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Essential oils — General rules for packaging, conditioning and storage

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National foreword

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Essential oils — General rules for packaging, conditioning and storage

Huiles essentielles — Règles générales d'emballage, de conditionnement et de stockage

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Foreword

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The committee responsible for this document is ISO/TC 54, *Essential oils*.

This first edition of ISO/TS 210 cancels and replaces ISO/TR 210:1999 which has been technically revised.

Essential oils — General rules for packaging, conditioning and storage

1 Scope

This Technical Specification describes the specifications to be met by the containers intended for containing essential oils, as well as recommendations relating to their conditioning and storage.

Essential oils are used for different purposes:

— food use;

— pharmaceutical use;

— perfumery and cosmetic use;

— reference samples or test samples;

— industrial raw materials.

According to the use of the essential oils, it is necessary to use appropriate containers which also meet the requirements of national, European, or international regulations.

This Technical Specification describes the materials to be used for the containers intended for containing essential oils, depending on the uses listed above. It also gives some general rules and recommendations relating to the properties of these containers and their conditioning and storage.

NOTE The information given in this Technical Specification does not substitute for the regulations in force in the different countries.

2 Composition of the containers

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.

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

2.1.1 Glass[1]

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

Tinted antiactinic glass is always advisable.

2.1.2 Metals and alloys

2.1.2.1 Stainless steel[2]

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.

Table 1

Tantalum	1 % max.
Niobium	1 % max.
Zirconium	1 % max.
Molybdenum	4 % max.
Titanium	4 % max.
Aluminium	4 % max.
Copper	4 % max.

2.1.2.2 Aluminium and aluminium alloys[3][4][5]

2.1.2.2.1 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.

Table 2

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 0,10 % (m/m) and 0,20 % (m/m), on condition that the chromium and manganese contents are less than 0,05 % (m/m)

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

Table 3

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.

Table 3

Tin	0,1 % max.
Arsenic, Tantalum, Beryllium, Thallium, Lead, and each of the other impurities present.	0,05 % max, with a total ≤ to 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 of 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, provided that they are authorized by the regulations in force in the countries concerning the materials and products in contact with food. (See Clause 3).

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 the 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 and particularly the temperature and the 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.

2.1.2.3 Tin[6][7]

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.

2.1.2.4 Copper, zinc, galvanized iron[6]

Except during the distillation process, direct contact between the essential oil and these materials is forbidden.

2.1.3 Polymers: plastics and varnishes

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

The authorized global migration limit is established by the national or international regulations in force in the countries,[9][10][11][12][13][14] and, depending on the case, 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,[16] which also include migration limits for some of these substances[15][17] are authorized as components of plastics materials.

2.1.4 Ceramic, vitrified, enamelled materials, used for internal coating

These materials shall not release lead and cadmium in larger quantities than those laid down by the national or international regulations in force in the countries.[8]

2.2 Materials for containers intended for containing essential oils for pharmaceutical use

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

All packaging shall have 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 differ, but generally refer to

— general principles of Pharmacopoeia (European,[1] American,[21] or Japanese,[22] 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.

2.2.1 Glass

The glass used is of type III and shall comply with the Pharmacopoeia standards concerning its hydrolytic resistance.

Tinted antiactinic glass is advisable in all cases.

2.2.2 Metals and alloys

These materials shall have the same properties and stresses as those described throughout 2.1.2.

2.2.3 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, and

— a control of water or solvent extraction, etc.

2.2.4 Ceramic, vitrified, enamelled materials, used for internal coatings

Varnished, enamelled, vitrified, ceramic coatings shall meet the same constraints as the materials used for food essential oils, as described in paragraph 2.1.4.

2.3 Materials for containers intended for containing essential oils for perfumery and cosmetic use

All the previously listed materials (see 2.1 and 2.2) may be used, on condition that they do not alter the composition of the essential oil or its organoleptic properties: appearance, colour, odour, etc.

Because they are oxidation catalysts, copper and iron are not advisable.

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

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

— the ageing of the packed product.

2.4 Materials for containers intended for containing reference samples or test samples of essential oils

The only advisable material is tinted antiactinic glass.

2.5 Materials for containers intended for containing essential oils used as industrial raw materials

Tinted antiactinic glass is advisable, but all the materials quoted in 2.1 to 2.4 may also be used.

3 Pigments or colourings[18]

If containers intended for containing essentials oils for food use (2.1) or pharmaceutical use (2.2) are coloured, the pigments or colourings used shall comply with the regulations in force, similar to those of the additives of plastics.

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

Table 4

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 [19].

4 Characteristics for containers intended for containing essential oils

4.1 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 2).

The most frequently used types of container are the following:

— flasks;

— cans;

— barrels;

— drums;

— tanks.

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

4.2 Capacity

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

It varies from few millilitres to several thousand litres.

4.3 Closures

4.3.1 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 apply also to all types of closures without any restriction.

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

4.4 External solderings

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

5 Conditioning and storage

5.1 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 made sure that they do not contain any products likely to alter the quality of the essential oil.

Glass containers which are not made of tinted antiactinic glass shall be protected from light.

The containers shall not be completely filled. A head space, the volume of which is determined following the expected changes in temperature conditions during transport (in general, it represents a maximum of 5 % to 10 % depending on the capacity of the container), shall be left free.

This head space between the essential oil and the container shall be filled with nitrogen or another inert gas at the time of the filling.

5.2 Storage

Essential oils are flammable liquids[1)], and shall be stored in special places.

It is necessary, in addition, to check that the containers do not permit any loss of liquid or vapour.

1) Transport is not included in this Technical Specification. See the national or international regulations in force in the different countries relating to the storage and transport of dangerous goods.

The containers shall be protected against any accidental breakage.

They shall be stored in a place sheltered from light and heat and maintained at a constant temperature.

5.3 Special cases

By agreement between the parties concerned, it can happen that, only for transportation, the essential oils are provisionally packed in containers made of aluminium or tin-plate.

In this case, the essential oils shall be decanted on receipt into tinted antiactinic glass containers for storage.

Any container which has been opened either for decantation or the taking of samples, shall be re-stoppered immediately after use in such a way it will be as tight as possible.

If there is a large quantity of the essential oil taken from the container, decant the remaining essential oil into a smaller container for storage.

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[5] EN 602, *Aluminium and aluminium alloys — Wrought products — Chemical composition of semi-products used for the fabrication of articles for use in contact with food*

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[18] Council directive — Resolution AP (89) 1, 1989-09-13

[19] Order dated 19 July 1985 relating to the method for the determination of the benzo (A) pyrene in coffee ; published in the Official Journal dated 18 August 1985

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[22] Japanese Pharmacopoeia

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