

ITALY

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9. ITALY**PETROLEUM WAXES**
NATURAL ESTER WAXES

USAGE : **In/on food** - As coating

REGULATIONS

Decreto Ministeriale 31 March 1965 : "Control of chemical additives permitted for the preparation and preservation of food substances".

The above is modified by later regulations, namely :

- Decreto Ministeriale 28 July 1967
- Decreto Ministeriale 20 February 1968
- Decreto Ministeriale 1 July 1972.

GENERAL TERMS OF REGULATIONS

(a) **Paraffina solida** (by implication in the later regulations this term in Decreto 31 March 1965 appears to include both paraffin and microcrystalline waxes) of specified purity is permitted to be used for surface treatment of listed foods, namely :

- cheese
- dried fruit with skin/rind
- products of pork butchery not subsequently to be cooked.

In all instances the usage must be according to "good industrial practice".

(b) **Carnauba wax** of specified purity is permitted to be used for coating confectionery and chocolate in accordance with good industrial practice. Similarly the pure wax, and also specified mixtures containing refined carnauba wax, are permitted to be used for coating citrus fruits.

WAX QUALITY

(a) **Petroleum waxes**

Definitions : **Paraffin wax** - a solid mass of saturated hydrocarbons with macro-crystalline structure.

Microcrystalline wax - a solid mass of saturated hydrocarbons with microcrystalline molecular structure.

Melting point (for both wax types) : not less than 52°C

Polycyclic aromatic hydrocarbons : Waxes must pass a test similar to that in the US FDA regulations : Section 172.886 procedure is given in Decreto 20 February 1968 and differs only in slight detail from that of the US test devised by Howard, Haenni and Joe. UV extinction requirements are identical with the US test, namely :

- 280 to 289 nm : 0.15 max.
- 290 to 299 nm : 0.12 max.
- 300 to 359 nm : 0.08 max.
- 360 to 400 nm : 0.02 max.

(b) Carnauba wax

Appearance : Smooth mass of yellowish colour

Melting point : 83 to 86°C

Saponification number : 78 to 88

Unsaponifiable matter : Less than 55 %

Arsenic : Less than 3 mg/kg

Lead : Less than 10 mg/kg

Other heavy metals : Less than 20 mg/kg

Must be free from paraffins and stearic acid.

9. ITALY**PETROLEUM WAXES**
NATURAL ESTER WAXES

USAGE : **In contact with food**

REGULATIONS

Decreto Ministeriale 21 March 1973 : "Health regulations regarding packaging materials, containers, and implements destined for contact with foodstuffs or with articles for personal use".

The above is modified by later regulations, namely :

- Decreto ministeriale 3 August 1974
- Decreto ministeriale 19 November 1974
- Decreto ministeriale 27 March 1975
- Decreto Ministeriale 13 September 1975
- Decreto ministeriale 18 June 1979.

SUMMARY OF GENERAL TERMS OF REGULATIONS**(a) Petroleum waxes**1. Decreto 21 March 1973**Title 1 - "General rules"**

States the general requirement that global migration as determined by specified tests, shall not exceed 8 mg/dm² or 50 ppm.

Title 2 - "Regulations regarding specific materials"

Under Chapter IV - "Articles of paper and cardboard" specifies :

- Article 27 :
 - a) For foodstuffs of types I, II, III, IV (listed in the Decreto, Annex III), composition must be at least 75 % fibrous material, not more than 10 % of charge substances (fillers) and not more than 15 % of auxiliary substances.
 - b) For foodstuffs of type V, composition must be at least 60 % fibrous materials, 25 % maximum of charge substances, and a maximum 15 % of auxiliary substances.

(Waxes are regarded as auxiliary substances).

- Article 33 : Paper and cardboard used in contact with food must conform to the regulations for "Plastic Materials" in Title 2 Chapter I which specifies the global migration tests to be used; for fatty foods (types II and III) sunflower oil is specified as simulant - procedure and conditions are given in Annex IV Section I. (See also Decreto 18 June 1979 below).

Annex II - "List of authorised substances for the preparation of articles destined for contact with foodstuffs"

Section 4 - "Paper and Cardboard" : The requirements of Title 2, Article 27 above for fibrous materials, charge substances and auxiliary substances are repeated, and the permitted substances listed and defined. Auxiliary substances, total 15 % maximum, of which 10 % must be soluble or partially soluble in water and/or solvent, and 5 % insoluble in water and/or solvent.

- The solvent is defined as a 1:2 ethanol/benzene mixture in Annex IV Section VI which also specifies the procedure for testing solubility.
- Paraffin waxes and microcrystalline waxes are listed as "soluble and/or partially soluble", and must comply with purity requirements given in Annex IV Section IV Item 1.

Purity requirements - Annex IV Section IV Item 1 - "Paraffin and microcrystalline waxes" specifies that waxes must pass a test for polycyclic aromatic hydrocarbons of the type devised by Howard, Haenni and Joe and differing in only slight detail from that in the US FDA regulations Section 172.886. Procedure is identical to that of Decreto Ministeriale 20 February 1968. UV extinction requirements are also identical, namely :

- 280 to 289 nm : 0.15 max.
- 290 to 299 nm : 0.12 max.
- 300 to 359 nm : 0.08 max.
- 360 to 400 nm : 0.02 max.

Classification of foodstuffs - Annex III specifies types I, II, III, IV and V by means of lists of particular foods and the type of simulant to be used in the migration tests.

Global migration tests - Annex IV Section I specifies for fatty foods (types II and III) sunflower oil is specified as the simulant. This is modified by Decreto 3 August 1974 stating that olive oil or (in certain instances) sunflower oil is to be used.

Analytical control of composition of paper and cardboard - Annex IV Section VI specifies analytical methods, including estimation of soluble substances.

Components of plastic materials, rubbers and regenerated cellulose contacting food - Paraffin waxes and microcrystalline waxes meeting the above purity requirements are listed as permitted for use in connection with the above materials as follows :

- Plastics : Annex II Section 1 - Paraffin waxes as additives
- Rubbers : Annex II Section 2 - Microcrystalline waxes as additives
- Regenerated cellulose : Annex II Section 3 - Both paraffin and micro-crystalline waxes as auxiliary components.

2. Decreto 3 August 1974

Gives new specifications for the global migration test : olive oil or sunflower oil to be used.

3. Decreto 27 March 1975

This extended the above postponement.

4. Decreto 18 June 1979

This stated that the following should be added to Article 33 of Decreto Ministeriale 21 March 1973 :

"Paper and cardboard and articles made of these materials which are waxed ("paraffinati") on the side in direct contact with the food, and which have a wax content greater than that provided for in Annex II Section 4A of the Decreto Ministeriale 21 March 1973, may only be used as counter paper ("carte da banco") and as containers of refrigerated, frozen or deep-frozen food. The above-mentioned paper, cardboard and articles are not subject to migration tests provided that the paper and paraffin wax or microcrystalline wax conform to the respective properties given in Decreto Ministeriale 21 March 1973 and subsequent modifications."

This Decreto also added to the tests for purity of paper and cardboard given in Annex IV Section 6A.

[**Decreto 19 November 1974** - Relates to method for determining migration of vinyl chloride monomer.

Decreto 13 September 1975 - Relates to various plastic materials and regenerated cellulose.]

(b) Non-petroleum waxes

1. Decreto 21 March 1973

Plastic materials : Beeswax, carnauba wax, montan wax - Annex II Section 1 lists these waxes as permitted additives for plastics contacting food. No specific requirements are mentioned.

Regenerated cellulose : Carnauba wax and montan wax are listed as permitted auxiliary components for regenerated cellulose contacting food. No specific quality requirements are mentioned.

9. ITALY**PARAFFIN WAX**
NATURAL ESTER WAXES

USAGE : **In pharmacy**

REGULATIONS

Italian Pharmacopoeia, 1972.

GENERAL TERMS OF REGULATIONS

The Pharmacopoeia has sections on

1. Paraffinum solidum (hard paraffin)
2. Cera alba (white beeswax)
3. Cetaceum (spermaceti)

QUALITY REQUIREMENTS**1. Paraffinum solidum (hard paraffin)**

Definition : A purified mixture of solid hydrocarbons derived from petroleum.

Description : A solid mass, colour white to yellowish, practically free from odour and taste.

Solubility : Insoluble in water; the solubility in certain other solvents is described in general terms.

Melting point : In the range of 68°C to 72°C (test method specified).

Identification : A burning test, and reaction on heating the wax with sulphur are described as means of identification.

Acidity/alkalinity : The molten wax is mixed with an equal volume of hot alcohol, which has previously been neutralised; after having been heated to boiling then cooled, the alcohol must be neutral to paper impregnated with tincture of sunflower.

Carbonisable substances : A test similar to that described in the Italian Pharmacopoeia for "Paraffina liquida" is specified.

2. Cera alba (white beeswax)

As from 1983 the requirements of the Italian Pharmacopoeia have become identical with those of the European Pharmacopoeia for this wax (Section 19 : European Economic Community gives a summary).

3. Cetaceum (spermaceti)

Definition : The wax is defined by its origin and by its principal constituent cetyl palmitate.

Description : A somewhat translucent mass, white, slightly greasy to the touch, with a crystalline fracture and the appearance of mother-of-pearl; practically odourless and tasteless.

Solubility : Insoluble in water; practically insoluble in cold alcohol, soluble in boiling alcohol. The solubility in certain other solvents is described in general terms.

Melting point (flow point) : 42°C - 50°C (test method is specified).

Iodine value : Not greater than 8.0 (method specified).

Saponification value : 115 to 135 (method specified).

Acid value : Not greater than 1.0 (method specified).

Paraffin, foreign wax, free acid : 0.5 g wax is heated under reflux with 45 ml 90 % v/v alcohol. The solution should be clear and colourless, and after the addition of 0.15 ml of 0.1 N sodium hydroxide solution should become alkaline to phenolphthalein.

Stearic acid : Approximately 1 g wax is heated in a closed vessel with 10 ml ammonia solution (specified) until completely melted. The mixture is shaken vigorously for some minutes, is cooled, filtered and the filtrate acidified with hydrochloric acid. The liquid may become opalescent but must not form a precipitate.

Ash, sulphated : 0.1 % max.

9. ITALY**NATURAL ESTER WAXES**
(ADDENDUM)

USAGE : Pharmacy

REGULATIONS

The European Pharmacopoeia, 2nd Edition, includes monographs for white beeswax and yellow beeswax; for details refer to Section 19 - European Economic Community - as at August 1987 these are the only sections on waxes in the European Pharmacopoeia although it is understood that a monograph on carnauba wax is to be issued.

The Pharmacopoeia requirements for beeswax in all countries adopting the European Pharmacopoeia are therefore now identical and as given in Section 19; these requirements supersede those of the individual national pharmacopoeias.

It is understood that the following countries have agreed to adopt the requirements of the European Pharmacopoeia, either as original parties to the Convention on the Elaboration of a European Pharmacopoeia or through subsequent decisions (the European Pharmacopoeia has official status in the laws of the European Economic Community) :

Austria
Belgium
Denmark
EIRE
Finland
France

Germany
Greece
Italy
Luxembourg
Netherlands
Norway

Portugal
Spain
Sweden
Switzerland
United Kingdom

9. ITALY**SOLID PARAFFINS**
WHITE PETROLEUM JELLY

USAGE : **In pharmacy**

REGULATIONS

Italian Pharmacopoeia Ed. 8, 1973.

QUALITY REQUIREMENTS**1. Solid paraffins (paraffine solida)**

Description : Mixture of solid hydrocarbons obtained from petroleum. White and translucent.

Melting/congealing range : 68-72°C.

Carbonisable substances : Sulphuric acid test. Heat 5 ml of the molten substance with 5 ml 95 % H₂SO₄ at 100°C for 10 minutes, shaking after 2, 4, 6 and 8 minutes. Colour to be no greater than that of a specified mixture of salts solution or the corresponding lovibond colour.

2. White petroleum jelly (vaselina bianca)

Description : Mixture of refined semi-solid hydrocarbons. May contain a suitable stabilizer. White and translucent.

Melting range : 38 to 56°C.

Carbonisable substances : Sulphuric acid test. 20 mg of the petroleum jelly together with 40 g liquid paraffin are shaken with 40 g 95 % sulphuric acid for 16 minutes at 20°C. Colour of acid layer to be no greater than a specified standard solution or a quoted corresponding ASTM D1500 colour.

Fluorescence in daylight : Faint.