FINAL
DRAFT

INTERNATIONAL
STANDARD

**ISO/FDIS
210**

ISO/TC **54**

Secretariat: **UNE**

Voting begins on:
2023-02-06

Voting terminates on:
2023-04-03

Essential oils — General requirements and guidelines for packaging, conditioning and storage

Reference number
ISO/FDIS 210:2023(E)

COPYRIGHT PROTECTED DOCUMENT

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

Published in Switzerland

Contents

Page

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 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 54, *Essential oils*.

This first edition cancels and replaces ISO/TS 210:2014, which has been technically revised.

The main changes are as follows:

— addition of Clause 2 (Normative references) and Clause 3 (Terms and definitions);

— revision of the Bibliography.

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.

Essential oils — General requirements and guidelines for packaging, conditioning and storage

1 Scope

This document describes the requirements for containers which are intended for containing essential oils. It also provides some general requirements and guidelines relating to the conditioning and storage of essential oils.

Essential oils are used for different purposes:

— food use;

— pharmaceutical use;

— perfumery and cosmetic use;

— reference samples or test samples;

— industrial raw materials.

It is expected that the containers used for essential oils also meet the requirements of national or international regulations.

This document describes the materials which are used for the containers intended for containing essential oils, depending on the uses listed above.

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 terminology databases for use in standardization at the following addresses:

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

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

4 Composition of the containers

4.1 General

Essential oils shall be packed in containers which, by their nature, do not cause alteration of the product and which protect it against any external attack.

Generally, the container materials shall be inert towards the packed product so as to prevent any simultaneous damage of the product and of the material.

4.2 Materials for containers intended for containing essential oils for food use

4.2.1 Glass

Type III glass (soda-calcic glass, according to Pharmacopoeia standards), is recommended as it permits to keep the organoleptic properties of the essential oils[1].

Tinted non-actinic glass is always advisable.

4.2.2 Metals and alloys

4.2.2.1 Stainless steel

These materials shall contain at least 13 % of chromium.

They also may contain nickel and manganese.

Furthermore, one or more of the following elements in Table 1 may be included, with the following limit for each of them[2].

Table 1 — Maximum content of some elements in stainless steel containers

Element	Content
Tantalum	1 % max
Niobium	1 % max
Zirconium	1 % max
Molybdenum	4 % max
Titanium	4 % max
Aluminium	4 % max
Copper	4 % max

4.2.2.2 Aluminium and aluminium alloys

Aluminium shall be at least 99 % pure.

The total content of impurities shall not exceed 1 %, and they are limited as shown in Table 2[3][4][5].

Table 2 — Maximum content of impurities in aluminium containers

Impurities	Content
Iron + Silicon	Lower than 1 %
Titanium	0,15 % max
Chromium, Zinc, Copper, Manganese, Magnesium, Nickel, Tin	0,1 % max (for each of these elements)
Lead, Thallium, Beryllium, and each of the other present impurities	0,05 % max (for each of these elements
Copper	Between the mass fraction of 0,10 % and of 0,20 %, on the condition that the chromium and manganese contents are less than the mass fraction of 0,05 %

In the aluminium alloys, the mass fraction of the elements (in percentage) which may be added, or which are present as impurities, shall not exceed the following values in Table 3.

Table 3 — Maximum content of impurities in aluminium alloys containers

Impurities	Content
Silicon	13,5 % max
Magnesium	11 % max
Manganese	4 % max
Nickel	3 % max
Iron	2 % max
Copper	0,6 % max
Antimony	0,4 % max
Chromium	0,35 % max
Titanium	0,3 % max
Zirconium	0,3 % max
Zinc	0,25 % max
Strontium	0,2 % max
Tin	0,1 % max
Arsenic, Tantalum, Beryllium, Thallium, Lead, and each of the other impurities present	0,05 % max, with a total ≤0,15 %

The anodization of aluminium or aluminium alloy materials and objects complying with the provisions of Article 2 and 3 of Reference [3] shall be only carried out in a diluted bath using the following acids or their mixtures:

— sulfuric acid;

— sulfomaleic acid;

— sulfosalicilic acid;

— oxalic acid;

— phosphoric acid.

The anodic layer may be coloured by pigments or colourings. Regulations in force concerning the materials and products in contact with food can apply (see Clause 5).

It is expected that a compulsory final filling operation is applied with the exception of the aluminium or aluminium alloy materials and products anodized in a phosphoric medium or covered by coating, in conformity with Article 4 of Reference [3]. This operation shall be carried out with distilled or demineralized water containing either 8 g/l of nickel acetate and 1 g/l of cobalt acetate or one of these two salts at the maximum concentrations indicated.

All the technical conditions, particularly the temperature and standing time, shall be chosen in such a way that, at the end of the operation, the oxide layer formed during the anodization process, loses its absorption power due to its natural porosity, and acquires optimum inertness.

4.2.2.3 Tin

This material shall contain at least 97 % of tin, determined as metastannic acid, and not more than 0,5 % of lead or 300 mg/kg of arsenic[6][7].

4.2.2.4 Copper, zinc, galvanized iron

Except during the distillation process, there shall be no direct contact between the essential oil and these materials[6].

4.2.3 Polymers: plastics and varnishes

Compatibility tests between the container and the content shall be carried out before using these materials[20].

The authorized global migration limit is established by the national or international regulations in force.[9][10][11][12] Depending on the case, the global migration limit is 60 mg/kg or 10 mg/dm^2 (according to the shape or dimensions of the container).

Only those substances listed in the national or international regulations,[14] which also include migration limits for some of these substances[13][15] are authorized as components of plastics materials.

4.2.4 Ceramic, vitrified and enamelled materials used for internal coating

National or international regulations can apply with respect to the amount of lead and cadmium released by these materials[8].

4.3 Materials for containers of essential oils for pharmaceutical use

4.3.1 General

No material or substance placed in contact with an essential oil for pharmaceutical use shall perceptibly adulterate its composition or modify its activity.

It is presupposed that all packaging has a Licensing Approval delivered by the relevant authorities.

NOTE This authorization forms a part of the Licensing Pharmaceutical dossier.

Depending on the country, the regulations applicable to containers and packaging can differ, but generally refer to:

— general principles of Pharmacopoeia (European[1], American[18], or Japanese[19] etc.), which specify, among other things, that a study relating to the possible interaction between the container and the product should be undertaken in each case where a hazard may appear, and

— national standards or regulations, if there is no specific or relevant Pharmacopoeia monograph.

4.3.2 Glass

The glass used is type III. It is presupposed that it complies with the Pharmacopoeia standards concerning its hydrolytic resistance.

Tinted non-actinic glass is recommended in all cases.

4.3.3 Metals and alloys

These materials shall have the same properties and stresses as those described throughout 4.2.2.

4.3.4 Plastics materials

These materials are generally described in the Pharmacopoeia monographs.

They are submitted to various analyses and tests, which comprise in particular:

— an identification;

— a determination of certain substances such as antioxidant monomer residues, anti-UVs, stabilizers, catalyst residues, heavy metals, or aromatic diamines;

— a control of water or solvent extraction, etc.

4.3.5 Ceramic, vitrified and enamelled materials, used for internal coatings

Legal requirements can also apply to varnished, enamelled, vitrified, ceramic coatings, as the materials used for food essential oils, as described in 4.2.4.

4.4 Materials for containers of essential oils for perfumery and cosmetic use

All the previously listed materials (see 4.2 and 4.3) may be used, on condition that they do not alter the composition of the essential oil or its organoleptic properties such as appearance, colour and odour.

Copper and iron are not recommended because they are oxidation catalysts.

Plastics materials intended for this use shall be submitted to prior testing, concerning:

— their carbon dioxide, oxygen, steam, fragrances, permeability, etc.;

— the ageing of the packed product.

4.5 Materials for containers of reference samples or test samples of essential oils

The only advisable material for containers intended for containing reference samples or test samples of essential oils is tinted non-actinic glass.

4.6 Materials for containers of essential oils used as industrial raw materials

Tinted non-actinic glass is advisable, but all the materials quoted in 4.2 to 4.5 may also be used for containers intended for containing essential oils used as industrial raw materials.

5 Pigments or colourings

If containers intended for containing essentials oils for food use (4.2) or pharmaceutical use (4.3) are coloured, it is presupposed that the pigments or colourings used comply with the regulations in force, similar to those of the additives of plastics[16].

They shall have a high level of purity and the maximum content in mineral elements is shown in Table 4.

Table 4 — Maximum content in mineral elements for pigments or colourings

Mineral element	Maximum content
Antimony	0,05 %
Arsenic	0,01 %
Barium	0,01 %
Cadmium	0,01 %
Chromium	0,1 %
Lead	0,01 %
Mercury	0,005 %
Selenium	0,01 %

One method of analysis of benzo-3,4 pyrene is given in Reference [17].

6 Characteristics for containers intended for containing essential oils

6.1 Types

The containers intended for containing essential oils differ in shape, nature, and capacity.

They shall be appropriate for their use (following the recommendations relating to the materials given in Clause 4).

The most frequently used types of containers are the following:

— flasks;

— bottles;

— cans;

— barrels;

— drums;

— tanks.

Drums of capacity equal to or greater than 200 l shall be provided with hoops or with moulded ribs.

6.2 Capacity

The capacity of the containers used differs according to the projected use.

It can vary from a few millilitres to several thousand litres.

6.3 Closures

The closure materials, including the joints or screw-type corks, shall be inert to the essential oils and submitted to compatibility tests.

The materials which may be used are glass, tin, tin plate, stainless steel, compatible and inert plastics, etc.

Cork which has not been treated previously is not advisable due to its porosity and because it contains waxes and tannins which are liable to be dissolved in the essential oils.

Pre-treated cork may be used, if its chemical inertness towards the essential oil placed in contact with it, can be proven.

The same constraints as those for essential oil for food or pharmaceutical uses can apply also to all types of closures without any restriction.

The closures or caps shall be as tight as possible. After closing, the containers shall be protected by a seal guaranteeing inviolability.

6.4 External weldings

Whatever the container and the destination of the essential oil inside, the use of tin and lead alloy is permitted for external weldings, but it is recommended to use other welding processes such as electric soldering.

7 Conditioning and storage

7.1 Conditioning

Containers intended for containing essential oils shall be new or in good condition, clean and dry (dried by dry steam), and perfectly tight.

If they have already served for other uses, it shall be ensured that they do not contain any products likely to alter the quality of the essential oil.