

<b>UNITED KINGDOM</b>
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**17. UNITED KINGDOM****PETROLEUM WAXES**

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

**REGULATIONS**

- The Mineral Hydrocarbons in Food Regulations 1966 - Statutory Instruments 1966 No. 1073 (sections also cover petrolatums and white oils).

(The general provisions of the Food and Drugs Act also apply - see page 17.3).

For equivalence of laws within England and Wales, Scotland and Northern Ireland, see page 17.5.

**GENERAL TERMS OF REGULATIONS**

- Mineral hydrocarbon can be used in the composition of preparation of any food.
- No person shall sell, consign or deliver, or import into England and Wales, any food containing any mineral hydrocarbon.
- Except for certain exemptions which are specified (in most instances a maximum limit for the amount of hydrocarbon is also specified : dried fruit, citrus fruit, sugar confectionery, chewing compound, pressed cheese, preserved eggs; food which has been in contact with mineral hydrocarbon used as lubricant or greasing agent on some surface contacting the food during its preparation; any food intended for export from the UK.

**Note** : The treatment of root vegetables with wax (e.g. as dispersion) is not specifically mentioned in these regulations, it therefore appears that such usage would be illegal in the UK.

**QUALITY REQUIREMENTS**

For all the above permitted uses, both paraffin and microcrystalline waxes shall comply with :

**Odour and taste** : Almost odourless and tasteless.

**Sulphated ash** : Not more than 0.1 percent weight.

**Acidity/alkalinity** : Test as in British Pharmacopoeia (see page 17.5).

**Sulphur compounds** : Test as for liquid paraffin in British Pharmacopoeia 1963, but carried out at 70°C or 5°C above the congealing point of the wax whichever is higher (this test has been deleted from later editions of the Pharmacopoeia).

In addition to the above, also the following quality requirements :

For all the above permitted uses <u>except</u> chewing compound		For use in chewing compound
Paraffin waxes	Microcrystalline waxes	Paraffin <u>and</u> microcrystalline waxes
<b><u>Viscosity</u></b>		
Max. 7.0 cs at 99°C	Min. 10.0 cs at 99°C	-
<b><u>UV absorption in iso-octane solution (1 g/l)</u></b>		
E 0.1% at 290 nm, 0.4 max cm	E 0.1% at 290 nm, 1.0 max cm	-
<b>or</b>	<b>or</b>	
<b><u>Control of polycyclic aromatic hydrocarbons (PCAHS) (*)</u></b>		
As alternative to these viscosity and UV absorption requirements the wax may be controlled by PCAHs as for use in chewing compounds.	As alternative to these viscosity and UV absorption requirements the wax may be controlled by PCAHs as for use in chewing compounds.	Test procedure specifies dimethyl sulphoxide/ phosphoric acid extraction followed by solution of PCAHs in iso-octane (also if necessary purification by reduction with sodium borohydrite then chromatography). Solution of PCAHs from 25 g wax in 25 ml iso-octane shall show UV extinction not more than following limits :  280-289 nm 0.15 290-299 nm 0.12 300-359 nm 0.08 360-400 nm 0.02

(\*) PCAHS : Test as described by J.W. Howard, E.O. Haenni and F.L. Joe, in the Journal of the Association of Official Agricultural Chemists, 1965, Vol. 48, No. 2, pages 304-315 (the same test as in US FDA Regulations, Section 172.886).

- **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).
- **Antioxidants in wrapping papers** : BHT may be used in coatings for wrapping papers for food contact at a maximum content of 2000 ppm.

**17. UNITED KINGDOM****PETROLEUM WAXES**

USAGE : **In/on food** - In food processing (e.g. chicken defeathering)

**REGULATIONS**

- (a) The Material and Articles in Contact with Food Regulations 1978 - Statutory Instruments 1978, No. 1927.
- (b) The Food and Drugs Act 1955.
- (c) The Food and Drugs Act (Scotland) 1956.

**GENERAL TERMS OF REGULATIONS**

These regulations make general requirements regarding quality of food and drugs - see page 17.2.

**■ Anti-foam in food processing**

This application is not specifically mentioned in any UK regulations. From Ministry statements it appears that use of petroleum wax for this purpose would probably be illegal in the UK.

**■ Defeathering of chicken**

This application is not specifically mentioned in any UK regulations, and the precise legal position is not clear. From statements by the Ministry of Agriculture, Fisheries and Food, it appears that this usage of wax is permitted so long as no wax remains on the carcass and the general requirements of the above regulations are met.

**■ Release aids**

The use of mineral hydrocarbons, including petroleum waxes, for this purpose is specifically covered by the paragraph (3 d 2) relating to lubricants and greasing agents in the Mineral Hydrocarbons in Food Regulations 1966 - see page 17.1. The Food and Drugs Act also apply - see page 17.2.

**17. UNITED KINGDOM****PETROLEUM WAXES**

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

**REGULATIONS**

- (a) The Material and Articles in Contact with Food Regulations 1978 - Statutory Instruments 1978, No. 1927.
- (b) The Food and Drugs Act 1955.

**GENERAL TERMS OF REGULATIONS**

■ **Regulation (a)**

Materials and articles to which this regulation applies shall be manufactured in accordance with good manufacturing practice, that is to say in such a way that under normal or foreseeable conditions of use they do not transfer their constituents to foods with which they are, or are likely to be, in contact, in quantities which could

1. endanger human health or
2. bring about a deterioration in the organoleptic characteristics of such food or an unacceptable change in its nature, substance or quality.

No person shall

1. sell or
2. import or
3. use in the course of a business in connection with the storage, preparation, packaging, selling or serving of food, any such material or article which does not comply with this regulation.

Materials and articles sold for use in contact with food must be labelled and described in a manner specified in the regulations.

■ **Regulation (b)**

No person shall add any substance to food, use any substance as an ingredient in the preparation of food, abstract any constituent from food, or subject food to any other process or treatment, so as (in any such case) to render the food injurious to health, with intent that the food shall be sold for human consumption in that state.

No person shall sell for human consumption, offer, expose or advertise for sale for human consumption, or have in his possession for the purpose of such sale, any food rendered injurious to health by means of any operation described above.

If a person sells to the prejudice of the purchaser any food or drug which is not of the nature, or not of the substance, or not of the quality, of the food or drug demanded by the purchaser, he shall be guilty of an offence.

Similar terms relate to drugs in this Act.

Note: Prior to regulation (a) - in force from 26 November 1979 - use of waxes in/on packaging materials was not specifically covered by UK regulations but was regarded as being permitted under the general requirements of regulations (b).

**17. UNITED KINGDOM****PETROLEUM WAXES**

USAGE : **In contact with food** - As component of plastic packaging materials

**REGULATIONS**

(a) The Material and Articles in Contact with Food Regulations 1978 - Statutory Instruments 1978, No. 1927.

(b) The Food and Drugs Act 1955.

(For equivalence of laws within England and Wales, Scotland and Northern Ireland, see page 17.6.)

**GENERAL TERMS OF REGULATIONS**

The general requirements of regulations (a) and (b) apply.

Note : Regulations (a) and (b) do not contain any detailed requirements as to the quality of materials permitted.

**17. UNITED KINGDOM****PETROLEUM WAXES**

**USAGE** : **Pharmacy**

**REGULATIONS**

British Pharmacopoeia 1988 - Section entitled "Hard Paraffin, Paraffinum Durum".

**QUALITY REQUIREMENTS**

**Definition** : Mixture of solid hydrocarbons obtained from petroleum or shale oil.

**Description** : A colourless or white substance, frequently crystalline; odourless even when freshly cut; slightly greasy to the touch. Burns with a luminous flame. When melted, liquid is free from fluorescence in day light.

**Solubility** : Practically insoluble in water and 90 % ethanol. Soluble in chloroform and in ether.

**Acidity or alkalinity** : Boil 5 g with 10 ml 90 % ethanol previously neutralised to litmus solution. Suspension to be neutral to litmus solution.

**Solidifying point** : 50°C to 57°C. Method stipulated.

**Sulphated ash** : Not more than 0.1 %. Method stipulated.

(Tests methods, reagents, etc. are specified in the British Pharmacopoeia 1988 or its Appendices).

**17. UNITED KINGDOM****PETROLEUM WAXES****UK REGULATIONS AFFECTING THE USE OF PETROLEUM WAXES IN/ON OR IN CONTACT WITH FOOD AND IN PHARMACY**

The regional coverage of these is summarized below. Where there are separate versions of a particular Act, or set of regulations, for Scotland and/or Northern Ireland as distinct from that applying to England and Wales, then all version of a particular set of regulations may be regarded as being identical as far as their essential requirements are concerned.

Equivalent Regulations applying in :

<b><u>England and Wales</u></b>	<b><u>Scotland</u></b>	<b><u>Northern Ireland</u></b>
The Food and Drugs Act 1955.	The Food and Drugs Act (Scotland) 1956.	The Food and Drugs (Northern Ireland) Act 1958.
The Mineral Hydrocarbons in Food Regulations 1966 (Statutory Instruments 1966, No. 1073).	The Mineral Hydrocarbons in Food (Scotland) Regulations 1966 (Statutory Instruments 1966, No. 1263).	The Mineral Hydrocarbons in Food (Northern Ireland) Regulations 1966 (Statutory Instruments 1966, No. 200).
<p>The materials and Articles in Contact with Food Regulations 1978 (Statutory Instruments 1978, No. 1927).</p> <p>Also amendments to these regulations :</p> <ul style="list-style-type: none"> <li>- Statutory Instruments 1980, No. 1838</li> <li>- Statutory Instruments 1982, No. 1701.</li> </ul> <p>These apply in England, Wales and Scotland.</p>		<p>The Materials and Articles in Contact with Food Regulations (Northern Ireland) 1981; S.R. 285/81.</p> <p>Also amendments to these regulations : Statutory Regulations SR 144/82 and SR 28/83.</p>

British Pharmacopoeia 1980 and its Addendum 1982 apply through England, Wales, Scotland and Northern Ireland.

**17. UNITED KINGDOM****SYNTHETIC HYDROCARBON WAXES**

USAGE : **In/on food**

**REGULATIONS**

- (a) The Material Hydrocarbons in Food Regulations 1966 - Statutory Instruments 1966, No. 1073.
- (b) The Food and Drugs Act 1955.

The UK Ministry of Agriculture, Fisheries and Food have stated that polyethylene waxes and Fischer-Tropsch waxes are regarded as complying with the definition of mineral hydrocarbon given in (a) namely, "... any hydrocarbon product... derived from any substance of mineral origin...", and that therefore the provisions of regulations (a) apply for petroleum waxes - see pages 17.1 and 17.2.

The general requirements of regulations (b) also apply - see page 17.3.

**17. UNITED KINGDOM****SYNTHETIC HYDROCARBON WAXES**

**USAGE** : **In contact with food**

**REGULATIONS**

- (a) The Materials and Articles in Contact with Food Regulations 1978 - Statutory Instruments 1978, No. 1927.
- (b) The Food and Drugs Act 1955.

The general provisions of both these sets of regulations apply - see page 17.3.

(There are no UK regulations specifically dealing with synthetic hydrocarbon waxes in contact with food.)

**17. UNITED KINGDOM****SYNTHETIC HYDROCARBON WAXES**

USAGE : **In pharmacy**

Synthetic hydrocarbon waxes are not mentioned in the British Pharmacopoeia 1980 and the Addendum 1982.

**17. UNITED KINGDOM****NATURAL ESTER WAXES**

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

**REGULATIONS**

- (a) The general provisions of the Food and Drugs Act apply (see pages 17.2 and 17.3).
- (b) The Miscellaneous Additives in Food Regulations 1974, Statutory Instruments 1974, No. 1121, also Amendment to these Regulations - Statutory Instruments 1975, No. 1485.

**GENERAL TERMS OF REGULATIONS**

- "Beeswax, white" and "Beeswax, yellow" are permitted to be used as food additives within the terms of the regulations (b) and subject to the specified quality requirements.
- "Carnauba wax" is permitted by regulations (b) to be used as food additive only in "chocolate confectionery" and "sugar confectionery" up to a maximum 200 ppm in each case; specified quality requirements must also be met.

**QUALITY REQUIREMENTS**

- "Beeswax, white" and "Beeswax, yellow" must respectively meet the criteria on pages 75 and 77 of the Food Chemicals Codex 1972, except that the ester value in each case shall be not less than 70 and not more than 80.
- "Carnauba wax" must meet the criteria on page 70 of the Food Chemicals Codex 1972.

**17. UNITED KINGDOM****NATURAL ESTER WAXES**

USAGE : **In contact with food**

**REGULATIONS**

- (a) The Materials and Articles in Contact with Food Regulations 1978 - Statutory Instruments 1978, No. 1927.
- (b) The Food and Drugs Act 1955.

The general provisions of both these sets of regulations apply - see page 17.3.

**17. UNITED KINGDOM****NATURAL ESTER WAXES**USAGE : **In pharmacy**REGULATIONS

British Pharmacopoeia 1988, sections entitled "White Beeswax", "Yellow Beeswax" and "Carnauba Wax".

QUALITY REQUIREMENTS

<u>Quality Requirements (BP 1988)</u>	<u>(a) White Beeswax</u>	<u>(b) Yellow Beeswax</u>
<u>Definition</u>	Obtained by bleaching yellow beeswax.	Obtained by melting with hot water the walls of the honeycomb of the bee, <i>Apis Mellifera</i> L., and removing foreign matter.
<u>Description</u>	White or yellowish-white; translucent when thin; with fine-grained matt non-crystalline fracture; soft and pliable when warmed by hand. Odour similar to yellow beeswax but fainter, never rancid. Tasteless, does not stick to the teeth. Relative density about 0.96.	Yellow or light brown; with fine-grained, matt non-crystalline fracture; soft and pliable when warmed by hand. Odour faint and characteristic of honey. Relative density about 0.96.
<u>Solubility</u>	Partially insoluble in water; practically insoluble in ethanol (90 %) and in ether; completely soluble in volatile and fixed oils.	As for (a).
<u>Melting point</u>	61°C to 65°C.	As for (a).
<u>Acid value</u>	17 to 24 by specified method.	17 to 22 by method as for (a).
<u>Ester value</u>	70 to 80 by specified method.	70 to 80 by method as for (a).
<u>Ratio number</u>	Ester value divided by acid value : 3.3 to 4.3.	As for (a).
<u>Saponification value</u>	87 to 104 by specified method.	87 to 102 by method as for (a).

<b><u>Quality Requirements (BP 1988)</u></b>	<b><u>(a) White Beeswax</u></b>	<b><u>(b) Yellow Beeswax</u></b>
<u>Test for ceresin, paraffin and certain other waxes</u>	Must pass specified test (saponification with ethanolic potassium hydroxide; mixture then cooled while swirling - no precipitation may form before temperature falls to 65°C).	As for (a).
<u>Test for glycerol and other polyhydric alcohols</u>	Must pass specified test to ensure not more than 0.5 % w/w calculated as glycerol, is present.	

(Tests, solvents and reagents are specified in the British Pharmacopoeia 1988 or its Appendices.)

<b><u>Quality Requirements (BP 1988)</u></b>	<b><u>Carnauba Wax</u></b>
<u>Definition</u>	Obtained from the leaves of <i>Copernicia cerifera</i> (Mart.), and purified to remove foreign matter.
<u>Description</u>	Light brown to pale yellow, moderately coarse powder, or flakes of irregular lumps of hard, brittle wax; odour characteristic and free from rancidity.
<u>Solubility</u>	Practically insoluble in water; soluble in warm chloroform and in warm toluenes; slightly soluble in boiling ethanol (96 %).
<u>Melting point</u>	78°C to 85°C.
<u>Acid value</u>	Not more than 12.0
<u>Iodine value</u>	7 to 14 (iodine monochloride method).
<u>Saponification value</u>	75 to 95.

(Tests, solvents and reagents are specified in the British Pharmacopoeia 1988 or its Appendices.)

**17. UNITED KINGDOM****NATURAL ESTER WAXES**  
**(ADDENDUM)**

USAGE : **In 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

**17. UNITED KINGDOM****PETROLATUMS**

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

**REGULATIONS**

- The Mineral Hydrocarbons in Food Regulations 1966 - Statutory Instruments 1966, No. 1073.

(The general provisions of the Food and Drugs Acts also apply - see page 17.3.)

For equivalence of laws within England and Wales, Scotland and Northern Ireland, see page 17.5.

**GENERAL TERMS OF REGULATIONS**

- No mineral hydrocarbons can be used in the composition or preparation of any food.
- No person shall sell, consign or deliver, or import in to England and Wales, any food containing any mineral hydrocarbons.
- Except for certain exemptions which are specified (in most instances a maximum limit for the amount of hydrocarbon is also specified) : dried fruit, citrus fruit, sugar confectionery, chewing compound, pressed cheese, preserved eggs; food which has been in contact with mineral hydrocarbon used as lubricant or greasing agent on some surface contacting the food during its preparation; any food intended for export from the UK.

**QUALITY REQUIREMENTS**

**Appearance** : Shall be a white translucent unctuous mixture, barely fluorescent in daylight, of semi-liquid mineral hydrocarbons.

**Sulphated ash** : Not more than 0.1 percent weight.

**UV absorption in iso-octane solution (1 g/l)** : E 0.1 % at 290 nm, 1.0 max.  
cm

**Acidity/alkalinity** : Shall comply.

**Sulphur compounds** : Shall comply (test as in British Pharmacopoeia 1963 - see page 17.4).

**17. UNITED KINGDOM****PETROLATUMS**

USAGE : **In/on food** - In food processing (as release aid, etc.)

**REGULATIONS**

- (a) The Mineral Hydrocarbons in Food Regulations 1966 - see above.
- (b) The Materials and Articles in Contact with Food Regulations 1978 - Statutory Instruments 1978, No. 1927 - see pages 17.3 and 17.4.
- (c) The Food and Drugs Acts also apply - see pages 17.3 and 17.4.

**17. UNITED KINGDOM****PETROLATUMS**

**USAGE** : **In contact with food** - In/on paper-based packaging materials  
- As component of plastic packaging materials

**REGULATIONS**

- (a) The Materials and Articles in Contact with Food Regulations 1978 - Statutory Instruments 1978, No. 1927 - see pages 17.3 and 17.4.
- (c) The Food and Drugs Acts - see pages 17.2 and 17.3.

**17. UNITED KINGDOM****PETROLATUMS**

USAGE : **In pharmacy**

**REGULATIONS**

British Pharmacopoeia 1988, sections entitled :

- (a) "White Soft Paraffin", "White Petroleum Jelly"  
 (b) "Yellow Soft Paraffin", "Yellow Petroleum Jelly".

**QUALITY REQUIREMENTS**

<b><u>Quality Requirements</u></b>	<b>(a) <u>White Soft Paraffin</u></b>	<b>(b) <u>Yellow Soft Paraffin</u></b>
<b><u>Definition</u></b>	Semi-solid mixture of hydrocarbons obtained from petroleum, and bleached.	Semi-solid mixture of hydrocarbons obtained from petroleum.
<b><u>Description</u></b>	A white, translucent, soft mass, unctuous to the touch and retaining these characters on storage and when melted and allowed to cool without stirring; not more than slightly fluorescent in daylight, even when melted; odourless when rubbed on the skin.	A pale yellow to yellow, translucent soft mass (rest of description as for (a)).
<b><u>Solubility</u></b>	Practically insoluble in water and alcohol (96 %); soluble in chloroform, ether and petroleum spirit (boiling range 40 to 60°C), the solutions sometimes showing slight opalescence.	As for (a).
<b><u>Acidity or alkalinity</u></b>	Boil 5 g with 10 ml ethanol (96 %) previously neutralised to litmus solution; the ethanol is then still neutral to litmus solution.	As for (a).
<b><u>UV absorption</u></b>	Absorbance of a 0.05 % w/w solution in 2,2,4-trimethyl-pentane, at 290 nm, not greater than 0.5.	Absorbance-tested as for (a) - shall be no greater than 0.75.
<b><u>Melting point</u></b>	38°C to 56 °C.	38°C to 56°C.
<b><u>Foreign organic matter</u></b>	Heat 1 g, until fumes appear; no acrid odour is evolved.	As for (a).
<b><u>Sulphated ash</u></b>	Not more than 0.1 %.	As for (a).

(Tests, solvents and reagents are specified in the British Pharmacopoeia 1988 or its Appendices.)