BS ISO 16128-1:2016

BSI Standards Publication

Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients and products

Part 1: Definitions for ingredients

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National foreword

This British Standard is the UK implementation of ISO 16128-1:2016.

The UK committee draws users' attention to Note 1 in section 2.1. The committee feels that the terms "natural" and "genetically modified" are diametrically opposed by definition and deprecates the potential for GMO-sourced ingredients to be listed in a document that defines the criteria for natural and organic cosmetic ingredients. In some other regions of the world genetically modified ingredients can be considered as natural ingredients, as stated in Note 1, but this is not the case in the UK.

The UK participation in its preparation was entrusted to Technical Committee CW/217, Cosmetics.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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INTERNATIONAL STANDARD

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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

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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 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.

INTERNATIONAL STANDARD ISO 16128-1:2016(E)

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.

Annex A
(informative)

Solvents for ingredient processing and manufacturing

For the purpose of these guidelines, a solvent can be defined as follows:

— a substance, usually a liquid, capable of dissolving or dispersing one or several ingredients.

There are two categories of solvents:

— ingredient solvents: solvents in which ingredients have been dissolved or dispersed before and/or during the manufacture (ingredient extraction) of an ingredient and which remain in the final ingredient. Such final ingredient is a mixture of ingredients. See Table A.1.

— process solvents: solvents used in the manufacture of ingredients which do not remain in the ingredient except as traces. See Table A.2.

After use, process solvents should be completely removed or at least removed to such an extent that they are only contained in technologically unavoidable trace concentrations in the final ingredient.

If a non-natural ingredient solvent is used alone or mixed, the final ingredient category is considered non-natural.

Table A.1 — Category of ingredient solvent

Categories of initial ingredient (dispersed or dissolved)	Categories of ingredient solvents	Categories of final ingredient
Natural (Clause 2)	Natural (Clause 2) Water (2.4)	Natural
	Derived natural of wholly natural origin (Clause 3)	Mixture of natural and derived natural ingredients [a]
Natural mineral (2.2)	Natural (Clause 2) Water (2.4)	Natural
	Derived natural of wholly natural origin(Clause 3)	Mixture of natural and derived natural ingredients [a]
Organic (2.3)	Organic (2.3)	Organic
	Derived organic (3.2) Natural (Clause 2) Water (2.4) Derived natural of wholly natural origin (Clause 3)	Mixture of organic and derived organic, or natural, or derived natural ingredients [a]
If mixtures of different categories of ingredient solvent are used, the classification of the final ingredients will be a mixture of different categories of ingredient involved. [a] In cases where categories of dispersed or dissolved ingredients and categories of ingredient solvents are different, it can be a mixture of ingredients belonging to different categories. When a mixture contains ingredients of different categories, the calculation of an index is needed.		

Table A.1 *(continued)*

Categories of initial ingredient (dispersed or dissolved)	Categories of ingredient solvents	Categories of final ingredient
Derived natural (Clause 3)	Natural (Clause 2) Water (2.4)	Mixture of natural and derived natural ingredients [a]
	Derived natural (Clause 3)	Derived natural
Derived organic (3.2)	Organic (2.3)	Mixture of organic and derived organic ingredients [a]
	Derived organic (3.2)	Derived organic
	Natural (Clause 2) Water (2.4) Derived natural of wholly natural origin (Clause 3)	Mixture of derived organic and natural or derived natural ingredients [a]
Derived mineral(Clause 4)	Natural (Clause 2) Water (2.4)	Mixture of natural and derived mineral ingredients[a]
	Derived natural (Clause 3)	Mixture of derived natural and derived mineral ingredients [a]
If mixtures of different categories of ingredient solvent are used, the classification of the final ingredients will be a mixture of different categories of ingredient involved. [a] In cases where categories of dispersed or dissolved ingredients and categories of ingredient solvents are different, it can be a mixture of ingredients belonging to different categories. When a mixture contains ingredients of different categories, the calculation of an index is needed.		

Table A.2 — Category of process solvent

Categories of initial ingredient	Categories of process solvents
Natural (Clause 2)	a
Natural mineral (2.2)	a
Organic (2.3)	Organic (2.3) Derived organic (3.2) Natural (Clause 2) Water (2.4) Derived natural of wholly natural origin (Clause 3)
Derived natural (Clause 3)	a
Derived organic (3.2)	Organic (2.3) Derived organic (3.2) Natural (Clause 2) Water (2.4) Derived natural of wholly natural origin (Clause 3)
Derived mineral (Clause 4)	a
a Renewable solvents that pose minimal safety or environmental risk should be used for the purpose of extraction or reaction processes. If renewable alternatives are not available, non-natural solvents that pose minimal safety or environmental risk can be used.	

Annex B
(informative)

List of chemical and biological processes for derived natural, derived organic, and derived mineral ingredients

Table B.1 shows an informative list of reactions that may be used to manufacture derived natural, derived organic and derived mineral ingredients.

This list of reactions resulted from work carried out by ISO/TC 217 and from a worldwide benchmark of natural and organic standards.

Principles of green chemistry are recommended for these processes.

As this list is not exhaustive and in order to allow innovation, other processes following green chemistry principles may be used.

The use of halogenated non-mineral derivatives is not recommended during the processing of derived natural organic and mineral ingredients.

The guidelines do not limit the use of catalysts or auxiliaries for the list of chemical and biological processes, as long as they are removed from the reaction. If they are not removed, they are considered as ingredients and part of the mixture.

Table B.1 — Reactions that may be used to manufacture derived natural, derived organic and derived mineral ingredients

Process	Remarks
Acylation	Amidation and esterification are covered by this process.
Addition	Hydration is covered by this process.
C/O/N-alkylation	Etherification and amination are covered by this process.
Calcination/carbonisation	
Carbonation	
Condensation	Aldol reaction (condensation of aldehyde and ketone), the Knoevenagel condensation (condensation of aldéhyde or ketone and activated carbon), the claisen condensation (condensation of ester and aldehyde or ketone), and the guerbet reaction (condensation of two primary alcohols) are covered by this process.
Enzymatic and microbiological processes	Natural fermentation is excluded.
Glycosidation	
Hydrogenation	
Hydrogenolysis	
Hydrolysis	Saponification is covered by this process.
Ionic exchange	Neutralization is covered by this process.
Olefin metathesis	
Oxidation	
Phosphorylation	
Reduction	
Sulphatation	Sulphatation equals sulphation.

Annex C
(informative)

Examples of calculations when the molecular weight is known or not known

In relation to Clauses 3 and 5, this annex shows examples of calculations when the molecular weight is known or not known.

Calculation when molecular weight is known:

— Example: Cocamidopropylbetaine

— Molecular weight of the natural part: 183 g/mol

— Molecular weight of the whole molecule: 342 g/mol

$$\% \text{ natural origin} = \frac{183}{342} \times 100 = 53{,}5$$

Calculation when exact molecular weight is not known:

EXAMPLE Catechines extracted from tea, natural origin mixture of molecules with different molecular weight, esterification with propanoic acid (derived from petrochemistry)

$$\% \text{ natural origin} = \frac{m_{\mathrm{n}} - m_{\mathrm{ne}}}{m_{\mathrm{a}} - m_{\mathrm{ae}}} \times 100$$

where

m_{n} is the weight of natural starting raw materials;

m_{ne} is the weight of natural starting raw materials in excess;

m_{a} is the weight of all starting raw materials;

m_{ae} is the weight of all starting raw materials in excess.

“Excess” means the amount of starting raw material that is recycled or removed later on.

Non-reacting solvents are not considered as starting raw materials.

Annex D
(informative)

List of derived mineral ingredients

INCI name	Chemical name	Examples of occurrence in nature
ALUMINA	Aluminium oxide	corundum, clay
ALUMINIUM HYDROXIDE	Aluminium hydroxide	bauxite, gibbsite, hydrargillite
ALUMINIUM IRON SILICATES	Silicate ceramics	
ALUMINIUM SULFATE	Aluminium sulphate and its salts	milosevichite
ALUMINUM SILICATE	Aluminium iron silicates	ceramics
AMMONIUM SULFATE	Ammonium sulphate	mascagnite
CALCIUM ALUMINIUM BOROSILICATE	Calcium aluminium borosilicate	tourmalines
CALCIUM FLUORIDE	Calcium fluoride	fluorite or fluorspar
CALCIUM SULFATE	Calcium sulfate	gypsum, β-anhydrite
CERIUM OXIDE	Ceric oxide	
CI 77007 / ULTRAMARINES	Lazzurite	lapis lazuli
CI 77120 / BARIUM SULFATE	Barium sulfate	baryte
CI 77163 / BISMUTH OXYCHLORIDE	Bismuth chloride oxide	bismoclite
CI 77220 / CALCIUM CARBONATE	Calcium carbonate	calcite, aragonite, vaterite
CI 77288 / CHROMIUM OXYDE GREENS	Chromic oxide	guyanait, grimaldiit bracewellit, eskolaite
CI 77289 / CHROMIUM HYDROXYDE GREEN	Chromic oxide hydrated	
CI 77489 / IRON OXYDES	Ferrous oxide	bernalite
CI 77491 / IRON OXYDES	Ferric oxide	feroxygite
CI 77492 / IRON OXYDES	Iron oxide yellow	ferrihydrite, goethite
CI 77499 / IRON OXYDES	Iron oxide black	lepidocrocit
CI 77510 / PIGMENT BLUE 27	Ferric ferrocyanide; prussian blue	kafehydrocyanite
CI 77711 / MAGNESIUM OXIDE	Magnesium oxide	
CI 77713 / MAGNESIUM CARBONATE	Magnesium carbonate	magnesite
CI 77742 / MANGANESE VIOLET	Ammonium manganese(3+) di-phosphate	niahite
CI 77745	Trimanganese bis orthophosphate	
CI 77820 / SILVER	Silver	
CI 77891 / TITANIUM DIOXIDE	Titanium dioxide	
CI 77947 / ZINC OXIDE	Zinc oxide	wulfingit, ashoverit
COPPER SULFATE	Copper sulphate	sulphidic copper ore, chalcanthite
CUPROUS OXYDE	Copper oxide	tenorite
DICALCIUM PHOSPHATE DIHYDRATE	Calcium hydrogenorthophosphate	
FERROUS SULFATE	Iron sulphate	
HYDRATED SILICA	Hydrated silica	

INCI name	Chemical name	Examples of occurrence in nature
HYDROXYAPATITE	Hydroxy apatite	sand
IRON HYDROXIDE	Iron hydroxide	
MAGNESIUM ALUMINIUM SILICATE	Silicic acid, aluminium magnesium salt	
MAGNESIUM CARBONATE HYDROXIDE	Magnesium carbonate hydroxide	artinite, hydromagnesite, dypingite
MAGNESIUM CHLORIDE	Magnesium chloride	bischofite
MAGNESIUM SILICATE	Magnesium silicate	
MAGNESIUM SILICATE	Silicic acid, magnesium salt	talc sepiolite
MAGNESIUM SULFATE	Magnesium sulphate	kieserite
MICA	Mica	annite, phlogopite, and muscovite
POTASSIUM CARBONATE	Potassium carbonate	
POTASSIUM CHLORIDE	Potassium chloride	sylvite, carnallite, kainite
POTASSIUM IODIDE	Potassium iodide	
POTASSIUM SULFATE	Potassium sulphate	arcanite
SILICA	Silica	quartz
SILVER CHLORIDE	Silver chloride	
SILVER OXIDE	Silver oxide	
SILVER SULFATE	Silver sulphate	
SODIUM BICARBONATE	Sodium bicarbonate	natron, nahcolith
SODIUM BORATE	Sodium borate	borax
SODIUM CARBONATE	Sodium carbonate	soda
SODIUM FLUORIDE	Sodium fluoride	
SODIUM MAGNESIUM SILICATE	Sodium magnesium silicate	
SODIUM METASILICATE	Disodium metasilicate	
SODIUM MONOFLUOROPHOSPHATE	Disodium fluorophosphate	
SODIUM SILICATE	Silicic acid, sodium	
SODIUM SULFATE	Sodium sulphate	thenardite
SODIUM THIOSULFATE	Sodium thiosulphate	
TIN OXIDE	Tin dioxide	cassiterite
ULTRAMARINES	Ultramarines	lapis lazuli
ZINC CARBONATE	Zinc carbonate	smithsonite

Bibliography

[1] ISO 9235:2013, *Aromatic natural raw materials — Vocabulary*

[2] Reference to the twelve principles of Green Chemistry originally published by Paul Anastas and John Warner in Green Chemistry: Theory and Practice (Oxford University Press: New York, 1998). Available from: http://www.epa.gov/greenchemistry/

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