

FRANCE

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6. FRANCE**PETROLEUM WAXES**

USAGE : **In/on food** a) As additive or component
b) As food coating

REGULATIONS

- (a) Decree of 15 April 1912 (general) modified by Decrees n° 72-937 of 12 October 1972 and n° 73-138 of 12 February 1973
- (b) Decree of 26 October 1953 (cheese)
- (c) Circular of 16 July 1964 (cheese)
- (d) Circular Letter of 12 July 1946 (fruit)
- (e) Decree n° 73138 of 12 February 1973 modified by Decree n° 90-362 of 24 April 1990. Decree 92.631 of 8 July 1992 – Decree 94-46 of January 1994 and Decree 98-507 of 17 June 1998
- (f) Arrêté of 20 October 1997

GENERAL TERMS OF REGULATIONS

- (a) No person will be allowed to store food with the intention of selling it if it contains additives which have not been approved. Only approved chemicals may be used in the manufacture of such foods.
- (b) For the glazing of cheese paraffin wax may be used.
- (c) See A.2. Circular n° 162 of 25 April 1992.
- (d) Fruit may be coated with wax if there is no simultaneous use of antiseptics and with the appropriate labelling.
- (f) Paraffin waxes are no more used on fruits
Microcrystalline waxes are no more allowed on fruits, in confectionary and edible cheese coating (cf. Directive 95/2/EC).
They will be allowed after 4/5/2000 for the treatment of surface of
 - confectionary excluding chocolate
 - chewing gum
 - melon papaya, mango and avocado
 (cf. Directive 98/72/EC).

Even not specifically mentioned in the legislation, the paraffin waxes comply with the pharmacopoeia and the microwax with the FDA.

6. FRANCE

PETROLEUM WAXES

USAGE : **In/on food** c) In food processing

One Arrêté for one use

6. FRANCE**PETROLEUM WAXES**

USAGE : In contact with food

REGULATIONS

- (a) Decree of 15 April 1912 (general) modified by Decrees n° 72-937 of 12 October 1972 and n° 73-138 of 12 February 1973
- (b) Circulars n° 159 of 23 June 1950 and 162 of 25 April 1952 (coatings and varnishes for containers) (JORF 1227)
- (c) Circular n° 170 of 2 April 1955 (wrapping papers)
- (f) Arrêté of 9 November 1994 : rubber materials and articles intended to come into contact with food (and drinks)
Paraffin and microcrystalline waxes as plastifier and “agent de mise en oeuvre”
LMS = 0,3 mg/kg
LMS = 3 mg/kg for hydrotreated waxes

GENERAL TERMS OF REGULATIONS

- (a) No person will be allowed to store or sell food which has been in contact with materials and articles which do not comply with Decree 73-138.
- (b) These materials and articles must be specified on positive lists.
- (c) Materials and articles concerned by this regulation must be inert to food. In particular, they must not bring about an unacceptable change in the nature, substance or quality of such food (such as organoleptic or injurious characteristics).
- (d) Materials and articles sold for use in contact with food (or the bill) must be labelled as described in Decree 73-138.

QUALITY REQUIREMENTS

- Paraffin wax and refined microwax may be used provided that they do not contain any trace of carcinogenic substance.
- Inertia (to be controlled at agreed laboratories).
- **Antioxidants in coating and packaging** : Propyl gallate, octylgallate, dodecyl-gallate, BHT, BHA, EACMG and their mixtures may be used in coating and varnishes for food contact at a maximum content of 1250 ppm (decision of 3 September 1959) (JORF of 20/9/59)
- **Antioxidants in wrapping papers** : BHT may be used in coatings for wrapping papers for food contact at a maximum content of 2000 ppm.

6. FRANCE**PETROLEUM WAXES**

USAGE : **In pharmacy**

REGULATIONS

- French Pharmacopoeia ed. 8 - 1965
- French Pharmacopoeia ed. 9 - 1976
- French Pharmacopoeia ed. 10 – 1996 – see European Pharmacopoeia 1997

Sections entitled a) Paraffine solide (see European Pharmacopoeia 1997)
 Paraffine liquide – (see European Pharmacopoeia 1997)
 Paraffine liquide légère – (see European Pharmacopoeia 1997)
 b) Vaseline officinale (petrolatum album) – January 1990

GENERAL TERMS OF REGULATIONS

a) **Paraffin (paraffine)**

Identical to the European Pharmacopoeia

a) **Petrolatum album (vaseline officinale)**

Quality : Mixture of hydrocarbons obtained by purification of heavy fractions of crude oil.

Description : Unctuous pasty mass. White colour, translucent in thin layers, slightly fluorescent in daylight in molten state. Practically odourless.

Solubility : Not miscible with water. Miscible with methylene chloride in all proportions.

Melting/Congeaing range : 36-60°C.

Acidity/alkalinity test : Specified test for neutrality to phenolphthalein.

Absorbance : Solution of 0.1 g in 200 ml hexane should have absorbencies at 250-275 nm of not more than 0.2, and at 300-350 nm of not more than 0.05.

Sulphated ash : Not more than 0.03 % on a weight of A g.

Carbonisable substances : Sulphuric acid test : Heat 0.5 g petroleum jelly with 20 ml 95 % H₂SO₄ at 100°C for 10 minutes, shaking for 5 seconds every two minutes. Separate lower layer and examine at 400-450 nm using sulphuric acid as control. Absorbance to be not more than 0.4.

Homogeneity : Hold at temperature of 20°C lower than melting point for 1 hour. Vaseline to remain homogeneous.

Specification No. : On 2 g to be no more than 2.

Identification tests : Tests quoted for examination by IR spectrophotometry and iodine absorption.

6. FRANCE**SYNTHETIC HYDROCARBON WAXES**

USAGE : **In contact with food**

REGULATIONS

- (a) Decree of 15 April 1912 (general) modified by Decrees n° 72-937 of 12 October 1972 and n° 73-138 of 12 February 1973
- (b) Circular n° 159 of 23 June 1950 and Circular of 2 April 1969 amended by circular of 26 May 1971
- (c) Instructions of 30 November 1987
- (d) Arrêté of 9 November 1994

GENERAL TERMS OF REGULATIONS

- (a) Circular n° 162 of 25 April 1992.
- (b) - Natural and synthetic resins, high polymers which are insoluble and inactive with food may be used in food contact.
- (b) - Polydienic synthetic resins may be used for food contact provided that
 - . average molecular weight is 1.100;
 - . they are obtained by polymerisation of petroleum distillates ($30^{\circ}\text{C} < \text{boiling point} < 280^{\circ}\text{C}$);
 - . acid number ≤ 2 ;
 - . saponification number ≤ 2 .
- (d) Polyethylene waxes may be used as an “agent de mise en oeuvre” in rubber articles and material

6. FRANCE**NATURAL ESTER WAXES**

USAGE : In contact with food

REGULATIONS

- (a) Decree of 15 April 1912 (general) modified by Decrees n° 72-937 of 12 October 1972 and n° 73-138 of 12 February 1973
- (b) Circular n° 159 of 23 June 1950 (general)
- (c) Circular n° 162 of 25 April 1952
- (d) Circular n° 175 of 25 March 1959

GENERAL TERMS OF REGULATIONS

- (c) The following substances may be used :
 - ozokerite, provided that it does not contain carcinogenic substances,
 - beeswax
 - carnauba wax.
- (d) Refined, esterified (3 % max.) montan wax may be used.

6. FRANCE**NATURAL ESTER WAXES****USAGE : Pharmacy****REGULATIONS**

The European Pharmacopoeia, 3rd Edition, includes monographs for white beeswax and yellow beeswax (p. 659) and carnauba wax (p. 561); details refer to Section 19 - European Economic Community.

The Pharmacopoeia requirements for beeswax and carnauba wax 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