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

**Part 2:  
Criteria for ingredients and products**

**iTeh STANDARD PREVIEW**  
*Cosmétiques — Lignes directrices relatives aux définitions techniques et aux critères applicables aux ingrédients et produits cosmétiques naturels et biologiques*  
**(standards.iteh.ai)**

*Partie 2: Critères relatifs aux ingrédients et aux produits*  
ISO 16128-2:2017

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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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](http://www.iso.org/directives)).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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](http://www.iso.org/iso/foreword.html). (standards.iteh.ai)

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. [www.iso.org/iso/16128-2-2017](http://www.iso.org/iso/16128-2-2017)

## 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.

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# 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.

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### 2 Normative references (standards.iteh.ai)

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.

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## 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 \(1\)](#):

$$I_n = 1 - \frac{m_{DNS}}{m_T} \quad (1)$$

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.

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#### 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 \(3\)](#):

$$H_2O_E = m_{H_2O} - H_2O_R \quad (3)$$

where

$H_2O_E$  is the extraction water;

$m_{H_2O}$  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  $m_{H_2O}$ ;
- 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  $m_{H_2O}$ ;

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 \(3\)](#):

$$H_2O_E = m_{H_2O} - H_2O_R$$

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where

$H_2O_E$  is the extraction water;

$m_{H_2O}$  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  $m_{H_2O}$ ;
- 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  $m_{H_2O}$ ;

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).