

<b>BELGIUM</b>
----------------

**INDEX**

TYPE OF WAX etc.	USAGE	PAGE
Petroleum waxes Natural ester waxes	<ul style="list-style-type: none"> <li>■ In/on food - As additive/component, coating or surface treatment</li> </ul>	2.1
	<ul style="list-style-type: none"> <li>■ In contact with food - In/on food packaging materials</li> </ul>	2.5
Petroleum waxes Natural ester waxes Montan wax and derivatives	In contact with food, as coating on cellophane film. See Section 19 - EEC	19.3
Paraffin wax	In pharmacy	2.8
Natural ester waxes	In pharmacy See also EU summary	2.9

**2. BELGIUM****PETROLEUM WAXES**  
**NATURAL ESTER WAXES**

USAGE : **In/on food** - As additive/component, coating or surface treatment

**REGULATIONS**

- (a) Royal decree, 28th February 1962, concerning materials approved as cheese coatings.
- (b) Law of 24th January 1977, concerning protection of consumers' health.
- (c) Royal decree, 27th July 1978, listing authorized food additives.
- (d) Royal decree, 2nd October 1980, concerning selling and labelling of food additives, and modifying (C).

**GENERAL TERMS OF REGULATIONS****Decree (d)**

This gives definitions of various terms namely : additive, colouring agent, preservative, antioxidant, emulsifying agent, thickening agent, gelling agent. Annex I lists permitted additives in the aforementioned categories and also under the additional headings : flavourings, anti-agglomerating agents, acids basis and salts, coatings and coverings, gases, miscellaneous.

It is clearly stated that the decree does not apply to :

- vitamins used by reason of their properties as vitamins,
- nutrients used by reason of their properties as nutrients,
- processing aids,
- artificial aromatizing agents,
- sweetening agents sold directly to consumers.

The decree states that, with the above exceptions, it is forbidden to market food additives which are not listed in Annex I of the decree, or which do not comply with the purity requirements specified in Annex II, or which contain solvents or carrier substances not listed in Annex III. Rules are also given concerning trading in, and labelling of food additives.

In Annex I of decree (d), Chapter 8 entitled "Coatings and Coverings", the following are permitted :

- beeswax
- candelilla wax
- carnauba wax
- spermaceti
- officinal paraffin
- shellac
- gum benzoin
- vegetable wax

In Chapter 3 of this Annex, entitled "Antioxidants", butylated hydroxyanisole (BHA) and butylated hydroxytoluene (BHT) are listed as permitted

In Annex III, as an authorized solvent and carrier for colouring agents is listed :

- Beeswax.

### **Decree (c)**

This lists additives permitted under the types of food for which they may be used, specifying the maximum concentrations allowed. In some instances restrictions on use are given. It also lists coatings (release aids) for moulds and plates, and in regard to cheese coatings refers to regulation (a). The references to waxes are summarized below.

<u>Usage</u>	<u>Waxes permitted</u>	<u>Quantities allowed</u>
On eggs	Officinal paraffin	QS <sup>*</sup>
On confectionery gums and marzipan shape	Officinal paraffin shellac	max. 1 g/kg <sup>**</sup> - not to be used along with
On coffee and roasted malt	Beeswax Candelilla wax Carnauba wax Colophony	max. 10 g/kg <sup>***</sup>
On coffee roasted with sugar	Beeswax Candelilla wax Carnauba wax Colophony	max. 30 g/kg <sup>****</sup>
On moulds and plates	Beeswax Spermaceti (liquid or solid) Vegetable wax	QS <sup>*</sup> QS <sup>*</sup> max. 50 g/kg
On cheese	Officinal paraffin	QS <sup>*</sup>

\* Quantum Satis

\*\* the content expressed as unsaponifiable matter, extractable with petroleum ether 40/70

\*\*\* the content expressed as ether, alcohol and water rinsable and soluble matter

\*\*\*\* the content expressed as alcohol and water rinsable and soluble matter

Decrees (c) and (d) both refer to law (b).

QUALITY REQUIREMENTS are given in Annex II of decree (d) under the same chapter headings as for the lists of approved additives in Annex I, and are given below for waxes.

## Chapter 8 : Coatings and coverings

### 8.1. General Purity Requirements

- Cd : max. 1.5 mg/kg
- Hg : max. 1.5 mg/kg
- As : max. 3 mg/kg
- Pb : max. 10 mg/kg
- Zn : max. 25 mg/kg
- Zn and Pb together : max. 50 mg/kg
- They may not contain quantities of other ingredients, notably other heavy metals, which are dangerous from a toxicological point of view.

### 8.2. Special Purity requirements

General remark : Behind the name, a number indicates the source from the purity requirements.

- (1) Purity Requirements from the advices of the Higher Health Council (H.G.R.-C.S.H.)
- (2) Purity Requirements from FAO
- (3) Purity Requirements from the Food Chemical Codex, 2nd Edition
- (4) Purity Requirements from the Belgian Pharmacopoeia, 5th Edition
- (5) Purity Requirements from the European Pharmacopoeia

#### ■ B 800 : Beeswax (1)

- Identification** : See "Traité de Matière Médicinale L. Reuter".  
**Melting zone** : 62-66, 5°C.  
**Purity requirements** : No unsaponifiable matter originating from mineral oil or paraffin.

#### ■ B 801 : Candelilla wax (3)

- Appearance** : Solid, yellow-brown, cloudy to translucent wax.  
**Spec. weight** : 0.983  
**Solubility** : Soluble in chloroform and in toluene, insoluble in water.  
**Acid number** : Between 12 and 22.  
**Melting zone** : Between 68.5°C and 72.5°C.  
**Ester number** : Between 43 and 65.  
**Purity requirements** : Lead : max. 3 mg/kg.  
 Heavy metals (as Pb) : max. 40 mg/kg.

#### ■ B 802 : Carnauba wax (3)

- Density** :  $\pm 0.997$   
**Solubility** : Partially soluble in boiling alcohol, soluble in chloroform and in either but insoluble in water.

<b>Acid number</b>	: Between 2 and 7.
<b>Ester number</b>	: Between 75 and 85.
<b>Melting zone</b>	: Between 82°C and 86°C.
<b>Unsaponifiable matter</b>	: Between 50 and 55 %.
<b>Purity requirements</b>	: Heavy metals (as Pb) : max. 40 mg/kg.

■ B 804 : Spermaceti (1)

<b>Melting zone</b>	: Between 35°C and 43°C.
<b>Identification</b>	: See "Traité de Matière Médicinale L. Reuter".

■ B 805 : Officinal paraffin (1)

The paraffin must be of officinal quality and must fulfil the requirements of the European Pharmacopoeia.

<b>Melting zone</b>	: Between 52°C and 54°C.
<b>Identification</b>	: See Pharmacopée Belge, 5th Edition, Vol. III, p. 371.
<b>Oil content</b>	: max. 0.4 %
<b>Penetration</b>	: 16
<b>Acid number</b>	: 0
<b>Saponification number</b>	: 0

■ B 806 : Shellac (1)

<b>Appearance</b>	: Thin platelets, of different sizes, light lemon yellow to brownish orange, translucent, solid and brittle, without smell and taste.
<b>Solubility</b>	: Insoluble in water, soluble in warm ethanol.
<b>Identification</b>	: See "Traité de Matière Médicinale L. Reuter".
<b>Purity requirements</b>	: Arsenic (as As) : max. 2 mg/kg, free from wax and added pigments.

■ B 807 : Gum Benzoin (4)

<b>Identification</b>	: See FAO, Serie n° 57, p. 19.
<b>Acid insoluble</b>	: Benzoin of Siam : 0.5 %.
<b>Ash content</b>	: Benzoin of Sumatra : 1 %.
<b>Drying loss</b>	: Max. 2.0 % (after 48 hours with sulphuric acid present).

■ B 808 : Vegetable wax

**Description** : Extracts of the leaves of various palm trees which have been purified to conform to the best quality specified in the Food Chemical Codex (see above for individual waxes).

**2. BELGIUM****PETROLEUM WAXES**  
**NATURAL ESTER WAXES**

USAGE : **In contact with food** - In/on food packaging materials

**REGULATIONS**

- (a) Law, 20th June 1964 : Control of foods, food substances and other products.
- (b) Royal decree,  
12th September 1972 : General rules for materials and objects intended for food contact, excluding cheese wax.
- (c) Royal decree,  
4th April 1974 : Amendments of (b),  
Rules for tin and tin alloys,  
Rules for reconstituted cellulose film.
- (d) Royal decree,  
25th August 1976 : Rules for plastic materials and articles,  
Rules for paper and cartons,  
Rules for ceramic products,  
Rules for glass articles.
- (e) Royal decree,  
29th July 1977 : Amendments of (d).
- (f) Royal decree,  
25th April 1980 : Amendments of (b) and classification of foodstuffs according to the type of migration test to be used on plastic materials in contact with the food.
- (g) Royal Decree,  
11th May 1992

(Decreets (b) - (f) are based on law (a)).

(Decree (f) refers to the law of 24th January 1977 concerning protection of consumers' health).

**GENERAL TERMS OF REGULATIONS****Decree (c)** - Appendix 2 : Reconstituted cellulose film

This lists the following waxes :

- montan waxes
- natural refined waxes (i.e. carnauba wax, beeswax, esparto wax and candelilla wax)
- pure paraffin.

The above are classified as "Special additives, Class I"; these substances are allowed on the film only in an amount equal or lower than 2 mg/dm<sup>2</sup> of the surface of the film in contact with food, and in total amount equal to or lower than 6 mg/dm<sup>2</sup>.

**Decree (d)** - Appendix 3 : Plastic materials and additives

Substances listed for use during processing include :

- microcrystalline paraffin
- natural waxes (carnauba wax, beeswax, Japanese wax, damar wax, candelilla wax, etc.)
- solid paraffin (including synthetic paraffin) complying with Pharmacopée Belge Ed. V (see 3. Pharmacy).

For the above no specific migrations are specified but the allowable maximum residue value of each of these substances in free state in the final material or article may not be more than 0.1 wt %.

For plastic materials and articles, a global migration limit of 60 mg/kg food or 10 mg/dm<sup>2</sup> contact surface is specified.

**Decree (d)** - Appendix 4 : Paper and cartons to be used in direct contact with moist or fatty foodstuffs

- Under "3.1 - Auxiliary materials, moisture and oil repellents" are listed dispersions of waxes, paraffins and polyolefins.  
The maximum amount employed is limited to 2 % of the finished product, whether in the bulk or in the surface.
- Under "3.12 - Miscellaneous materials" are listed paraffin, microcrystalline waxes - used molten, or as dispersion, or in solution.

No specific migration limit is set for these materials. The global (total) migration of components of papers and cartons (paperboard) may not exceed 60 mg/6 dm<sup>2</sup> of surface in contact with food.

**Decree (g)** - Section A, page 34/2

- Plastic materials and additives
- Ceresine
- Natural refined waxes

No specific migration required.

**Decree (g)** - Section A, page 34/9

- Paraffin waxes and oils (complying with Belgian and European pharmacopoeia)
- Microcrystalline waxes

Maximum migration 0.3 mg/kg.

**Decree (g)** - Annex 3, 2nd part, page 34/41

- Montan waxes
- Natural refined waxes
- Pure paraffin
- Refined paraffin and microcrystalline waxes

Classed as specific additives for lacquers allowed in an amount equal or lower than 2 mj/dm<sup>2</sup> of the surface of the film in contact with food and in total amount equal or lower than 6 mg/dm<sup>2</sup>.

**Decree (g)** - Annex 4, page 35

- Paper and cartons to be used in direct contact with moist or fatty foodstuffs.

§ 3.1.6 = equivalent to "Under 3.1 with no change

§ 3.12.2 = equivalent to "Under 3.12 with no change

## 2. BELGIUM

## PARAFFIN WAX

USAGE : **Pharmacy**

### REGULATIONS

(a) Belgian Pharmacopoeia 6th Edition

(b) European Pharmacopoeia

### GENERAL REQUIREMENTS OF REGULATIONS

#### **(a) Belgian Pharmacopoeia**

- solid paraffin
- white petroleum jelly.

#### **(b) European Pharmacopoeia**

- liquid paraffin
- yellow beeswax (cera flava)
- white beeswax (cera alba)

### QUALITY REQUIREMENTS

#### ■ **Solid Paraffin**

Description : White, solid and odourless substance.

Melting point : between 50°C and 60°C

Carbonisable substances : Sulphuric acid test. 5 ml of the melted wax is heated with 5 ml of 94.5-95.5 % H<sub>2</sub>SO<sub>4</sub> at 70°C for 20 minutes, shaking after 2, 4, 6 and 8 minutes. Colour of acid layer to be no greater than that of stipulated metal salt solution.

Sulphides : Must pass a specified test involving heating with basic lead acetate solution in presence of ethanol. No colour must develop.

#### ■ **White petroleum jelly**

Description : Whitish, odourless and tasteless substance obtained from the treatment of the distillation residues of petroleum. Unctuous mass. White and translucent in thin layers.

Melting/congealing range : 36-50°C open capillary.

Fluorescence : Faintly fluorescent in molten state.

## 2. BELGIUM

## NATURAL ESTER WAXES

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