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Cosmetics — Methods of extract evaporation and calculation of organic indexes — Supplemental information to use with 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
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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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 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.

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

ISO 16128 (all parts) 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.

This document was prepared to identify existing industry operations involved in extraction concentration and its impact on organic content. The preparation of this document involved the collection of information based on current market practices, including the concentration of extracts and processes, as well as equipment and solvents used.

Extraction processes involve contact between a solvent and a material (solute). This physical process involves the dissolution of solute molecules in the solvent and their extraction. The remaining insoluble material is then separated, and the remaining solution or dispersion might be concentrated.

If the extracted solution is concentrated to dryness, the rules and formulae presented in ISO 16128-2 apply.

If the extract is concentrated using the information contained in this document then the calculation of the organic content should be identified as such.

Cosmetics — Methods of extract evaporation and calculation of organic indexes — Supplemental information to use with ISO 16128-2

1 Scope

This document describes the industry best practices to address the concentration of extracts which is related to ISO 16128-2:2017, 4.2. Evaporation of solvents to dryness it not addressed in this document.

This document aims to delineate the cases when an extract is produced and, afterwards the mixture of evaporated solvents used, regardless of the categories, are partially evaporated.

The producer of the extract can utilize different approaches (e.g. measurement by instrumentation, characterization of solvent volatility, published values of evaporation rates, etc.) to determine the index (es) of the extract. Despite the approach and justification, the rational and determinations used is made available to interested parties, when requested.

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 http://www.iso.org/obp

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

4 Extraction

4.1 General

The extraction process aims to deliver specific, soluble fractions of materials rather than the material in whole. The extracts of organic plants, animals and microorganisms meet the need for delivering specific constituents in the finished cosmetic product without changing their structures or properties.

4.2 Principles to apply when determining indexes

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 an 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.

4.3 Extraction process

The extraction process involves the close contact of the extracted material (e.g. plant, animal, microbiological or mineral) with a solvent (single or mixture) for a determined time at a selected temperature.

The extraction process ends when the extract is physically separated from the unextracted material.

Results indicate that, after the extraction process ends, manufacturers could either distribute the extract as it is, or perform additional operations, such as addition (e.g. preservation, dilution) and/or concentration as discussed in 4.3.

After this physical/chemical extraction and separation process, directed to obtain and concentrate plants in one or a variety of ingredients, the extract might be used or submitted to following operations.

Nevertheless, some manufacturers use extracts without further concentration.

4.3.1 Solvents

Categories of ingredient solvents are explained in ISO 16128-1:2016, Table A.1

4.4 Operations performed after extraction

After the extraction process ends, transportation and/or usage may require the extract to undergo additional operations that lead to partial solvent removal.

NOTE Complete removal or evaporation to dryness would render the substance a “process solvent” not an “ingredient solvent.” See ISO 16128-1:2016 Tables A.1 and A.2 for the respective requirements.

Addition of any ingredient, such as preservatives, antioxidants or other non-solvent to the extract would render the ingredient a mixture with the appropriate index(es) to be calculated accordingly.

4.4.1 Concentration

4.4.1.1 General

There are generally two methods used to concentrate extracts:

— cold temperature vacuum extraction; and

— heating to evaporate.

4.4.1.2 Solvent removal during concentration process

Solvent recovery is performed by some manufacturers to allow subsequent reuse, while others do not recollect the solvents used. Among the manufacturers that recollect, some separate and quantify the solvents individually.

Calculation of evaporations may take into consideration the formation of azeotropes (water and ethanol) or it just considers that solvent removal is directly related to the individual physical chemical properties (vapor pressure and boiling point). For the latter, solvents with lower boiling points are considered to evaporate first.

4.4.1.3 Influence of solvent evaporation in the calculations

Solvents that are evaporated are considered process solvents. In the case of partial evaporation, the remaining solvent is an ingredient solvent.

For example, in a water and ethanol extraction:

When extraction is performed with 100 kg of ethanol and 100 kg of water. There are two possibilities.

a) There is complete evaporation of ethanol; therefore, ethanol is considered a process solvent.

b) If only 50 kg of ethanol is evaporated, the remaining 50 kg of ethanol in the extract is considered an ingredient solvent.

It is also possible to directly apply the principles described in 16128-2:2017, 4.2 regarding solvent calculation in ISO 16128-2:2017, 4.4.1, without having to consider the weight of the solvents evaporated. For example, when extraction is performed with 100 kg of ethanol and 100 kg of water, and 50 kg of ethanol is evaporated, 100 kg of ethanol is considered an ingredient solvent.

4.4.1.4 Equipment used for solvent evaporation

Manufacturers use mainly evaporation apparatus refrigerated that evaporates under vacuum.

5 Determination of organic and organic origin indexes of extracts after evaporation

5.1 Organic index

ISO 16128-2 indicates that the organic index is a value indicating the extent to which a cosmetic ingredient meets the definition of organic ingredients (see ISO 16128-1:2016, 2.3.)

This value is assigned to each ingredient, between 0 and 1, according to defined guidance.

Therefore, 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.

In other cases, the organic index of extracts is calculated according to ISO 16128-2:2017, 4.4.1, Formula (2).

5.2 Organic origin index

ISO 16128-2 indicates that the organic origin index is a value indicating the extent to which a cosmetic ingredient meets the definition of derived origin ingredients (see ISO 16128-1:2016, 3.2)

This value is assigned to each ingredient, between 0 and 1, according to defined guidance.