

<b>DENMARK</b>
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**3. DENMARK****GENERAL REQUIREMENTS**

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

**REGULATIONS**

- (a) The Food Act dated 6 June 1973 and subsequent amendments.
- (b) Order Concerning Food Additives - No. 316 dated 8th June 1973, as amended by
  - order No. 70, dated 12 February 1974,
  - order No. 470, dated 15 September 1975,
  - order No. 523, dated 3 October 1975.
- (c) List of approved Food Additives (positive list) - published annually.
- (d) Order on the production, sale, export and import of cheese and processed cheese, etc., dated 3 December 1969, as amended by
  - order No. 558 dated 2 November 1978
  - order No. 392 dated 5 September 1980
- (e) Order No. 26 on cocoa and chocolate products dated 20 January 1977.

**GENERAL TERMS OF REGULATIONS**

Under the general terms of regulation (a) rules concerning food additives are given in (b) and (c). Regulation (c) lists foodstuffs divided into groups and the additives permitted for each, along with the function of the additive and the maximum concentration permitted. The regulation also gives a separate list of the additives classified according to their function, and an alphabetical list of permitted additives.

Orders (d) and (e) give rules relating to the respective products under the terms of regulation (a).

The provisions, or absence thereof, of the various regulations in relation to waxes and petrolatums used in/on food are summarized below.

**List of permitted additives - Regulation (c)**

- This does not show any type of wax, or petrolatum, amongst approved food additives in any of the various lists : additives for various types of food, additives listed by function, and the alphabetical index of additives.
- There is a mere mention of "cheese wax" in connection with certain colouring agents which may be used; there is no other definition given of the wax.
- The list of additives does not specifically mention "coatings" or "surface treatments" for foodstuffs.

### **Cheese - Regulation (d)**

- This contains a section entitled "Treatment of cheese surfaces etc." which mentions cheese waxing several times and states, in connection with the use of certain preservatives etc., that it is permitted to use such materials "together with coating materials including paraffin (cheese wax), plastic emulsions and plastic foils, which are approved for such purpose by the State authorities under closely specified conditions.
- Regulation (d) does not provide any further details or quality requirements for waxes used for cheese coatings.
- Regulation (c), the positive list, provides guidance concerning colouring agents which may be used in cheese wax but no details in regard to the base wax.

### **Chocolate products**

Regulation (c) does not mention use of wax as a surface treatment for chocolates.

### **Chewing gum**

Regulation (c) contains a statement to the effect that bases for chewing gum must be specially approved by the National Food Institute.

### **General note**

Advice from the Danish authorities indicates that foodstuffs containing wax etc. (as in the case of chewing gum) have to be individually approved by the Danish Food Institute.

### **Antioxidants**

The following are listed in Regulation (c) among permitted "Antioxidants and Antioxidant Synergists" and the foods in which they may be used are specified :

- butylated hydroxyanisole (BHA)
- butylated hydroxytoluene (BHT)
- tocopherols and tocopherol concentrate.

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

### REGULATIONS

In Danish legislation there are no specific regulations concerning wax in food packaging materials, however general requirements for food packaging are indicated in :

- Promulgation Order No. 121 dated 2 March 1980, (Section 32, Sub-Section 2).

### GENERAL TERMS OF REGULATIONS

Food packaging shall be of materials that give foodstuffs sufficient protection against pollution or odours from the surroundings, and which prevent the transmission of pollution or smell from food products to the surroundings, and which do not give off substances which can affect taste, smell or colour of the food, and which do not give rise to misgivings regarding health hazards.

### 3. DENMARK

PARAFFIN WAX  
NATURAL ESTER WAXES  
PETROLATUMS

USAGE : **Pharmacy**

REGULATIONS : With regard to waxes and petrolatums the Pharmacopoeia Nordica applies.

#### GENERAL REQUIREMENTS OF REGULATIONS

The Pharmacopoeia has sections on the following :

- a) Paraffinum solidum (hard paraffin)
- b) Cera alba (white beeswax)
- c) Cera flava (yellow beeswax)
- d) Cetaceum (spermaceti)
- e) Vaselinum (yellow petrolatum)
- f) Vaselinum album (white petrolatum)

#### QUALITY REQUIREMENTS

a) **Paraffinum solidum (hard paraffin)**

Definition : A mixture of solid hydrocarbons.

Description : Colourless or white to almost white, solid translucent mass, often with crystalline structure. Without odour or taste. Greasy to the touch. The aqueous extract has a neutral or almost neutral reaction.

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

Melting point : 50 to 65°C (method specified).

Solution turbidity : Solution in chloroform must pass a specified test.

Solution colour : The above solution must pass a specified test against a colour standard.

Acidity/alkalinity : Must pass a specified test limiting acidic and alkaline impurities (titration using bromocresol green as indicator).

Carbonisable impurities : Must pass a sulphuric acid test (method specified).

Residue on ignition : Max. 0.2 % (method specified).

**b) Cera alba (white wax, white beeswax)**

Definition : Manufactured from yellow beeswax by bleaching.

Description : Solid, white to yellowish-white mass. Slight Characteristic smell; almost without taste. Becomes plastic by warming in the hands. The aqueous extract has a neutral to weakly acidic reaction. In daylight the melted material exhibits a faint bluish fluorescence.

Solubility : As for cera flava.

Melting point :

Acid value :

Ester value :

Ester value/acid value ratio :

Must meet the requirements given under cera flava.

Paraffin, ceresin, carnauba wax :

Fats, fatty acids, soap, rosin :

Residue on ignition :

Peroxides : Not more than equivalent to 0.80 ml of 0.1 N thiosulphate.

Chloride : In a specified test must be more than 0.1 mg/g calculated as chlorine.

Sterilisation : 140°C, 3 hours.

**c) Cera flava (yellow wax, yellow beeswax)**

Definition : Wax obtained by melting and purifying the honeycomb constructed by the honey bee, *Apis mellifica* L.

Description : Solid, yellowish-white to yellowish-brown or greyish-brown mass with dull granular fracture. Slight smell and taste reminiscent of honey. Becomes plastic by warming in the hands. The aqueous extract has a neutral to weakly acidic reaction.

Solubility : Practically insoluble in water; solubility in certain other solvents is described in general terms. In the molten state the wax is miscible in all proportions with fatty oils and paraffin oil.

Melting point : 62°C to 65°C (method specified).

Acid value : 17 to 24 mg KOH/g (method specified).

Ester value : 66 to 81 mg KOH/g (method specified).

Ester value/acid value ratio : 3.3 to 4.3.

Paraffin, ceresin, carnauba wax : Must pass specified test indicating absence of these.

Fats, fatty acids, soap, rosin : Must pass specified test indicating absence of these.

Peroxides : Not more than equivalent to 0.03 ml of 0.1 N thiosulphate.

Residue on ignition : 0.1 % max. (method specified).

**d) Cetaceum (spermaceti)**

Definition : Wax obtained by cooling and refining of oily material from cavities, especially in the head, of *Physeter macrocephalus* L.

Description : White, brittle mass crystallizing in large flakes, translucent in thin layers, has faint characteristic smell and characteristic insipid taste; greasy to the touch. The aqueous extract has a neutral to weakly acidic reaction.

Solubility : Practically insoluble in water; solubility in certain other solvents is described in general terms. In the molten state the wax is miscible in all proportions with fatty oils and paraffin oil.

Melting point : 43°C to 50°C (method specified).

Saponification value : 115 to 135 mg KOH/g (method specified)

Acid value : Max. 1.0 mg KOH/g (method specified).

Unsaturated compounds : Iodone number max. 8.0 (method specified).

Paraffin, foreign wax : The solution from the saponification test is diluted with water and must then (at 60°C) pass a specified test for turbidity.

Residue on ignition : 0.1 % max. (method specified).

**e) Vaselineum (vaselinum flavum, yellow petrolatum)**

Definition : A salve-like mixture of hydrocarbons. It is permitted to be stabilized with Ca. 0.001 % of tocopherol.

Description : Yellow to brownish-yellow, homogeneous, soft, translucent mass with faint bluish fluorescence. Without or almost without smell and taste. Greasy to the touch. The aqueous extract has a neutral or almost neutral reaction.

Solubility : Practically insoluble in water; solubility in certain other solvents is described in general terms.

Melting point :

Melting test :

Must meet the requirements given  
under vaselinum flavum

Acidity/alkalinity :

Residue on ignition :

Solution colour : Solution in chloroform must pass a specified test against colour standard.

Organic impurities : Must pass a test with potassium permanganate which limits these (method specified).

(The standards for the last three tests are more stringent than for vaselinum).

Peroxides : Not more than equivalent to 0.10 ml of 0.1 N thiosulphate (method specified).

Sterilisation : As for vaselinum flavum.

### 3. DENMARK

### 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