TECHNICAL REPORT

ISO/TR 210

First edition
1999-03-01

Essential oils — General rules for packaging, conditioning and storage

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

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 main task of technical committees is to prepare International Standards, but in exceptional circumstances a technical committee may propose the publication of a Technical Report of one of the following types:

— type 1, when the required support cannot be obtained for the publication of an International Standard, despite repeated efforts;

— type 2, when the subject is still under technical development or where for any other reason there is the future but not immediate possibility of an agreement on an International Standard;

— type 3, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example).

Technical Reports of types 1 and 2 are subject to review within three years of publication, to decide whether they can be transformed into International Standards. Technical Reports of type 3 do not necessarily have to be reviewed until the data they provide are considered to be no longer valid or useful.

ISO/TR 210, which is a Technical Report of type 2, was prepared by Technical Committee ISO/TC 54, *Essential oils*.

This document is being issued in the Technical Report (type 2) series of publications (according to subclause G.3.2.2 of part 1 of the ISO/IEC Directives, 1995) as a "prospective standard for provisional application" in the field of essential oils because there is an urgent need for guidance on how standards is this field should be used to meet an identified need.

This document is not to be regarded as an "International Standard". It is proposed for provisional application so that information and experience of its use in practice may be gathered. Comments on the content of this document should be sent to the ISO Central Secretariat.

A review of this Technical Report (type 2) will be carried out not later than three years after its publication with the options of: extension for another three years; conversion into an International Standard; or withdrawal.

This first edition of ISO/TR 210 cancels and replaces ISO/R 210:1961, which has been technically revised.

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Essential oils — General rules for packaging, conditioning and storage

1 Scope

This Technical Report 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, as follows:

— 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 Report 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 Report does not substitute for the regulations in force in the different countries.

2 Composition of the containers

2.1 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.

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

2.2.1 **Glass** (see reference [1])

Type II glass (soda-calcic glass, according to Pharmacopoeia standards), is advisable as it maintains unchanged the organoleptic properties of the essential oils.

Tinted anti-actinic glass is always recommended.

2.2.2 Metals and alloys

2.2.2.1 **Stainless steel** (see reference [2])

These materials shall contain at least 13 % of chromium.

They also may contain nickel and/or manganese.

Furthermore, one or more of the following elements may be included, provided they do not exceed the limits given in Table 1 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.

2.2.2.2 **Aluminium and aluminium alloys** (see references [3] to [5])

Aluminium shall be at least 99 % pure.

The total content of impurities shall not exceed 1 %, and they are limited as given 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 impurities present	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*)

In the aluminium alloys, the percentage by mass of the elements which may be added or which are present as impurities shall not exceed the values given 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.
Tin	0,1 % max.
Arsenic, tantalum, beryllium, thallium, lead and each of the other impurities present	0,05 % max, with a total less than or equal to 0,15 %

The anodization of aluminium or aluminium alloy materials and objects complying with the provisions of clauses 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;

— sulfosalicylic 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 concerned for materials and products in contact with food. (See clause 3.)

A compulsory final filling operation is carried out with the exception of the aluminium or aluminium alloy materials and products anodized in a phosphoric medium or covered by coating, in conformity withclause 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.

2.2..3 Tin (see references [6] and [7])

The 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.

2.2.24 Copper, zinc and galvanized iron (see reference [6])

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

2.2.3 Polymers: plastics and varnishes

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

The authorized global migration limit is established by the national or international regulations in force in different countries (see references [9] to [14]), and, depending on the case, is 60 mg/kg or 10 mg/dm² (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.

2.2.4 Ceramic, vitrified or enamelled materials used for internal coatings

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 country concerned [8].

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

2.3.1 General

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

All packaging shall have a Licencing Approval delivered by the relevant authorities.

NOTE This authorization forms a part of the Licencing 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;

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

2.3.2 Glass

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

Tinted anti-actinic glass is recommended in all cases.

2.3.3 Metals and alloys

These materials shall have the same properties as those described in 2.2.2.

2.3.4 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.

2.3.5 Ceramic, vitrified or 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 2.2.4.

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

All the previously listed materials (see 2.2 and 2.3) 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 permeability to carbon dioxide, oxygen, steam, fragrances, etc., and

— the ageing of the packed product.

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

The only recommended material is tinted anti-actinic glass.

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

Tinted anti-actinic glass is recommended, but all the materials quoted in 2.2 to 2.5 may also be used.

3 Pigments or colourings (see reference [18])

If containers intended for containing essentials oils for food use (see 2.2) or pharmaceutical use (see 2.3) 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 given 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 of 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 a 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 shall be 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 to contain 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.

Glass containers which are not made of tinted anti-actinic 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, this 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 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.

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 may be 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 anti-actinic 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, the remaining essential oil shall be decanted into a smaller container for storage.

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