Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients and products —
Part 1: Definitions for ingredients

Lignes directrices relatives aux définitions techniques et aux critères applicables aux ingrédients et produits cosmétiques naturels et biologiques —
Partie 1: Définitions des ingrédients
## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foreword</td>
<td>iv</td>
</tr>
<tr>
<td>Introduction</td>
<td>v</td>
</tr>
<tr>
<td>1 Scope</td>
<td>1</td>
</tr>
<tr>
<td>2 Natural ingredients</td>
<td>1</td>
</tr>
<tr>
<td>2.1 General</td>
<td>1</td>
</tr>
<tr>
<td>2.2 Natural mineral ingredients</td>
<td>1</td>
</tr>
<tr>
<td>2.3 Organic ingredients</td>
<td>2</td>
</tr>
<tr>
<td>2.4 Water</td>
<td>2</td>
</tr>
<tr>
<td>3 Derived natural ingredients</td>
<td>2</td>
</tr>
<tr>
<td>3.1 General</td>
<td>2</td>
</tr>
<tr>
<td>3.2 Derived organic ingredients</td>
<td>3</td>
</tr>
<tr>
<td>4 Derived mineral ingredients</td>
<td>3</td>
</tr>
<tr>
<td>5 Non-natural ingredients</td>
<td>3</td>
</tr>
<tr>
<td>Annex A (informative) Solvents for ingredient processing and manufacturing</td>
<td>4</td>
</tr>
<tr>
<td>Annex B (informative) List of chemical and biological processes for derived natural, derived organic, and derived mineral ingredients</td>
<td>6</td>
</tr>
<tr>
<td>Annex C (informative) Examples of calculations when the molecular weight is known or not known</td>
<td>8</td>
</tr>
<tr>
<td>Annex D (informative) List of derived mineral ingredients</td>
<td>9</td>
</tr>
<tr>
<td>Bibliography</td>
<td>11</td>
</tr>
</tbody>
</table>
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).

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 meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO’s adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 217, Cosmetics.

ISO 16128 consists of the following parts, under the general title Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients and products:

— Part 1: Definitions for ingredients

The following part is under preparation:

— Part 2: Criteria for ingredients and products
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.

However, it is common, based on other references in the public domain, to cover criteria for ingredients, as well as definitions and criteria for finished products. This will be covered in ISO 16128-2, which will build on and enhance this part.
Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients and products —

Part 1: Definitions for ingredients

1 Scope

This part of ISO 16128 provides guidelines on definitions for natural and organic cosmetic ingredients. In addition to natural and organic ingredients, other ingredient categories which may be necessary for natural and organic product development are defined with associated restrictions.

ISO 16128 does not address product communication (e.g. claims and labelling), human safety, environmental safety and socio-economic considerations (e.g. fair trade), and the characteristics of packaging materials or regulatory requirements applicable for cosmetics.

2 Natural ingredients

2.1 General

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. grinding, drying, distillation),
— fermentation reactions occurring in nature and leading to molecules which occur in nature, and

— other procedures of preparation including traditional ones (e.g. extraction using solvents) without intentional chemical modification (Annex A includes the definition of solvents and the categories of extracts using solvents for ingredient processing and manufacturing).

The following materials, and materials originating from them, shall be considered to fall under the general heading of natural origin:

a) plants including fungi and algae;
   
   NOTE 1 Ingredients coming from genetically modified plants can be considered as natural ingredients in certain regions of the world.
   
   NOTE 2 In the context of these guidelines, the term “herb” can be used as a synonym for the word plant.

b) minerals;

c) animals;

d) micro-organisms.

Ingredients obtained from fossil fuels are excluded from the definition.
For reasons of clarity, the term “natural” is not used in this part of ISO 16128 to indicate the characteristics of a scent, a colour, or a taste.

NOTE 3 Based on the definitions given in this part of ISO 16128 that are cosmetic product specific, an aromatic natural raw material according to ISO 9235 can be composed of natural ingredients, derived natural ingredients or a mixture of the two. ISO 9235 defines aromatic natural raw materials that can be used in different sectors including cosmetics. As these are complex mixtures, the necessary information can be obtained from the aromatic raw material supplier.

### 2.2 Natural mineral ingredients

Natural mineral ingredients are natural ingredients which are inorganic substances (i.e. non-carbon derived and carbonate salts) occurring naturally in the earth having a distinctive chemical formula and consistent set of physical properties (e.g. crystalline structure, hardness, colours).

### 2.3 Organic ingredients

Organic ingredients are natural ingredients originating from organic farming methods or from wild harvesting in compliance with national legislation or equivalent International Standards where applicable.

NOTE The term “organic farming” can be defined as per individual national jurisdiction where applicable.

Water, as defined in 2.4, except for constitutive water, and minerals are outside the scope of organic farming.

### 2.4 Water

Water is considered as natural.

However, the types of water defined in the following list may be treated differently.

— **Constitutive water** is the liquid (juice) content of fresh plants.

— **Reconstitution water** is equivalent to the water found in the original material and is used to restore the dry material to its original content.

— **Extraction water** is the water used to physically extract ingredients from a material mixture.

For the purposes of ISO 16128, water which is not defined above is designated as "**formulation water**".

### 3 Derived natural ingredients

#### 3.1 General

Derived natural ingredients are cosmetic ingredients of greater than 50 % natural origin, by molecular weight, by renewable carbon content, or by any other relevant methods, obtained through defined chemical and/or biological processes with the intention of chemical modification.

An informative list of such processes is provided in Annex B. Enzymatic and microbiological processing may also give rise to derived natural ingredients, where an intentional chemical modification takes place.

The degree of natural origin is generally quantified by molecular weight or by renewable carbon resulting in certain cases of ingredients of wholly natural origin.

**Annex A** gives information on solvents in relation to ingredient manufacturing.

**Annex C** includes calculations in the case that the molecular weight is known or not known.
3.2 Derived organic ingredients

Derived organic ingredients are cosmetic ingredients of organic or mixed organic and natural origin obtained through defined chemical and/or biological processes (see Annex B) with the intention of chemical modification, which do not contain any fossil fuel origin moiety.

An informative list of such processes is provided in Annex B.

If the chemical or biological reaction results in multiple compounds, the main chemicals determining the ingredient properties shall contain a moiety of organic origin in the molecule.

Enzymatic and microbiological processing may also give rise to derived organic ingredients, where an intentional chemical modification takes place.

Annex A gives information on solvents in relation to ingredient manufacturing.

4 Derived mineral ingredients

Derived mineral ingredients are cosmetic ingredients obtained through chemical processing of inorganic substances occurring naturally in the earth, which have the same chemical composition as natural mineral ingredients.

An informative list of such processes is provided in Annex B.

Annex A gives information on solvents in relation to ingredient manufacturing.

An informative list of derived mineral ingredients is included in Annex D.

5 Non-natural ingredients

Non-natural ingredients are ingredients that are greater than or equal to 50 % by molecular weight of fossil fuel origin or other ingredients which do not fall into one of the other categories defined in these guidelines.

Annex C includes calculations in the case where the molecular weight is known or not known.