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Cosmetics — Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients —

Part 2: Criteria for ingredients and products

Cosmétiques — Lignes directrices relatives aux définitions techniques et aux critères applicables aux ingrédients et produits cosmétiques naturels et biologiques —

Partie 2: Critères relatifs aux ingrédients et aux produits

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 217, *Cosmetics*.

A list of all parts in the ISO 16128 series can be found on the ISO website.

Introduction

ISO 16128 provides guidelines on definitions and criteria for natural and organic cosmetic ingredients and products. These guidelines are specific to the cosmetics sector, taking into account that most existing approaches written for the agricultural and food sector are not directly transferrable to cosmetics. They apply scientific judgment and offer principles towards a consistent logical framework for natural and organic cosmetic ingredients and products incorporating common approaches employed in existing references. The purpose of these guidelines is to encourage a wider choice of natural and organic ingredients in the formulation of a diverse variety of cosmetic products to encourage innovation.

Cosmetics — Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients —

Part 2:
Criteria for ingredients and products

1 Scope

This document describes approaches to calculate natural, natural origin, organic and organic origin indexes that apply to the ingredient categories defined in ISO 16128-1. This document also offers a framework to determine the natural, natural origin, organic and organic origin content of products based on the ingredient characterization.

Neither ISO 16128-1 nor this document addresses product communication (e.g. claims and labelling), human safety, environmental safety, socio-economic considerations (e.g. fair trade), characteristics of packaging materials or regulatory requirements applicable for cosmetics.

This document builds on and enhances ISO 16128-1. It is intended to be used in conjunction with ISO 16128-1.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 16128-1:2016, *Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients and products — Part 1: Definitions for ingredients*

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

4 Approach to determine natural, natural origin, organic and organic origin indexes for cosmetic ingredients

4.1 General

This clause applies to ingredients, either as defined chemical substances, or as animal, mineral, microorganism or plant materials (in whole, in part or as an extract).

In case of a mixture of two or more ingredients, each ingredient contribution shall be taken separately.

4.2 Extracts

When a solvent is partially evaporated, the producer of the extract may utilize industry best practices (e.g. measurement by instrumentation, characterization of solvent volatility, published values of evaporation rates) to determine the index/indices of the extract. The approach and justification for this determination should be made available to interested parties, when requested.

Extracts indexes calculation follow the rules described in 4.3 and 4.4.

In the case of extracts, the following principles apply when determining indexes.

— The indexes of finished extracts should reflect the starting materials [i.e. ingredient solvent(s) and un-extracted mass].

— Extracts may be produced from fresh or dried materials.

— The extraction procedure stops at separation of the extract from the insoluble residue (e.g. at filtration). If subsequent operations are performed (e.g. dilution, preservation, etc.), their contributions to the indexes are treated as additions of new ingredients.

— The final extract (e.g. in the case of concentration) cannot display more organic or natural content than the starting materials.

— Reconstitution of dry plants with water to their original fresh mass is allowed. The reconstitution water should be present in the finished extract in order to count towards its natural or organic content.

— When calculating the organic index, reconstitution water is considered organic while any extraction water in excess is natural.

— An extract made from non-organic plants has an organic index and organic origin index of 0.

— Ingredient solvents are defined in ISO 16128-1:2016, Table A.1.

— The use of non-natural ingredients (e.g. alcohol denaturants) is allowed in ingredient solvents. However, if the mixture contains a non-natural ingredient solvent, then the entire mixture is non-natural.

4.3 Determination of natural and natural origin indexes of ingredients

4.3.1 Natural index

The natural index is a value indicating the extent to which a cosmetic ingredient meets the definition of natural ingredients from ISO 16128-1:2016, Clause 2.

The value is assigned to each ingredient according to the following guidance:

Natural index = 1: Ingredient meets the definition of natural ingredients. The natural indexes of constitutive water, reconstitution water, extraction water and formulation water are each considered to equal 1.

Natural index = 0: Ingredient does not meet the definition of natural ingredients.

The natural index of extract is calculated according to Formula (1):

$$I_{\mathrm{n}} = 1 - \frac{m_{\mathrm{DNS}}}{m_{\mathrm{T}}} \tag{1}$$

where

I_n is the natural index;

m_{DNS} is the mass of derived natural solvent introduced;

m_T is the total mass introduced (natural ingredients and ingredient solvents).

For example, extracts of natural ingredients have a natural index of 1 if the solvents used are natural, including water.

4.3.2 Natural origin index

The natural origin index is a value indicating the extent to which a cosmetic ingredient meets the definitions of either natural ingredients in ISO 16128-1:2016, Clause 2, derived natural ingredients from ISO 16128-1:2016, Clause 3, or derived mineral ingredients from ISO 16128-1:2016, Clause 4.

The value is assigned to each ingredient according to the following guidance:

Natural origin index = 1: Ingredient meets the definition of natural ingredients, constitutive water, reconstitution water, extraction water or formulation water. Extracts of natural ingredients using ingredient solvents that are natural or derived natural of wholly natural origin (according to ISO 16128-1:2016, Table A.1) have a natural origin index of 1.

0,5 < Natural origin index ≤ 1: Ingredient meets the definition of derived natural ingredients or derived mineral ingredients. The value is calculated as the ratio of the natural origin moiety, as determined by molecular mass, renewable carbon content or any other relevant methods, to the total molecular composition of that ingredient.

Natural origin index = 0: Ingredient neither meets the definition of natural ingredients nor derived natural ingredients nor derived mineral ingredients, including those with natural origin indexes calculated to be ≤0,5.

4.4 Determination of organic and organic origin indexes of ingredients

4.4.1 Organic index

The organic index is a value indicating the extent to which a cosmetic ingredient meets the definition of organic ingredients from ISO 16128-1:2016, 2.3.

The value is assigned to each ingredient according to the following guidance:

Organic index = 1: Ingredient meets the definition of organic ingredients, constitutive water or reconstitution water.

Organic index = 0: Ingredient does not meet the definition of organic ingredients. The organic indexes of both extraction water and formulation water are considered to be equal to 0.

Extracts of organic ingredients in organic ingredient solvents have an organic index of 1. Oily macerates of dried or fresh organic ingredients in organic oil have an organic index of 1. Essential oils and fully dried extracts of organic ingredients have an organic index of 1 if the process solvent follows ISO 16128-1:2016, Table A.2 (because the extraction solvent is removed, it is considered as a process solvent). In other cases, the organic index is calculated according to Formula (2):

$$I_o = 1 - \frac{m_{NS} + m_{DNS} + m_{DOS}}{m_T} \quad (2)$$

where

I_o is the organic index;

m_{NS} is the mass of natural solvent introduced;

m_{DNS} is the mass of derived natural solvent introduced;

m_{DOS} is the mass of derived organic solvent introduced;

m_T is the total mass introduced (organic ingredients and ingredient solvents).

In order to determine m_{NS} in the above calculation for dried plants when water is used as an ingredient solvent, it is important to subtract the mass of the reconstitution water to represent the mass of the fresh plant.

For extracts of dried plants in which water is used, the extraction water is calculated as Formula (3):

$$H_2O_E = m_{H2O} - H_2O_R \quad (3)$$

where

H_2O_E is the extraction water;

m_{H2O} is the total mass of water introduced;

H_2O_R is the reconstitution water which is determined as follows:

— when the original fresh plant mass of the dried plant is known, H_2O_R is the lower value between ($m_{FP} - m_{DP}$) and m_{H2O};

— when the original fresh plant mass of the dried plant is not known, H_2O_R is the lower value between ($k \times m_{DP} - m_{DP}$) and m_{H2O};

where

m_{FP} is the mass of the original fresh plant;

m_{DP} is the mass of dried plant;

k is the dry/fresh ratio;

— wood, bark, seeds, nuts and roots : k = 2,5

— leaves, flowers and aerial parts : k = 4,5

— water fruits: k = 8

or as otherwise specified by the raw material supplier.

4.4.2 Organic origin index

The organic origin index is a value indicating the extent to which a cosmetic ingredient meets the definitions of either organic ingredients from ISO 16128-1:2016, 2.3, or derived organic ingredients from ISO 16128-1:2016, 3.2.

The value is assigned to each ingredient according to the following guidance:

Organic origin index = 1: Ingredient meets the definition of organic ingredients, constitutive water or reconstitution water.

0 < Organic origin index ≤ 1: Ingredient meets the definition of derived organic ingredients. The value is calculated as the ratio of the organic origin moiety, as determined by molecular mass, renewable carbon content or any other relevant methods, to the total molecular composition of that ingredient.

Organic origin index = 0: Ingredient neither meets the definition of organic ingredients nor derived organic ingredients. The organic origin indexes of both extraction water and formulation water are considered to equal 0.

Extracts of organic ingredients in organic or derived organic ingredient solvents have an organic origin index of 1. Oily macerates of dried or fresh organic ingredients in organic or derived organic oil have an organic origin index of 1. Essential oils and fully dried extracts of organic ingredients have an organic origin index of 1 if the process solvent follows ISO 16128-1:2016, Table A.2 (because the extraction solvent is removed, it is considered a process solvent). In other cases, the organic origin index is calculated according to Formula (4):

$$I_{oo} = 1 - \frac{m_{NS} + m_{DNS}}{m_T} \quad (4)$$

where

I_{oo} is the organic origin index;

m_{NS} is the mass of natural solvent introduced;

m_{DNS} is the mass of derived natural solvent introduced;

m_T is the total mass introduced (organic ingredients and ingredients solvents).

In order to determine m_{NS} for the above calculations when dried plants are used, it is important to subtract the mass of the reconstitution water from the mass of the extraction water to represent the mass of the plant before drying.

For extracts of dried plants in which water is used, the extraction water is calculated as Formula (3):

$$H_2O_E = m_{H2O} - H_2O_R$$

where

H_2O_E is the extraction water;

m_{H2O} is the total mass of water introduced;

H_2O_R is the reconstitution water which is determined as follows:

— when the original fresh plant mass of the dried plant is known, H_2O_R is the lower value between ($m_{FP} - m_{DP}$) and m_{H2O};

— when the original fresh plant mass of the dried plant is not known, H_2O_R is the lower value between ($k \times m_{DP} - m_{DP}$) and m_{H2O};

where

m_{FP} is the mass of the original fresh plant;

m_{DP} is the mass of dried plant;

k is the dry/fresh ratio:

— wood, bark, seeds, nuts and roots : $k = 2,5$

— leaves, flowers and aerial parts : $k = 4,5$

— water fruits: $k = 8$

or as otherwise specified by the raw material supplier.

For extracts, ingredient solvents could be organic, derived organic, natural (including water) or natural derived of wholly natural origin (as indicated in ISO 16128-1:2016, Table A.1).

Table 1 — Indexes for the different categories of non-mixture ingredients

Ingredient category	Index and value			
	Natural index	Natural origin index	Organic index	Organic origin index
Constitutive water	1	1	1[b]	1[b]
Reconstitution water	1	1	1[b]	1[b]
Extraction water, with exclusion of reconstitution water	1	1	0	0
Formulation water	1	1	0	0
Natural	1	1	0	0
Natural mineral	1	1	0	0
Organic	1	1	1[b]	1[b]
Derived natural[a]	0	>0,5	0	0
Derived organic[a]	0	1	0	To be calculated[b]
Derived mineral[a]	0	1	0	0
Non-natural	0	0	0	0

[a] Annex A shows sample index values and calculations for derived ingredients.

[b] Only if the source material is organic. Otherwise, the value is 0.

Annex A provides examples of calculation for derived ingredients containing a derived natural or derived organic component. Annex B provides examples of calculation for extracts.

5 Approaches to determine natural and/or organic content of finished cosmetic products

5.1 Natural content

5.1.1 General

The natural content of a product is the mass percentage, between 0 % and 100 %, of all natural ingredients in that product. It is calculated as the sum of the relative concentrations of a product's ingredients multiplied by their corresponding natural indexes. This calculation can be performed either by including formulation water, as in Formula (5) or by excluding formulation water, as in Formula (6).

5.1.2 Calculation of natural content by including formulation water

$$C^{N}_{+H_2O} = \sum_{\alpha=1}^{n} (P_\alpha \times I_{n\alpha}) \quad (5)$$

where

$C^{N}_{+H_2O}$ is the natural content of a product, as calculated by including formulation water as an ingredient;

P_α is the percentage, by mass, of each ingredient, α, in the product and includes formulation water as an ingredient;

$I_{n\alpha}$ is the natural index corresponding to each ingredient, α, in the product.

5.1.3 Calculation of natural content by excluding formulation water

$$C^{N}_{-H_2O} = \sum_{\beta=1}^{n} \left[\frac{P_\beta}{\left(1 - \frac{H_2O_F\,\%}{100\ \%}\right)} \times I_{n\beta} \right] \quad (6)$$

where

$C^{N}_{-H_2O}$ is the natural content of a product, as calculated by excluding formulation water as an ingredient;

P_β is the percentage, by mass, of β, each ingredient except formulation water (H_2O_F) in the product. P_β excludes formulation water as an ingredient (i.e. the percentage of formulation water is not part of the numerator);

$I_{n\beta}$ is the natural index corresponding to each ingredient, β, in the product;

H_2O_F % is the percentage, by mass, of formulation water in the product.

5.2 Natural origin content

5.2.1 General

The natural origin content of a product is the mass percentage, between 0 % and 100 %, of all natural ingredients and natural portions of derived natural ingredients in that product. It is calculated as the sum of the relative concentrations of a product's ingredients multiplied by their corresponding natural origin indexes. This calculation can be performed either by including formulation water, as in Formula (7) or by excluding formulation water, as in Formula (8).

5.2.2 Calculation of natural origin content by including formulation water

$$C^{no}_{+H_2O} = \sum_{\alpha=1}^{n} \left(P_\alpha \times I_{no\alpha} \right) \quad (7)$$

where

$C^{no}_{+H_2O}$ is the natural origin content of a product, as calculated by including formulation water as an ingredient;

P_α is the percentage, by mass, of each ingredient, α, in the product and includes formulation water as an ingredient;

$I_{no\alpha}$ is the natural origin index corresponding to each ingredient, α, in the product.

5.2.3 Calculation of natural origin content by excluding formulation water

$$C^{no}_{-H_2O} = \sum_{\beta=1}^{n} \left[\frac{P_\beta}{\left(1 - \frac{H_2O_F\,\%}{100\ \%}\right)} \times I_{no\beta} \right] \quad (8)$$

where

$C^{no}_{-H_2O}$ is the natural origin content of a product, as calculated by excluding formulation water as an ingredient;

P_β is the percentage, by mass, of β, each ingredient except formulation water (H_2O_F), in the product. P_β is not calculated for H_2O_F as an ingredient, β, since H_2O_F is excluded from contribution toward natural origin content in this case;

$I_{no\beta}$ is the natural origin index corresponding to each ingredient, β, in the product;

H_2O_F % is the percentage, by mass, of formulation water in the product.

5.3 Organic content

5.3.1 General

The organic content of a product is the mass percentage, between 0 % and 100 %, of all organic ingredients in that product. It is calculated as the sum of the relative concentrations of a product's ingredients multiplied by their corresponding organic indexes. This calculation can be performed either by including formulation water, as in Formula (9) or by excluding formulation water, as in Formula (10).

5.3.2 Calculation of organic content by including formulation water

$$C^{O}_{+H_2O} = \sum_{\gamma=1}^{n} \left(P_\gamma \times I_{o_\gamma} \right) \tag{9}$$

where

$C^{O}_{+H_2O}$ is the organic content of a product, as calculated by including formulation water as an ingredient;

P_γ is the percentage, by mass, of each ingredient, γ, in the product and includes formulation water as an ingredient;

I_{o_γ} is the organic index corresponding to each ingredient, γ, in the product.

5.3.3 Calculation of organic content by excluding formulation water

$$C^{O}_{-H_2O} = \sum_{\delta=1}^{n} \left[\frac{P_\delta}{\left(1 - \frac{H_2O_F\,\%}{100\,\%} \right)} \times I_{o\delta} \right] \tag{10}$$

where

$C^{O}_{-H_2O}$ is the organic content of a product, as calculated by excluding formulation water as an ingredient;

P_δ is the percentage, by mass, of δ, each ingredient except formulation water (H_2O_F), in the product. P_δ is not calculated for H_2O_F as an ingredient, δ, since H_2O_F is excluded from contribution toward organic content in this case;

$I_{o\delta}$ is the organic index corresponding to each ingredient, δ, in the product;

H_2O_F % is the percentage, by mass, of formulation water in the product.

5.4 Organic origin content

5.4.1 General

The organic origin content of a product is the mass percentage, between 0 % and 100 %, of all organic ingredients and organic portions of derived organic ingredients in that product. It is calculated as the sum of the relative concentrations of a product's ingredients multiplied by their corresponding organic origin indexes. This calculation can be performed either by including formulation water, as in Formula (11) or by excluding formulation water, as in Formula (12).

5.4.2 Calculation of organic origin content by including formulation water

$$C^{OO}_{+H_2O} = \sum_{\gamma=1}^{n} \left(P_\gamma \times I_{oo_\gamma} \right) \tag{11}$$

where

$C^{OO}_{+H_2O}$ is the organic origin content of a product, as calculated by including formulation water as an ingredient;

P_γ is the percentage, by mass, of each ingredient, γ, in the product and includes formulation water as an ingredient;

I_{oo_γ} is the organic origin index corresponding to each ingredient, γ, in the product.

5.4.3 Calculation of organic origin content by excluding formulation water

$$C^{OO}_{-H_2O} = \sum_{\delta=1}^{n} \left[\frac{P_\delta}{\left(1 - \frac{H_2O_F\,\%}{100\ \%} \right)} \times I_{oo\delta} \right] \tag{12}$$

where

$C^{OO}_{-H_2O}$ is the organic origin content of a product, as calculated by excluding formulation water as an ingredient;

P_δ is the percentage, by mass, of each ingredient, δ, in the product and excludes formulation water as an ingredient (i.e. the percentage of formulation water is not part of the numerator);

$I_{oo\delta}$ is the organic origin index corresponding to each ingredient, δ, in the product;

$H_2O_F\%$ is the percentage, by mass, of formulation water in the product.

Annex C shows calculation examples of each content calculations in a finished cosmetic products.

Annex A
(informative)

Examples of calculations to determine indexes of ingredients containing a derived natural or organic component

Table A.1 — Examples of calculations to determine indexes of ingredients containing a derived natural or organic component

Ingredient type	Example (all percentages listed are % mass fraction)	Natural index	Natural origin index	Organic index	Organic origin index
Derived natural	C18-38 Alkyl Beeswax: Made by reacting 45 % C18-38 alkyl alcohols from naphtha (non-natural) with 55 % C24-36 beeswax acid (organic)	0	0,55	0	0
Derived organic	Stearyl Beeswax: Made by reacting 35 % stearyl alcohol from animal fat (organic) with 65 % C24-36 beeswax acid (organic)	0	1	0	1
Derived organic	Butyl Avocadate: Made by reacting 70 % butyl alcohol (natural) with 30 % avocado fatty acids (organic)[a]	0	1	0	0,3
Non-natural	PPG-6 Castorate: Made by reacting 30 % castor oil (natural) with 70 % PPG-6 (non-natural)[b]	0	0	0	0
Non-natural	Silica silylate: Made by reacting 57 % silicone dioxide (natural – mineral) with 43 % methylsilane (from 67 % natural – mineral, and 33 % non-natural reactants)[c]	0	0	0	0

[a] There is no minimum concentration requirement for organic source material used to make derived organic ingredients.

[b] There is a maximum content limit for fossil fuel source material used to make derived natural ingredients (<50%).

[c] Substances made from mineral sources should have the same chemical composition as a naturally occurring mineral in order to be considered derived mineral ingredients. In this case, although the bulk of the ingredient (approximately 86 %) is made from natural mineral reactants, silica silylate is considered non-natural because it does not occur in nature.