconut carbon chain  $C_{8-16}$ , in a process known as acetalization. Although the raw materials used in the synthesis of the surfactant are natural, the process involves the addition of chemical aids for the reaction to occur, so the product is called "coconut glucoside made with fatty acid of coconut and glucose". Decyl glucoside has low toxicity, is biodegradable and assimilated by aerobic and anaerobic bacteria.
- 14. Cocamidopropyl betaine: raw material produced with coconut fatty acid and dimethyl carboxymethyl betaine (synthetic), therefore a semi-synthetic derivate, where one of the parts of the molecule is natural and the other not. Therefore it is not accepted by IBD norms.
- **15.** Potassium or sodium stearate: surfactant substance, obtained from natural or animal stearic acid reaction with potassium or sodium hydroxide. Stearates are used in the cosmetic industry in emulsion formulations, shaving foam, soaps and framed formulations making.

#### F. Hydrofilic Thickeners

- 1. Clay: hydrated aluminum silicate, made of aluminum (aluminum oxide), sílica (silica oxide) and water, resulting from the chemical or physical decomposition of feldspar rocks, in very tiny particles.
- 2. Xanthan gum: normally obtained by means of biotechnological process. Permitted for organics.
- 3. Natural starches: the natural starches of manioc, potato and corn, normally used as thickeners, if not modified, can be used in organic formulations.
- **4.** Sclerotium gum (Amigel®): polymer obtained by biotechnology with fermentation of sugar with Esclerotium rolfisii fungus.
- 5. Carragenas: hydrocolloid extracted from red marine algae largely used in the food industry as a thickener, gellifier, stabilizer and suspension agent.
- 6. Alginates: polysaccharides derived from brown algae used in the food industry as thickener.

#### G. <u>Humectants</u>

- 1. Vegetal glycerine: glycerol exists in all natural oils and fats combined with fatty acids to form triglycerides. Glycerine is obtained largely from saponification of vegetal oil or animal fat. Glycerine of animal origin cannot be used in organic and natural cosmetics.
- 2. Sorbitol: alcohol sugar that can be found naturally, or obtained from glucose.
- 3. Biosaccharide Gum-1 (Fucogel 1000®): polysaccharide, biopolymer, Obtained by biotechnological professors. Can be used in cosmetic formulations as a humectant and also to improve the sensorial effect.

# H. Prohibited Ingredients:

- 1. Vegetal ingredients obtained with propylene glycol, butilene glycol or ethylene glycol (use only those obtained by extraction with glycerine, water and/ or sorbitol).
- **2.** Carboximethyl cellulose sodium is a derivate of cellulose, basic polymer for its synthesis, hydrolized in smaller polymers than the original, which react with sodium mono chloro acetate or other synthetic compounds.
- 3. Phenova: mixture of phenoxiethanol and parabens.
- 4. Alkyl acrylate cross polymer/ acrylate. Polymer 100% synthetic.
- 5. Lauryl ether sodium sulphate: is an etoxilated surfactant
- 6. Isopropylic alcohol
- 7. Dimethicone
- 8. Hydroxyethylcellulose
- 9. Cocoamidopropyl betaine
- 10. Diethanolamine of oleic fatty acid
- 11. Monoethanolamide of babaçu oil
- 12. Monoethanolamide of olive fatty acid
- 13. Pentaerythrityl tetrastearate: etoxilated
- 14. Lauryl ether sodium sulphate: etoxilated surfactant

#### ANNEX IV:

ORGANIC PORTION OF DERIVED NATURAL SUBSTANCES IF THEY HAVE BEEN PROCESSED FROM ORGANIC RAW MATERIALS ACCORDING TO THE CRITERIA LAID DOWN IN REGULATION (EC) NO 834/2007, FORMER (UNTIL 31 DECEMBER 2008) REGULATION (EEC) NO 2092/91, IN THE USDA NATIONAL ORGANIC PROGRAM (NOP) OR BR 10.831.

Main process involved to produce derived natural ingredient	Organic percentage of derived natural ingredient
Hydrolysis, saponification, esterification or transesterification	98%
Hydrogenation or Hydrogenolysis	98%
Glycosidation	98%
Sulphatation	60%
Acylation	85%

### ANNEX V:

# EXAMPLES FOR THE CALCULATION OF THE NATURAL (ORGANIC) PORTION OF PLANT EXTRACTS AND HYDROLATES / FLORAL WATERS

In the scheme below the letters mean the following:

- P = weight of the plant material used (organic, if applicable)
- E = weight of the extraction medium used or of the water used for distillation

F = weight of the extract recovered (after extraction and filtration) or of the hydrolate recovered (after distillation)

- O = weight of the plant oil recovered (in case of distillation)
- X = natural or organic portion of the extract / hydrolate [%] according to paragraph B. 1.



Case 1: Distillation or extraction of organic plant material with water or another extraction medium from plant origin (derived natural, not organic):

Extract / Hydrolate:  $X = P/(P + E) \times 100 = X \%$  natural and organic

Oil (in case of distillation): 100 % natural and organic

Case 2a: Extraction of organic plant material with an extraction medium from plant origin (natural, not organic):

Extract: 100 % natural, thereof  $X = P/(P + E) \times 100 = X$  % organic

Case 2b: Extraction of organic plant material with an extraction medium from plant origin (natural, partly organic):

Extract: 100 % natural, thereof  $X = (P+Eorganic)/(P+Etotal) \times 100 = X$  % organic

Case 3: Extraction of organic plant material with an organic extraction medium:

Extract: 100 % natural and organic

The plant residue which will remain after distillation or extraction can be processed further as natural substance (and as organic, where applicable).

Example 1: Extraction of calendula (organic) with vegetable oil (natural and organic, where applicable):

P = 20 kg dried plant material (organic) E = 80 kg vegetable oil (organic, where applicable) F = 70 kg extract after filtration

Extract: 100 % natural, thereof  $X = 20/(20 + 80) \times 100 = 20$  % organic If organic vegetable oil is used, the extract has to be counted as 100 % natural and organic.

Example 2: Manufacturing of a hydrolate through distillation of rose blossoms with water (first distillation):

P = 500  kg fresh rose bloss	oms (organic)
E = 500  kg water	F = 500  kg hydrolate

Oil: 100 % natural and organic

Hydrolate:  $X = 500/(500 + 500) \times 100 = 50$  % natural and organic

Example 3: Manufacturing of a hydrolate through distillation of rose blossoms with water (first distillation):

P = 500 kg fresh rose blossoms (organic) $E = 1000 \text{ kg water} \qquad F = 1000 \text{ kg hydrolate}$ 

Oil: 100 % natural and organic Hydrolate: X = 500/(500 + 1000) x 100 = 33,3 % natural and organic

Example 4: Manufacturing of a hydrolate through distillation of lavender with water:

P = 1000 kg lavender (organic, almost dried)E = 350 kg steam (is added until F = 350 kg) F = 350 kg hydrolate

Oil: 100 % natural and organic Hydrolate: X = 1000/(1000 + 350) x 100 = 74,1 % natural and organic

Example 5: Manufacturing of floral water (without extraction of oil): Same calculation of the natural and organic portion applies as in the case of hydrolates.