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Cosmetics — Answers to frequently asked questions on ingredients and product characterization according to ISO 16128-1 and ISO 16128-2

Cosmétiques — Réponses aux questions fréquemment posées sur la caractérisation des ingrédients et des produits conformément à l'ISO 16128-1 et à l'ISO 16128-2

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: 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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This document was prepared by Technical Committee ISO/TC 217, *Cosmetics*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The ISO 16128 series 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 the ISO 16128 series is to encourage a wider choice of natural and organic ingredients in the formulation of a diverse variety of cosmetic products to encourage innovation.

The purpose of this document is to help ingredient manufacturers and cosmetic companies, or any reader, to qualify cosmetic ingredients as natural, natural derived or non-natural when using the ISO 16128 series.

Cosmetics — Answers to frequently asked questions on ingredients and product characterization according to ISO 16128-1 and ISO 16128-2

1 Scope

This document provides answers to questions which can arise when calculating indexes and contents according to ISO 16128-1 and ISO 16128-2.

It clarifies conditions on process, solvents and carbon sources to qualify ingredients regarding the ISO 16128 series. Detailed examples, explaining how to use the ISO 16128 series are also provided.

2 Normative references

There are no normative references in this document.

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:

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

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

4 Questions and answers

4.1 General

Table 1 — General questions

No.	Question	Answer
0	How can an ingredient manufacturer and/or a cosmetic manufacturer assign the category and index of an ingredient?	Ingredient manufacturers are recommended to provide cosmetic manufacturers with information related to composition, origin and processing of ingredients to determine ingredient indexes. For all ingredients, cosmetic manufacturers verify the category and index based on information provided. Therefore, dialogue between ingredient and cosmetic manufacturers is encouraged.
1	What are the differences between the following terms: ingredient, substance, raw material, and renewable material?	A cosmetic raw material is an ingredient or a mixture of ingredients. An ingredient is a substance, i.e. a chemical element and its compounds in the natural state or the result of a manufacturing process, excluding any solvent which may be separated without affecting the stability of the substance or changing its composition. Certain substances are renewable if they are replenished naturally at a rate at least the same as their consumption.
2	How does the definition of an extract relate to its INCI composition?	An extract is a substance or a mixture of substances. In most cases, its INCI name is the same as the natural ingredient it comes from, with, when relevant, the INCI name(s) of the ingredient solvent(s) used for extraction.

Table 1 *(continued)*

No.	Question	Answer
3	Can the INCI ingredient lists be used to determine if a product is natural, derived natural or non-natural?	No. More information is needed to make that determination. INCI ingredients can be produced in different ways and process solvents used will not appear in the INCI ingredients list. For example, it is possible to have two products with the exact same INCI names list be classified differently when using the methods set out in ISO 16128-1.
4	How do the different categories of solvents relate to their INCI nomenclature?	ISO 16128-1 refers to two categories of solvents: ingredient solvents and process solvents, which are defined in ISO 16128-1:2016, Annex A. Ingredient solvents appear in the INCI ingredients list. Process solvents do not remain in the ingredient (except as traces) and will not appear in the INCI ingredient list.

4.2 Natural ingredients

Per ISO 16128-1, natural ingredients are cosmetic ingredients obtained only from plants, animals, micro-organisms, or minerals, including those obtained from these materials by:

— physical processes (e.g. as grinding, drying, distillation);

— fermentation reactions occurring in nature and leading to molecules occurring in nature; and

— other processes of preparation, including traditional ones (e.g. extraction using solvents) without intentional chemical modification.

See Table 2.

Table 2 — Questions on natural ingredients

No.	Question	Answer
5	How is water defined in ISO 16128-1?	Water is defined as always natural in ISO 16128-1:2016, 2.4.
6	The definition of water of crystallization is not provided in ISO 16128-1. How is it defined?	In chemistry, water of crystallization is water molecules that are present inside crystals of minerals. It can be considered as constitutive water in natural minerals. In the cases which water is either added during or produced after a reaction, it is considered as formulation water.
7	How is aromatic water obtained by distillation classified in ISO 16128-1?	It is classified as extraction water.
8	Are ingredients such as ethanol, amino acids, or nucleic acids considered natural if obtained by fermentation reaction using a substance occurring in nature as a starting material?	Yes. As long as the feedstock is natural, the reaction fermentation occurs in nature and the fermentation product is one that occurs in nature, the result is natural.
9	Can Formula (1) in ISO 16128-2:2017, 4.3.1 be used to calculate the natural index of an ingredient that does not contain ingredient solvents?	Formula (1) in ISO 16128-2:2017, 4 3 1 is used only for extracts when ingredient solvents are present. Otherwise, the natural index is assigned, according to the same paragraph, is either 1 or 0.
10	Aromatic natural raw materials are defined according to ISO 9235. How are the indexes of aromatic natural raw materials calculated per ISO 16128?	“Fragrance/Parfum” are often mixtures including aromatic natural materials. The calculation of indexes of all ingredients containing aromatic natural raw materials follows ISO 16128. The exact composition, according to ISO 16128-1, can be obtained from the suppliers.

4.3 Physical processes for natural ingredients

Table 3 — Questions on physical processes for natural ingredients

No.	Question	Answer
11	Can "processing by micro-waves" be considered as physical process?	Yes. Any sort of drying process can be considered as physical process if it does not lead to chemical modification.
12	Are new technologies for physical extraction considered as physical extraction process?	Yes, new technologies, such as use of micro-waves, sonication and ultrasounds can be considered, as long as there is no chemical modification. The use of solvents is defined in ISO 16128-1:2016 Table A.1.
13	In case of a plant extract extracted with a mixture consisting of a non-natural solvent and a natural solvent, is the final extract considered as a natural ingredient?	If a non-natural solvent remains in the final extract as an ingredient solvent, this extract is considered as a non-natural ingredient. If the non-natural solvent is eliminated, this extract can be considered as a natural ingredient if conditions of ISO 16128-1:2016, Table A.2 are fulfilled.
14	The value k is the dry/fresh ratio for leaves or flowers when calculating natural/organic index of plant extract. If a supplier can specify the actual dry/fresh ratio and it is different from k value, can the specified values be used for calculation?	Yes.
15	Provide index calculation examples for the extract of a dried organic plant.	EXAMPLE 5 kg of dry plant (organic flower) was extracted by 90 kg of 30 % glycerin (a derived natural solvent) aqueous solution was obtained. (k=4,5) — Starting materials: 5 kg of dry plant is equivalent to 5 × 4,5 = 22,5 kg of fresh plant — Solvent: 63 kg of water, 27 kg of glycerin — Reconstitution water: 22,5 – 5 = 17,5 kg — Extraction water: 63 – 17,5 = 45,5 kg NOTE Extraction water is as defined in ISO 16128-1. Natural index of the extract: 1 – (27/(5 + 63 + 27)) = 0,71 Natural origin index of the extract: 1 as all ingredients meet the definition of derived natural ingredients Organic index of the extract: 1 – ((45,5+27)/ (5+63+27)) = 0,24 Organic derived index of the extract: 1 – ((45,5 + 27)/ (5 + 63 + 27)) = 0,24
16	According to ISO 16128-2:2017, 4.2: "*The use of non-natural ingredients (e.g. alcohol denaturants) is allowed in ingredient solvent. However, if the mixture contains a non-natural ingredient solvent, then the entire mixture is non-natural.*" Does it mean, for example, that the addition of phenoxyethanol to an extract is OK and only affects the index value, but if an extraction solvent of butylene glycol (non-natural) is used, then the index is 0, regardless? At what value does an added ingredient become a solvent (i.e. polysorbate-80) or does the definition refer only to extraction solvents?	The bullet from ISO 16128-2:2017, 4.2 stating that the use of non-natural ingredients (e.g. alcohol denaturants) is allowed in ingredient solvents means, for example, that denaturated alcohol can be used for extraction and leads to a natural extract. When phenoxyethanol is added to an extract after filtration, this is a mixture which has no longer an index but instead has a content. The use of butylene glycol (non-natural) as an extraction solvent leads to a non-natural ingredient. The use of polysorbate 80 during an extraction leads to a non-natural ingredient as it is not of natural origin. But its use after filtration leads to a mixture which has a content.

Table 3 *(continued)*

No.	Question	Answer
17	Is a dry herbal extract or a purified compound isolated from a natural source considered as a natural ingredient?	In the extent that solvents do not remain in the final ingredients except as traces (process solvents), they are considered as natural ingredients according to ISO 16128-1:2016, Table A.2 if: — renewable solvents that pose minimal safety or environmental risk are used; or — if no physical process or no renewable solvent can be used, a non-natural solvent that poses minimal safety or environmental risk is used.
18	What are the indexes of a rose extract, obtained by extraction with a mixture of water and butylene glycol, if the butylene glycol is of petrochemical origin?	As the butylene glycol is of petrochemical origin, it is a non-natural ingredient solvent. The rose extract is a non-natural ingredient. Both natural index and natural origin index are 0.
19	What are the indexes of a rose extract, obtained by extraction with a mixture of water and butylene glycol, if the butelyne glycol is of vegetal origin?	As the butylene glycol is a derived natural ingredient solvent, the natural index is determined using Formula (1) in ISO 16128-2:2017, 4.3.1. Starting material: 10 kg of flower Total solvent introduced: 90 kg = 67,5 kg water + 22,5 kg butylene glycol Mass of derived natural solvent introduced = 22,5 kg butylene glycol Total mass introduced (natural ingredients and ingredient solvents) = 10 + 67,5 + 22,5 = 100 kg The natural index is = 1 – (22,5/100) = 0,775 The natural origin index is 1.
20	Is native guar gum a natural ingredient? According to a February 2010 Opinion from AFSSA (ref. 2009-SA-0214), guar gum is obtained, using Cyamopsis tetragonolobus seeds through traditional methods in the grain milling industry. Guar gum is obtained through the following process: — seeds extracted from dried pods are mechanically broken down in order to eliminate the sprout; — the endosperm is husked to obtain flakes; — flakes are ground then sieved to obtain a powder; — powder or flakes are washed using ethanol or isopropanol to limit the microbial load.	Yes, the process of native guar gum used here is a physical separation of the molecules present in the seeds. The natural index of the native guar gum is 1, if process solvents used respect the natural category of ISO 16128-1:2016, Table A.2.
21	How is an extract from cell culture medium defined in ISO 16128? For example, an Aloe barbadensis Callus extract is an extract obtained through the culture of Aloe barbadensis Callus.	The culture and extraction of a plant callus is carried out in a medium. The natural index and the natural origin index depend on the composition of the medium as defined in ISO 16128-1. None of the ingredients are organically produced. OI=OOI =0