

U.S.A.

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18. U.S.A.**PETROLEUM WAXES**

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

REGULATIONS

- The US Department of Health, Education and Welfare, Food and Drug Administration, Code of Federal Regulations, Section 172.886 - Petroleum Wax.
- The general provisions for "Food Additives permitted for Direct Addition" to Food are given in Section 172.5.

GENERAL TERMS OF REGULATIONS

Petroleum wax may be safely used in or on food, in accordance with specified quality requirements and for certain specified uses only :

- in chewing gum base as a masticatory substance (Section 172.615),
- on cheese and raw fruits and vegetables as a protective coating,
- as a defoamer in food - see page 18.3.

QUALITY REQUIREMENTS

Definition : Petroleum wax is a mixture of solid hydrocarbons, paraffinic in nature, derived from petroleum, refined to meet the requirements below.

Antioxidants : Wax may contain any antioxidant permitted in food by FDA regulations - see below.

Control of polycyclic aromatic hydrocarbons (PCAHS) (*)

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 the UK Mineral Hydrocarbons in Food Regulations, 1966).

ANTIOXIDANTS

- Both butylated hydroxyanisole (BHA) and butylated hydroxytoluene (BHT) are listed in part 172 amongst additives permitted for direct addition to human food.
- Quality requirements are :
 - BHA - assay 98.5. % min (as total BHA) - melting point 48°C min.
 - BHT - assay 99 % min. (as total BHT)

18. U.S.A.**PETROLEUM WAXES**

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

REGULATIONS

The US Department of Health, Education and Welfare, Food and Drug Administration, Code of Federal Regulations, Sections 178.3710, 176.170 and 176.180.

GENERAL TERMS OF REGULATIONS

- **178.3710** : Petroleum wax may be safely used as a component of non-food articles in contact with food, in accordance with specified quality requirements.
- **176.170** : "Components of paper and paperboard in aqueous and fatty foods. - Substances identified may be safely used as components of the uncoated or coated food-contact surface of paper or paperboard intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding aqueous and fatty foods, subject to the provisions of this section."
Maximum limits are specified for the amount of chloroform - soluble components of material which can be extracted from the packaging by specified solvents under test conditions described, however, petroleum waxes of the quality specified are clearly listed as being "exempted from compliance" with this extractive limitation (however any other components of the food contact surface must also be exempt).
- **176.180** : "Components of paper and paperboard in contact with dry food." Substances identified may be safely used as components of the uncoated or coated food-contact surface of paper or paperboard intended for uses listed under 176.170 (above) but for dry food of type identified in 176.170. Substances permitted in 176.170 may be safely used.

QUALITY REQUIREMENTS

- For **176.170** and **176.180** quality requirements are those of 178.3710.
- In **178.3710** quality requirements include the definition, test for controlling PCAHs, and antioxidant clauses of 172.886, but in addition it is permitted that the wax contain up to 1 % wt of certain specified polymers where these are present as residues from wax processing aids, and also up to 0.01 % wt of 2-hydroxy-4-n-octoxybenzophenone as stabilizer.

18. U.S.A.**PETROLEUM WAXES**

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

REGULATIONS

The US FDA, Code of Federal Regulations, Sections 175.300 and 177.2600 (see also below : various specified uses).

GENERAL REQUIREMENTS

- **175.300** "Resinous and polymeric coatings" (wax as surface lubricant)
- **177.2600** "Rubber articles intended for repeated use" (wax as plasticizer)

QUALITY REQUIREMENTS

For both 175.300 and 177.2600 quality requirements, by cross reference, are as in 178.3710.

18. U.S.A.**PETROLEUM WAXES**

USAGE : **In contact with food** - Various specified uses

The US Department of Health, Education and Welfare, Food and Drug Administration, Code of Federal Regulations, contains a number of sections (other than those described on pages 18.1 and 18.2) dealing with particular minor uses of petroleum wax which involve food contact. These are listed below; since in each of these the quality requirements are those of one or other of the sections summarized on pages 18.1 and 18.2, no further details are given here.

<u>Section</u>	<u>Title</u>	<u>Quality Requirements</u>	
		<u>Section</u>	<u>Page</u>
173.340	Defoaming agents (for processing foods)	172.886	18.1
174.5	General provisions applicable to indirect food additives Adhesives	178.3710	18.3
175.105	Acrylate ester copolymer coatings	178.3710	18.3
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18. U.S.A.**PETROLEUM WAXES**

USAGE : **In pharmacy**

REGULATIONS

The US National Formulary, Fifteenth Edition, Official Monographs entitled :

1. "Paraffin"
2. "Microcrystalline wax".

Note : The US Pharmacopoeia and National Formulary were officially unified in July 1974, and with the issue in a combined edition of the Pharmacopoeia Twentieth Revision and the National Formulary Fifteenth Edition all official monographs on waxes appear only in the latter, whereas official monographs on petrolatum appear only in the USP.

QUALITY REQUIREMENTS

Requirements specified (the official monographs include details of test procedures or references to listed test methods where appropriate) are :

1. Paraffin

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

Congealing range : 47°C to 65°C.

Acidity/alkalinity : Must pass test for neutrality (to litmus).

Readily carbonisable substances : Sulphuric acid test. Must pass.

2. Microcrystalline wax

Definition : A mixture of straight-chain, branched-chain and cyclic hydrocarbons, obtained by solvent fractionation of the still bottom fraction of petroleum by suitable dewaxing or deoiling means.

Colour : Colour of the molten wax must be not darker than that of a specified reference solution.

Melting range : 54°C to 102°C.

Consistency : Needle penetration method similar to ASTM-D1321. Penetration at 25°C, 3 to 100 x 0.1 mm.

Acidity/alkalinity : Must pass tests for absence of alkalinity (phenolphthalein) and strong acids (methyl orange).

Residue on ignition : Must volatilise without emitting acrid odour, residue 0.1 % maximum.

Organic acids : Must pass test limiting these as trace impurities.

Fixed oils, fats and rosins : Must pass test indicating absence of these.

18. U.S.A.**SYNTHETIC HYDROCARBON WAXES**

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

REGULATIONS

- The US Food and Drug Administration (see page 18.1) Regulations, Sections 172.888 "Synthetic Petroleum Wax".
- The general provisions for "Food Additives permitted for Direct Addition", FDA Regulations, Section 172.5.

GENERAL TERMS OF REGULATIONS

- Synthetic petroleum wax may be safely used in or on food, in accordance with specified quality requirements and for certain specified uses only :
 - in chewing gum base as a masticatory substance (Section 172.615),
 - on cheese and raw fruits and vegetables as a protective coating,
 - as a defoamer in food in accordance with 173.340 (see page 18.5).

QUALITY REQUIREMENTS

Definition : Synthetic petroleum is a mixture of solid hydrocarbons, paraffinic in nature, prepared by catalytic polymerization of ethylene, and refined to meet the requirements below.

Molecular weight : Average molecular weight neither less than 500 nor greater than 1200 as determined by vapour pressure osmometry (*).

Control of polycyclic aromatic hydrocarbons : Test procedure and UV absorbance limits identical with those in 172.886 (page 18.1).

Antioxidants : May contain any antioxidant permitted in food by FDA regulations - see page 18.

(*) Section 172.615 also permits as a component of chewing gum base : "Polyethylene molecular weight 2000-21000".

18. U.S.A.**SYNTHETIC HYDROCARBON WAXES**

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

REGULATIONS

- The US Food and Drug Administration (see page 18.1) Regulations, Section 178.3720, 176.170 and 176.180.
- General provisions for "Indirect food additives", FDA Regulations, Section 174.5.

GENERAL TERMS OF REGULATIONS

- **178.3720** : Synthetic petroleum wax may be safely used in applications and under the same conditions where naturally derived petroleum wax is permitted - as a component of articles intended to contact food, provided that the synthetic petroleum wax meets the definitions and specifications prescribed in Section 172.888 (page 18.5).
- **176.170** : "Components of paper and paperboard in contact with aqueous and fatty foods", and
- **176.180** : "Components of paper and paperboard in contact with dry food" - Under both these sections synthetic petroleum waxes are permitted under the same terms as petroleum waxes (page 18.2) except that the quality requirements differ.

QUALITY REQUIREMENTS

In **178.3720**, **176.170** and **176.180** the quality requirements for synthetic petroleum waxes are those of Section 172.888 (page 18.5) - these waxes are therefore defined as being derived from ethylene.

(For Fischer-Tropsch waxes, see Section 175.250, page 18.6.1).

18. U.S.A.**SYNTHETIC HYDROCARBON WAXES**

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

REGULATIONS

- The US Food and Drug Administration (see page 18.1) Regulations, Section 175.250 - "Paraffin (synthetic)" (Fischer Tropsch wax).

GENERAL TERMS OF REGULATIONS

Synthetic Paraffin may be safely used as an impregnant in, coating on, or component of coatings or articles used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding food in accordance with prescribed conditions.

QUALITY REQUIREMENTS

Definition : The wax is synthesized by the Fischer-Tropsch process from carbon monoxide and hydrogen, and is further refined and treated by hydrogenation and percolation through activated charcoal.

Congealing point : ASTM-D938, min. 200°F, max. 210°F.

Properties : Oil content ASTM-D721, max. 0.5 % wt.

UV absorptivity : Absorptivity at 290 nm in decahydronaphthalene at 190°F by ASTM-D131, max. 0.01.

18. U.S.A.**SYNTHETIC HYDROCARBON WAXES**

USAGE : **In contact with food** - Various specified uses

The US FDA Code of Federal Regulations contains sections (other than those described on pages 18.5 and 18.6-18.6.1) dealing with uses of synthetic hydrocarbon waxes involving food contact. These are listed below together with a reference to one or other of the sections on previous pages which contain the appropriate quality requirements.

<u>Section</u>	<u>Title</u>	<u>Quality Requirements</u>	
		<u>Section</u>	<u>Page</u>
172.615	Chewing gum base	172.888 (polyethylene wax)	18.5
172.615	Chewing gum base	175.250 (Fischer Tropsch wax)	18.6.1
173.340	Defoaming agents for processing foods	172.888 (polyethylene wax)	18.5
175.105	Adhesives	175.250 (Fischer Tropsch wax)	18.6.1
175.300	Resinous and polymeric coatings	172.888 (polyethylene wax)	18.5

18. U.S.A.**SYNTHETIC HYDROCARBON WAXES**

USAGE : **In pharmacy**

Synthetic hydrocarbon waxes do not feature in either the US Pharmacopoeia or the US National Formulary.

18. U.S.A.**NATURAL ESTER WAXES**

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

REGULATIONS

- **Generally Recognized as Safe (GRAS)** - Certain naturally occurring ester waxes are accepted as Generally Recognized as Safe (GRAS) for use in food. The following Sections of the US FDA Regulations apply :
 - 182.1973 : Beeswax
 - 182.1975 : Bleached beeswax
 - 182.1978 : Carnauba wax
- The above waxes may therefore, in principle, be used for applications where the corresponding FDA section permits GRAS materials e.g. chewing gum base (Section 172.615).

REQUIREMENTS OF REGULATIONS**■ Rice bran wax : US FDA Regulations, Section 172.890**

This section permits the use of rice bran wax in certain specified foods (candy, fresh fruits and fresh vegetables, chewing gum) providing quality requirements are met; the function of the additive and concentration limits are also specified.

- **Definition** : Refined wax obtained from rice bran.

■ Quality requirements

Melting point : 75°C to 80°C

Free fatty acids : max. 10 %

Iodine number : max. 20

Saponification number : 75 to 120.

(Use of rice bran wax in chewing gum is also covered by Section 172.615 : "chewing gum base).

18. U.S.A.**NATURAL ESTER WAXES**

USAGE : In contact with food

- In/on paper-based packaging materials
- As components of plastic packaging materials
- Various specified uses

The following Sections of the US FDA Regulations specifically permit the use of named ester waxes in particular applications involving food contact :

<u>Section</u>	<u>Title</u>	<u>Waxes permitted</u>
175.300	Resinous and polymeric coatings	Spermaceti
175.320	Resinous and polymeric coatings for polyolefine films.	Candelilla, Carnauba, Spermaceti
176.170	Components of paper and paperboard in contact with aqueous and fatty foods.	Japan wax
176.180	Components of paper and paperboard in contact with dry food.	Japan wax
176.210	Defoaming agents used in the manufacture of paper and paperboard.	Montan wax

18. U.S.A.**NATURAL ESTER WAXES**

USAGE : **In pharmacy**

REGULATIONS

The US National Formulary, Fifteenth Edition, Official Monographs entitled :

1. Carnauba wax
2. Cetyl esters wax
3. White wax (Beeswax)
4. Yellow wax (Beeswax)

(See note under "Petroleum Waxes - Pharmacy".)

QUALITY REQUIREMENTS

Requirements specified (the official monographs include details of test procedures or references to listed test methods where appropriate) are :

1. Carnauba wax

Definition : Wax obtained from the leaves of Copernicia cerifera.

Melting range : 81°C to 86°C.

Residue on ignition : Must volatilise without emitting acrid odour; residue 0.25 % maximum.

Heavy metals : 0.004 %.

Acid value : 2 to 7 mg KOH per g.

Saponification value : 80 to 95 mg KOH per g.

2. Cetyl esters wax

Definition : A mixture consisting primarily of esters of saturated fatty alcohols (C₁₄ to C₁₈) and saturated fatty acids (C₁₄ to C₁₈)

Melting range : 43°C to 47°C.

Acid value : Maximum 5 mg KOH per g.

Saponification value : 109 to 120 mg KOH per g.

Iodine value : 1 maximum.

Paraffin and free acids : Must pass test indicating absence of paraffin and that alcoholic solution is neutral or acidic to moist litmus paper.

1. White wax

Definition : "The product of bleaching and purifying Yellow Wax that is obtained from the honeycomb of the bee (*apis mellifera*) and that meets the requirements of the saponification cloud test".

Melting range : 62°C to 65°C.

Carnauba wax : Must pass test indicating absence.

Saponification cloud test : Must pass.

Fats or fatty acids, Japan wax, rosin and soap : Must pass test indicating absence of these.

Acid value : 17 to 24 mg KOH per g.

Ester value : 72 to 79 mg KOH per g.

2. Yellow wax

Definition : "The purified wax from the honeycomb of the bee (*apis mellifera*)." The crude beeswax used to prepare yellow wax must itself conform to the saponification cloud test.

Other requirements : Yellow wax must meet the requirements specified for white wax as regard melting range, Carnauba wax, saponification cloud test, fats or fatty acids, Japan wax rosin and soap, acid value and ester value.

Acid value : Maximum 5 mg KOH per g.

Saponification value : 109 to 120 mg KOH per g.

Iodine value : 1 maximum.

Paraffin and free acids : Must pass test indicating absence of paraffin and that alcoholic solution is neutral or acidic to moist litmus paper.

18. U.S.A.**NATURAL ESTER WAXES****SPECIFICATIONS OF THE AMERICAN WAX IMPORTERS AND REFINERS ASSOCIATION, INC.****1. Specifications - Genuine pure beeswax (March 1968)**

Scope : Applies to yellow refined beeswax and white bleached beeswax, also to crude beeswax provided it has been filtered to remove "all insoluble impurities and moisture".

Composition : The purified wax rendered from the honeycomb of the bee, *apis mellifera* linné. It should be free of extenders or admixtures of other substances.

Visual examination : By transmitted light the molten wax at 70°C "shall show no cloudiness and no more than a negligible amount of insoluble precipitated or suspended matter".

Physical and chemical properties : Test methods for determining the following characteristics are specified and designated as Amerwax test methods.

<u>Minimum</u>	<u>Maximum</u>	
Melting point (capillary method), °C	62	65
Acid value	17	24
Ester value	72	79
Ratio number (ester value/acid value)	3.3	4.2
Saponification cloud point, °C	-	65

The specifications also give directions on sampling and homogenisation of the sample.

2. Specifications - Genuine pure candelilla wax (October 1960)

Scope : Applies to

Mexican designation	American designation	Colour
Prime crude	Prime crude	Tan to brown
-	USA pure refined	Light yellow to tan

Composition : The wax shall be an original virgin product made directly from the wax coating on the reeds of the plant (principally from the "*euphorbia antisiphilitica*", the "*euphorbia cerifera*" and the "*pedilanthus pavonis*").

It shall be free of extenders and admixtures of other substances and shall conform to the following requirements and shall be so guaranteed by the seller.

Genuine pure USA filter refined candelilla wax must conform to the specifications and the wax shall be free of extenders and admixtures of other substances and shall so be guaranteed by the seller.

Physical and chemical properties

	Prime crude	USA pure refined
Melting point - min.	68.5°C - 155.3°F	68.5°C - 155.3°F
Melting point - max.	72.5°C - 162.5°F	72.5°C - 162.5°F
Flash point - min.	241°C - 465°F	241°C - 465°F
Volatile matter (moisture incl.)- max. %	1.5	Negligible
Insoluble impurities - max. %	1.0	Negligible
Acid number - min.	12.0	12.0
Acid number - max.	22.0	22.0
Saponification number - min.	43.0	43.0
Saponification number - max.	65.0	65.0
Paraffinic hydrocarbons - max. %	45.0	45.0
Acetone soluble resinous matter - % at 15°C	min. 15.0 max. 28.0	15.0 28.0
Benzene solubility - max. % at 25°C	40.0	40.0

Test methods for determining the above characteristics are specified.

3. Specifications - Genuine pure carnauba wax (October 1976)

Scope : Applies to

Mexican designation

American designation

Type 1 - Flor
Primeira

Flor
Prime or No. 1 yellow

Type 2 - Mediana

Medium or No. 2 yellow

Type 3 - Cauipe
Gorda clara

Cauhype
Gorda clara or Light fatty or No. 2 north country

Type 4 - Gardarosa

Fatty grey or No. 3 north country

Composition : The wax shall be an original virgin product made directly from the powder obtained from the leaves of carnauba palm (copernicia cerifera). It shall be free of extenders and admixtures of other substances and shall conform to the following requirements and

shall be so guaranteed by the seller.

Physical and chemical properties

Colour : The colour of types 1, 2 and 3 shall be no darker than that of the official colour card of the American Wax Importers and Refiners Association, unless otherwise agreed upon by the seller and the purchaser.

	Crude		Centri- fuged Fatty type 4	Filter press Refined	
	Yellow types 1 & 2	Fatty types 3 & 4		Yellow types 1 & 2	Fatty types 3 & 4
Melting point - min.	83°C 181.4°F	82.5°C 180.5°F	82.5°C 180.5°F	83°C 181.4°F	82.5°C 180.5°F
Flash point - min.	310°C 590°F	299°C 570°F	299°C 570°F	310°C 590°F	299°C 570°F
Volatile matter (moisture incl.) - max. %	2.0	1.5	1.0	Neglig.	Neglig.
Insoluble impurities- max. %	1.0	2.0	0.5	Neglig.	Neglig.
Acid number - min.	2.0	4.0	4.0	2.0	4.0
Acid number - max.	6.0	10.0	10.0	6.0	10.0
Saponification number- min.	78.0	78.0	78.0	78.0	78.0
Saponification number- max.	88.0	88.0	88.0	88.0	88.0
Paraffinic hydrocarbons - max. %	2.0	2.0	2.0	2.0	2.0
Acetone soluble resinous matter - max. % at 15°C	5.0	3.5	3.5	5.0	3.5
Benzene solubility - max. % at 25°C	8.0	8.0	8.0	8.0	8.0

Test methods for determining the above characteristics are specified.

4. Specifications - Genuine pure ouricury wax (October 1960)

Scope : Applies to

Brazilian designation	American designation	Colour
Crude - original	Crude - original	Dark greenish Brown to dark Greenish black
-	USA pure refined	Light tan to dark brown

Composition : The Brazilian crude ouricury shall be an original virgin product made directly from the powder obtained from the leaves of the ouricury palm (syagrus coronata) and shall be free of extenders and admixtures of other substances and shall conform to the following requirements and shall be so guaranteed by the seller.

Genuine pure USA filter press refined ouricury wax must conform to the specifications and the wax shall be free of extenders and admixtures of other substances and shall so be guaranteed by the seller.

Physical and chemical properties

	Brazilian crude	USA pure refined
Melting point - min.	82.5°C - 180.5°F	62.5°C - 180.5°F
Flash point - min.	277°C - 530°F	277°C - 530°F
Volatile matter (moisture incl.)- max. %	1.0	Negligible
Insoluble impurities - max. %	3.0	Negligible
Acid number - min.	8.0	8.0
Acid number - max.	18.0	18.0
Saponification number - min.	80.0	80.0
Saponification number - max.	105.0	105.0
Paraffinic hydrocarbons - max. %	3.0	3.0
Acetone soluble resinous matter - max. % at 15°C	9.0	9.0
Benzene solubility - max. % at 25°C	18.0	18.0

Test methods for determining the above characteristics are specified.

18. U.S.A.**PETROLATUMS**

USAGE : In/on food - As additive or component
 - As coating
 - In food processing (anti-foams, release aids)

REGULATIONS

- The US Department of Health, Education and Welfare, Food and Drug Administration, Code of Federal Regulations, Section 172.880 - Petrolatum.
- The general provisions for "Food Additives permitted for Direct Addition" are given in the Code of Federal Regulations, Section 172.5.

GENERAL TERMS OF REGULATIONS

- Petrolatum may be safely used in food, subject to specified quality requirements and for certain specified uses only, with maximum concentration limits for each.
- Specified uses :
 - in bakery products, as release agent and lubricant
 - in confectionery, as release agent and as sealing and polishing agent
 - in dehydrated fruits and vegetables, as release agent
 - in egg white solids, as release agent
 - on raw fruits and vegetables, as protective coating
 - in beet sugar and yeast, as defoaming agent (*).

(*) FDA Section 173.340 - Defoaming Agents - also deals with this use but refers back to 172.880).

QUALITY REQUIREMENTS

- Definition and description, solubility, colour, specific gravity, melting range, consistency, alkalinity/acidity, residue on ignition, organic acids, and presence of fixed oils, fats and rosins must meet specifications in the US Pharmacopoeia for "Petrolatum" or "White Petrolatum" (pages 18.13 and 18.13.1).
- UV absorbance limits : Test procedure of Howard, Haenni and Joe as given in FDA Section 172.886 (for petroleum waxes used in/on food - see page 18.1), but UV absorbance per cm path length must be more than the following limits :
 - 280-289 nm : 0.25 max.
 - 290-299 nm : 0.20 max.
 - 300-359 nm : 0.14 max.
 - 360-400 nm : 0.04 max.
- Antioxidants : Petrolatums may contain any antioxidant permitted in food by FDA regulations in amount "not greater than that required to produce its intended effect" (see page 18.1).

18. U.S.A.**PETROLATUMS**

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

REGULATIONS

The US FDA, Code of Federal Regulations, Sections 178.3700, 176.170 and 176.180.

GENERAL TERMS OF REGULATIONS

- **178.3700** : Petrolatum may be safely used as a component of non-food articles in contact with food, in accordance with specified quality requirements and for the specified uses (in some cases with concentration limits) in FDA sections. Uses specified include coating of surfaces of metal or wood fermentation tanks.
- **176.170** : "Components of paper and paperboard in aqueous and fatty foods. For summary of general terms see page 18.2; petrolatums of the quality specified may be used and are exempted from compliance with the extractive limitation (however any other components of the food contact surface must also be exempt).
- **176.180** : "Components of paper and paperboard in contact with dry food." For summary of general terms see page 18.2. Substances permitted in 176.170 may be safely used, including petrolatum of specified quality.

QUALITY REQUIREMENTS

Definition and description, solubility, colour, specific gravity, melting range, consistency, alkalinity/acidity, residue on ignition, organic acids, presence of fixed oils, fats and rosins, UV absorbance limits and antioxidants :

"For 176.170 and 176.180 the quality requirements are those of 178.3700, which in turn are specified as identical with those of 172.880 - see pages 18.10 and 18.13."

18. U.S.A.**PETROLATUMS**

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

REGULATIONS

The US FDA, Code of Federal Regulations, Sections 177.2600 and 177.2800 (see also 177.1640 below).

GENERAL TERMS OF REGULATIONS

- **177.2600** : "Rubber articles intended for repeated use" in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding food. Amongst permitted plasticizers petrolatums (and petroleum waxes) are specifically mentioned; these must meet quality requirements.
- **177.2800** : "Textiles and textile fibres" intended for uses in contact with food as listed above for 177.2600. Permitted adjuvant substances listed include petrolatums (and petroleum waxes) subject to compliance with quality requirements.
- **177** : Other sections in Part 177 may by cross reference permit use of petrolatums of appropriate quality as components of other synthetic materials. For example 177.1640 : "Polystyrene and rubber-modified polystyrene" permits "optional adjuvant substances - permitted for such use by regulation in Parts 170 through 189".

QUALITY REQUIREMENTS

For all above uses the quality requirements are those of 172.880 - see pages 18.10 and 18.14.

18. U.S.A.**PETROLATUMS**

USAGE : **In contact with food** - Various specified uses

The FDA Code of Federal Regulations in sections other than those previously described, deals with uses of petrolatums involving food contact; the quality requirements of these refer to the sections dealt with on previous pages :

<u>Section</u>	<u>Title</u>	<u>Quality Requirements</u>	
		<u>Section</u>	<u>Page</u>
173.340	Defoaming agents.	172.888 (concentration limits specified)	18.10
172.615	Substances for use only as components of adhesives.	178.3700	18.11
173.340	Resinous and polymeric coatings (petrolatum as release agent or surface lubricant).	178.3700	18.11
175.105	Lubricants with incidental food contact.	178.3700 (limit of 10 ppm specified)	18.11

18. U.S.A.**PETROLATUMS**

USAGE : **In pharmacy**

REGULATIONS

The US Pharmacopoeia, Twentieth Revision, Official Monographs entitled :

1. Petrolatum
2. White petrolatum

(See note under "Petroleum Waxes - Pharmacy".)

QUALITY REQUIREMENTS

Requirements specified (the official monographs include details of test procedures or references to listed test methods where appropriate) are :

1. Petrolatum

Definition : A purified mixture of semi-solid hydrocarbons obtained from petroleum. It may contain a suitable stabilizer.

Specific gravity : at 60°C, 0.815 to 0.880.

Congealing range : 38°C to 60°C.

Consistency : Cone penetration method specified similar to ASTM-D937. Penetration at 25°C, 100 to 300 x 0.1 mm.

Acidity/alkalinity : Must pass test for absence of alkalinity (phenolphthalein) and strong acids (methyl orange).

Residue on ignition : Must volatilise without emitting acrid odour; residue 0.1 % maximum.

Organic acids : Must pass test limiting these as trace impurities.

Fixed oils, fats and rosins : Must pass test indicating absence of these.

Colour : Colour of the molten petrolatum must be no darker than that of a specified reference solution.

2. White petrolatum

Definition : A purified mixture of semi-solid hydrocarbons obtained from petroleum, and wholly or nearly decolorized. It may contain a suitable stabilizer.

Colour : Colour of the molten petrolatum must be no darker than that of a specified reference solution (different from that for petrolatum).

Residue on ignition : Must volatilise without emitting acrid odour; residue 0.05 % maximum.

Other requirements : White petrolatum must meet the requirements specified for petrolatum for specific gravity, melting range, consistency, alkalinity/acidity, organic acids and fixed oils, fats and rosins.

