



SLOVENSKI STANDARD
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Kozmetika - Odgovori na pogosto zastavljena vprašanja o karakterizaciji sestavin in izdelkov v skladu z ISO 16128-1 in ISO 16128-2

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

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

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2021-08

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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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).

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).

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For an explanation of 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 www.iso.org/iso/foreword.html.

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.

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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.

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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

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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.

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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.