

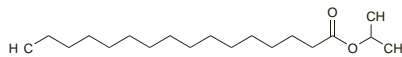
Isopropyl Palmitate

Isopropyl palmitát; Isopropyle, palmitate d'; Isopropylis palmitas; Isopropylpalmitat; Isopropylpalmitaatti; Izopropilo palmitatas; Izopropil-palmitát; Palmitato de isopropilo. Hexadecanoic acid 1-methylethyl ester; Isopropyl hexadecanoate.

Изопропилапальмитат

$C_{19}H_{38}O_2 = 298.5$.

CAS — 142-91-6.



Pharmacopoeias. In *Eur.* (see p.vii). Also in *USNF*.

Ph. Eur. 6.2 (Isopropyl Palmitate). A clear, colourless, oily liquid. Relative density about 0.854. Immiscible with water; miscible with alcohol, with dichloromethane, with fatty oils, and with liquid paraffin. Protect from light.

USNF 26 (Isopropyl Palmitate). A colourless, mobile, liquid with a very slight odour. Insoluble in water, in glycerol, and in propylene glycol; soluble in alcohol, in acetone, in castor oil, in chloroform, in cottonseed oil, in ethyl acetate, and in mineral oil. Store in airtight containers. Protect from light.

Profile

Isopropyl palmitate has properties and uses similar to those of isopropyl myristate (above).

Hypersensitivity. Sensitivity reactions to isopropyl palmitate have been reported rarely.

Preparations

Proprietary Preparations (details are given in Part 3)

Multi-ingredient: **Chile:** Fotoprotector Isdin Extrem.

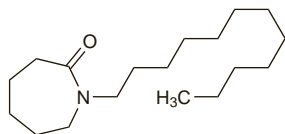
Laurocapram (*USAN, INN*)

Azone; Laurocapramum; N-0252. 1-Dodecylazacycloheptan-2-one; 1-Dodecylhexahydro-2H-azepin-2-one.

Лаурокапрам

$C_{18}H_{35}NO = 281.5$.

CAS — 59227-89-3.



Pharmacopoeias. In *Chin.*

Profile

Laurocapram has been investigated for enhancing the penetration of drugs through the skin.

Microcrystalline Wax

Amorphous Wax; Cera microcristalina; Cerum microcrystallinum; Cire microcristalline; E905; Petroleum Ceresin; Petroleum Wax (microcrystalline).

Микрокристаллический Воск

CAS — 63231-60-7.

Pharmacopoeias. In *USNF*.

USNF 26 (Microcrystalline Wax). 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 de-oiling means. A white or cream-coloured odourless waxy solid. Melting range 54° to 102°. Insoluble in water; sparingly soluble in dehydrated alcohol; soluble in chloroform, in ether, in volatile oils, and in most warm fixed oils. Store in airtight containers.

Profile

Microcrystalline wax is used as a stiffening agent in creams and ointments and as a coating agent for solid dosage forms, including modified-release preparations. Microcrystalline wax is also used in foods and cosmetics.

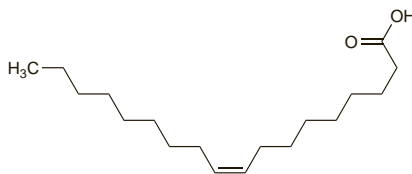
Oleic Acid

Acide oléique; Acidum oleicum; Elaïc Acid; Kwas oleinowy; Kyselina olejová; Olajsav; Oleico, ácido; Oleinic Acid; Oleino rūgštis; Oljesyra; Öljyhappo; Ölsäure. (Z)-9-Octadecanoic acid.

Масляная Кислота; Олеиновая Кислота

$C_{18}H_{34}O_2 = 282.5$.

CAS — 112-80-1.



Pharmacopoeias. In *Eur.* (see p.vii). Also in *USNF*.

Ph. Eur. 6.2 (Oleic Acid). It contains 65 to 88% of oleic acid together with varying amounts of saturated and other unsaturated fatty acids. It may contain a suitable antioxidant. It is a clear, yellowish or brownish, oily liquid. Practically insoluble in water; miscible with alcohol and with dichloromethane. Store in well-filled airtight containers. Protect from light.

USNF 26 (Oleic Acid). It is manufactured from fats and oils derived from edible sources, animal or vegetable, and consists chiefly of oleic acid. It may contain suitable stabilisers. Oleic acid solely for external use is exempt from the requirement that it be prepared from edible sources. It is a colourless to pale yellow oily liquid when freshly prepared with a characteristic lard-like odour. On exposure to air it gradually absorbs oxygen and darkens in colour. When strongly heated in air, it is decomposed with the production of acid vapours. Congealing point between 3° and 10° for oleic acid from animal sources and between 10° and 16° for oleic acid from vegetable sources. Practically insoluble in water; miscible with alcohol, with chloroform, with ether, with benzene and with fixed and volatile oils. Store in airtight containers.

Profile

Oleic acid forms soaps with alkaline substances and is used as an emulsifying or solubilising agent. It occurs in edible fats and oils which are used as foods or food components. Oleic acid is used in topical preparations, including transdermal films and patches, and in oral and inhalation preparations. It has also been used as a choleretic.

Preparations

BP 2008: Chloroxylene Solution; White Liniment.

Proprietary Preparations (details are given in Part 3)

Multi-ingredient: **Braz.:** Glavit; Primoris; **Chile:** Acnoxyl Jabon†.

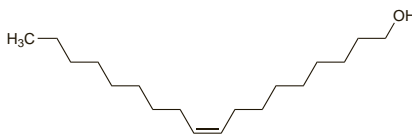
Oleyl Alcohol

Alcohol oleico; Alcohol oleicus; cis-9-Octadecen-1-ol; Oleic Alcohol; Oleilo alkoholis; Olélique (alcool); Oleo Alcohol; Oleol; Oleylalkohol; Olelylalkoholi. (Z)-Octadec-9-en-1-ol.

Олеиловый Спирт

$C_{18}H_{36}O = 268.5$.

CAS — 143-28-2.



Pharmacopoeias. In *Eur.* (see p.vii). Also in *USNF*.

Ph. Eur. 6.2 (Oleyl Alcohol). A mixture of unsaturated and saturated long-chain fatty alcohols consisting mainly of oleyl alcohol and elaidyl alcohol; (E)-octadec-9-en-1-ol; trans-9-octadeceno-1-ol) It may be of vegetable or animal origin. A colourless or light yellow liquid.

USNF 26 (Oleyl Alcohol). A mixture of unsaturated and saturated high molecular weight fatty alcohols consisting chiefly of oleyl alcohol. A clear, colourless to light yellow, oily liquid with a faint characteristic odour. Insoluble in water; soluble in alcohol, in ether, in isopropyl alcohol, and in light liquid paraffin. Store in well-filled airtight containers at a temperature not exceeding 25°.

Profile

Oleyl alcohol is used as an emollient, as an emulsifying and solubilising agent, and as a penetration enhancer in substances applied externally, including some delivered via transdermal patches. Oleyl alcohol has also been used in aerosol preparations for rectal use. The acetate has also been used.

Fractionated Palm Kernel Oil

Aceite de palma refinado.

Масло Пальмовое Косточковое Фракционированное; Фракционированное Пальмоядровое Масло

Pharmacopoeias. In *Br.*

BP 2008 (Fractionated Palm Kernel Oil). It is obtained by expression of the natural oil from the kernels of *Elaeis guineensis*

followed by selective solvent fractionation and hydrogenation. A white, odourless or almost odourless, solid, brittle fat. M.p. 31° to 36°. Practically insoluble in water and in alcohol; miscible with chloroform, with ether, and with petroleum spirit (boiling range, 40° to 60°). Store at a temperature not exceeding 25°.

Profile

Fractionated palm kernel oil is used as a basis for suppositories. It is also used in food manufacturing. The unfractionated oil has been used as an emollient and as an ointment basis.

The oil obtained from the flesh of the fruit is known as palm oil and is also used in cooking; the composition and properties of these 2 oils are, however, different.

Hard Paraffin

Cera de parafina; Hard Wax; Hartparaffin; Kietasis parafinas; Paraff. Dur.; Paraffin; Paraffin, fast; Paraffin Wax; Paraffine solide; Paraffinum Durum; Paraffinum solidum; Parafini, kintea; Parafin tvrdý; Parafina sólida; Parafina stala; Szilárd paraffin.

Твёрдый Парафин

CAS — 8002-74-2.

Pharmacopoeias. In *Chin.*, *Eur.* (see p.vii), *Int.*, and *Jpn.* Also in *USNF*.

USNF also includes Synthetic Paraffin.

Ph. Eur. 6.2 (Paraffin, Hard). A purified mixture of solid saturated hydrocarbons, generally obtained from petroleum. M.p. 50° to 61°. It is a colourless or white mass. The melted substance is free from fluorescence in daylight. Practically insoluble in water and in alcohol; freely soluble in dichloromethane. Protect from light.

USNF 26 (Paraffin). A purified mixture of solid saturated hydrocarbons obtained from petroleum. It may contain suitable antioxidants. It is a colourless or white, odourless, more or less translucent mass showing a crystalline structure, and is slightly greasy to the touch. It has a congealing range of 47° to 65°. Insoluble in water and in alcohol; slightly soluble in dehydrated alcohol; freely soluble in chloroform, in ether, in volatile oils, and in most warm fixed oils. An alcoholic extract is neutral to litmus. Store at a temperature not exceeding 40°. Protect from light.

USNF 26 (Synthetic Paraffin). A very hard odourless white wax containing mostly long-chain, unbranched, saturated hydrocarbons, with a small amount of branched hydrocarbons. The average molecular weight may range from 400 to 1400. Insoluble in water; very slightly soluble in aliphatic, oxygenated, and halogenated hydrocarbon solvents; slightly soluble in aromatic and normal paraffinic solvents.

Profile

Hard paraffin is used mainly as a stiffening agent in ointment bases. It is also used in creams, and as a coating for capsules and tablets.

Hard paraffin is used in physiotherapy in the form of paraffin-wax baths for the relief of pain in inflamed joints and sprains.

The injection of paraffins may produce granulomatous reactions.

Preparations

BP 2008: Paraffin Ointment; Simple Ointment; Wool Alcohols Ointment.

Proprietary Preparations (details are given in Part 3)

Fr.: Cuticerin.

Multi-ingredient: **Fr.:** Grassolind Neutral; **UK:** Melrose.

Liquid Paraffin

905 (mineral hydrocarbons); Aceite de parafina; Aceite de vaselina; Aceite mineral; Aceite mineral blanco; Dickflüssiges Paraffin; Folyékony paraffin; Heavy Liquid Petrolatum; Heavy Mineral Oil; Huile de Vaseline Épaisse; Liquid Petrolatum; Mineral Oil; Oleum Petrolei; Oleum Vaselini; Paraffin, flytande; Paraffin Oil; Paraffine liquide; Paraffinum liquidum; Paraffinum Subliquidum; Parafini, nestemäinen; Parafin tekutý; Parafina cieka; Parafina líquida; Skystasis parafinas; Sivi Parafin; Vaselineöl; Vaselinum Liquidum; White Mineral Oil.

Вазелиновое Масло; Жидкий Вазелин; Медицинское Парафиновое Масло; Парафин Жидкий

CAS — 8012-95-1.

ATC — A06AA01.

ATC Vet — QA06AA01.

Pharmacopoeias. In *Chin.*, *Eur.* (see p.vii), *Jpn.*, and *US*.

Ph. Eur. 6.2 (Paraffin, Liquid). A purified mixture of liquid saturated hydrocarbons obtained from petroleum. It is a transparent, colourless, oily liquid, free from fluorescence in daylight. Relative density 0.827 to 0.890. Viscosity 110 to 230 mPa.s. Practically insoluble in water; slightly soluble in alcohol; miscible with hydrocarbons. Protect from light.

USP 31 (Mineral Oil). A purified mixture of liquid hydrocarbons obtained from petroleum. It may contain a suitable stabiliser. It is a transparent, colourless, odourless or almost odourless, oily liquid, free, or practically free, from fluorescence. Insoluble in water and in alcohol; soluble in volatile oils; miscible with fixed oils (except castor oil). Store in airtight containers. Protect from light.

Light Liquid Paraffin

Dünnflüssiges Paraffin; Hígan folyó paraffin; Huile de Vaseline Fluide; Light Liquid Petrolatum; Light Mineral Oil; Light White Mineral Oil; Paraff. Liq. Lev.; Paraffin, lättflytande; Paraffine liquide légère; Paraffinum Liquidum Leve; Paraffinum Liquidum Tenue; Paraffinum perliquidum; Paraffini, kevyt nestemäinen; Paraffin tekutý lehký; Skystasis lengvas parafinas; Spray Paraffin; Vaselina líquida.

ATC — A06AA01.

ATC Vet — QA06AA01.

Pharmacopoeias. In *Eur.* (see p.vii) and *Jpn.* Also in *USNF US* also includes Topical Light Mineral Oil.

Ph. Eur. 6.2 (Paraffin, Light Liquid). A purified mixture of liquid saturated hydrocarbons obtained from petroleum. It is a transparent, colourless, oily liquid, free from fluorescence in daylight. Relative density 0.810 to 0.875. Viscosity 25 to 80 mPa s. Practically insoluble in water; slightly soluble in alcohol; miscible with hydrocarbons. Protect from light.

USNF 26 (Light Mineral Oil). A purified mixture of liquid hydrocarbons obtained from petroleum. It may contain a suitable stabiliser. It has similar characteristics to Mineral Oil but a lower kinematic viscosity. Store in airtight containers. Protect from light.

Adverse Effects and Precautions

Excessive oral or rectal dosage with liquid paraffin may result in anal seepage and irritation, excessive purgation, and watery diarrhoea. Liquid paraffin is absorbed to a slight extent and may give rise to foreign-body granulomatous reactions. Similar reactions have followed the injection of liquid paraffin and may be considerably delayed in onset. Injection may also cause vasospasm and prompt surgical removal may be required to prevent severe damage. Lipoid pneumonia has been reported after aspiration of liquid paraffin. Because of the risk of aspiration, oral liquid paraffin should not be given to patients who have difficulty swallowing, or to those with impaired neurodevelopment.

Some licensed product information warns that chronic ingestion of liquid paraffin may rarely be associated with impaired absorption of fat-soluble vitamins and possibly other compounds. There is little published evidence to support this. Prolonged use should, however, be avoided. Liquid paraffin should not be used when abdominal pain, nausea, or vomiting is present. The UK CSM considers that it should not be used in children under 3 years of age.

Granuloma. References.

- Di Benedetto G, *et al.* Paraffin oil injection in the body: an obsolete and destructive procedure. *Ann Plast Surg* 2002; **49**: 391–6.

Lipoid pneumonia. References.

- Becton DL, *et al.* Lipoid pneumonia in an adolescent girl secondary to use of lip gloss. *J Pediatr* 1984; **105**: 421–3.
- Ohwada A, *et al.* Exogenous lipoid pneumonia following ingestion of liquid paraffin. *Intern Med* 2002; **41**: 483–6.
- Karacan O, *et al.* Fire-eater's pneumonia after aspiration of liquid paraffin. *Turk J Pediatr* 2006; **48**: 85–8.
- Meltzer E, *et al.* Lipoid pneumonia: a preventable complication. *Isr Med Assoc J* 2006; **8**: 33–5.

Uses and Administration

Taken orally, liquid paraffin acts as a lubricant and, since it keeps the stools soft, it has been used in the symptomatic treatment of constipation (p.1693), although it should be used with caution because of its adverse effects. The recommended daily oral dose is 10 to 30 mL in divided doses, preferably before breakfast and at night. An emulsion of liquid paraffin may also be used in a dose of 10 to 30 mL at night. Liquid paraffin and its preparations should not, however, be taken immediately before going to bed. Liquid paraffin is an ingredient of several preparations that contain other laxatives such as cascara, magnesium hydroxide, or phenolphthalein. It has also been given as an enema in a usual dose of 120 mL.

Externally, liquid paraffin may be used as an ingredient of ointment bases, as an emollient and cleanser in certain skin conditions, and as an ophthalmic lubricant in the management of dry eye (p.2140).

Light liquid paraffin has similar uses to liquid paraffin.

Administration in children. UK licensed product information gives the following oral doses of liquid paraffin for constipation in children, to be taken at night:

- under 3 years: not recommended
- 3 to 5 years: 2.5 to 5 mL
- 5 to 12 years: 5 to 10 mL
- over 12 years: as for adults

For light liquid paraffin, the *BNFC* recommends a daily oral dose of 0.5 to 1 mL/kg, up to a maximum of 45 mL, for children aged 3 to 18 years. It should be taken after the evening meal but not immediately before going to bed, and may be mixed with ice-cream or yogurt to improve palatability.

The *BNFC* gives the following oral doses of liquid paraffin emulsion, to be taken once daily but not immediately before going to bed:

- under 3 years: not recommended
- 3 to 12 years: 0.5 to 1 mL/kg, up to a maximum of 30 mL
- 12 to 18 years: as for adults

The symbol † denotes a preparation no longer actively marketed

Preparations

BP 2008: Cetomacrogol Emulsifying Ointment; Cetrimide Emulsifying Ointment; Emulsifying Ointment; Light Liquid Paraffin Eye Drops; Liquid Paraffin and Magnesium Hydroxide Oral Emulsion; Liquid Paraffin Oral Emulsion; Simple Eye Ointment; Wool Alcohols Ointment;

USP 31: Bland Lubricating Ophthalmic Ointment; Mineral Oil Emulsion; Mineral Oil Rectal; Topical Light Mineral Oil.

Proprietary Preparations (details are given in Part 3)

Arg.: Babi; Lansoy; Lax Ewe Jalea; Laxante Arceli; Laxuave Enteral; Laxuave Jalea; Lexavitte; Lubritina Franklin; Modaton NI; Oilatium; **Austral:** Agarol; Hamilton Skin Therapy; Oilatium Bar; Oilatium Emollient; Oilatium Shower Gel; **Belg.:** Lansoy; **Braz.:** Nujol; **Canad.:** Fleet Enema Mineral Oil; Lansoy; Nujol; **Chile:** Laxonarol; **Cz.:** Oilatium Emollient; Oilatium Gel; **Fr.:** Lansoy; Laxamalt; Lubenty; Oilatium Emollient; Oilatium Soap; Restrical; **Ger.:** Agarol Nf; Obstinol M; **Gr.:** Agarol Plain; Nujol; Paragel; **Hong Kong:** Agarol; Hamilton Body Wash; Keni; Oilatium Bar; Oilatium Emollient; Oilatium Gel; Vigarol; **Indon.:** Oilatium Bar; Oilatium Gel; **Irl.:** Alcodemir; Oilatium Gel; Oilatium Junior; Oilatium Soap; **Ital.:** Agarol CM†; Duratirs†; **Malaysia:** Balneum; Egogize Protective Baby Lotion; Laxaron†; Oilatium; **NZ:** Fleet Mineral Enema†; Oilatium; **Philipp.:** Oilatium; **Pol.:** Oilatium; **S.Afr.:** Oilatium Bar; Oilatium Emollient; **Singapore:** Balneum; Laxarol; Nutradem†; Oilatium Bar; Oilatium Emollient; Oilatium Gel; **Spain:** Emulquen Simple; Hodernal; **Switz.:** Lansoy; Laxamalt; Paragol NI; **Thai:** Agarol; Oilatium Bar; Oilatium Emollient; Oilatium Gel; **Turk.:** Duratears; Sokol; **UK:** CetraBen Emollient; Dermamist; Keni; Oilatium Bath Formula; Oilatium Fragrance Free; Oilatium Gel; Oilatium Junior; Oilatium Soap; Zerobase; **USA:** Kondremul; Liqui-Doss.

Multi-ingredient: **Arg.:** Agarol; Alcon Lagrimas; Aqualane; Cold Cream Nature†; Mil-Par; Usar Fibras†; **Austral:** Alpha Keni; DermaVeen Shower & Bath; Dermaze; Duratears; E45; Egogize Baby Cream; Granugen; Hamilton Body Lotion†; Hamilton Cleansing Lotion†; Hamilton Dry Skin; Laci-Lube; Oilatium Plus; Parachoc; Pinetarsol; Rikodem†; Soov Prickly Heat; **Austria:** Balneum F; Neda Fruchtewurfel; **Belg.:** Duratears; Lacrytube; Tulle Vaseline†; **Braz.:** Agarol; Balmex; Fenogar†; Parapsy†; **Canad.:** Agarol Plain; Akwa Tears; Alpha Keni†; Duolube; Duratears†; Epise; Huile de Bain Therapeutique; Hypotears; Lubriderm Advanced Moisture†; Lubriderm†; Magnolax; Oilatium; Optilube; Penederm†; Puralube†; Refresh Laci-Lube; Tears Naturelle PM; Therapeutic Bath Oil†; Therapeutic Skin Lotion†; **Chile:** Acnaid; Acnoxyl Jabon†; Agarol; Cold Cream Avenue; Durasolets; Duratears; Laci-Lube; **Cz.:** Balmadol; Balneum Hermal F; Oilatium Plus; **Denm.:** Ojensalve Neutral; **Fin.:** Laci-Lube; **Fr.:** Cerat; Inalterable; Cold Cream Nature†; Dexeryl; Lubenty† a la Magnesie; Melaxose; Oilatium Body Oil†; Oilatium Cream†; Parapsyllium; Transulose; **Ger.:** Allergika†; Balneum F; Cellosorb; Coliquifim; Excipial; Gletgel; Oleobal; Parfenac Basisbad†; Vita-POS; Windol Basisbad†; **Gr.:** Duratears; **Hong Kong:** Alpha Keni; Balneum; Duratears; Ego Skin Cream; Egogize Baby Cream; Hydromol†; Oilatium Cream; Oilatium Plus; Polytar Emollient; Soov Prickly Heat; **India:** Agarol†; CetraBen; Cremaffin; EasyLax; **Indon.:** Laxadine; Oilatium Plus; Yanthi Baby Oil†; **Irl.:** Emulsiderm; Hydromol†; Laci-Lube; Oilatium Emollient; Oilatium Junior; Oilatium Junior Flare-Up†; Oilatium Plus; Polytar Emollient†; **Israel:** Balneum F; CleanEars; Duratears; Emulsiderm; Lacrimol; **Ital.:** Balneum Hermal Forte; Duolaxan†; LaciLube; **Malaysia:** Balneum; Duratears Naturelle; Ego Skin Cream; Egogize Baby Cream; LaciLube†; Oilatium; Oilatium Plus Antibacterial; QV Flare Up; Soov Prickly Heat†; **Mex.:** Acuafl†; Milpar; **Neth.:** Duratears J; Transulose; **Norw.:** Simplex; **NZ:** Alpha Keni; BK; DP; DP Lotion - HC; Ego Skin Cream; Egogize Baby Cream; Hydromol; Kari-care Breast and Body Cream†; LaciLube; Oilatium Plus; Poly-Visc; Polytar Emollient; **Philipp.:** Oilatium; Oilatium Plus; **Pol.:** Amfobase; Balneum Hermal F; Diprobaze; E45; Mentho-Paraffinol; Oilatium Plus; Unibasis; **Port.:** Banholeum Gele; Betacade†; Melaxose; Oleoban Gelf†; **S.Afr.:** Oilatium Plus; **Singapore:** Balneum; DermaVeen Shower & Bath; Duratears; Ego Skin Cream; Egogize Baby Cream; Egogize Protective Baby Lotion†; Laci-Lube; Oilatium Plus; QV Flare Up; Soov Prickly Heat†; **Spain:** Acete Acalorile; Emuliquen Laxante; Lubrillim; Vasetatum; **Switz.:** Antidry; Balmadol; Balmex Hermal F; Balneum Hermal F†; Coliquifim†; Paragol; Voloderma†; **Thai:** Balneum†; Duratears; Emulax; Oilatium Cream; Oilatium Plus; **Turk.:** Balmadol; **UK:** 5050; Alpha Keni; Ashbourne Emollient Medical Bath Oil†; CetraBen Emollient; Dermalmo; Dermalmo; Diprobaze; Diprobath; Doublebase; Emollin; Emulsiderm; Epaderm; Hydromol; Imuderm; Infaderm; Laci-Lube; Lubri-Tears; Mil-Par; Oilatium Cream; Oilatium Emollient; Oilatium Junior; Oilatium Junior Flare-Up†; Oilatium Plus; Polytar Emollient; **USA:** Agarol; Akwa Tears; Alpha Keni; Bodi Care Lotion; Bodi Oil; Destin Creamy; Dry Eyes; Duratears Naturelle; Geri-Silk; Haley's M-O; Hemorid For Women; Hydrocerin; Hypotears; Laci-Gel; Laci-Lube; Lacti-care; LubriFresh PM; LubriTears; Paladin; Puralube; Refresh PM; Soothe XP; Styte; Tears Again; Tears Renewed; Throat Discs; Vagisil; **Venez.:** Agarol†; Lacrimart†; Mil-Par; Milcor†; Oleoderm.

White Soft Paraffin

905 (mineral hydrocarbons); Minkštasis baltas parafinas; Paraff. Moll. Alb.; Paraffinum Molle Album; Parafina blanda blanca; Valk-ovaseiliini; Vaseline, vitt; Vaseline blanca; Vaseline Branca; Vaseline filante; Vaseline blanche; Vaseline Officinal; Vaselinum album; Vazelina bílá; Wazelina biala; White Petrolatum; White Petroleum Jelly.

Белый Вазелин

Pharmacopoeias. In *Chin.*, *Eur.* (see p.vii), *Int.*, *Jpn.*, *US*, and *Viet*.

Many pharmacopoeias use the title Vaselinum Album; in some countries the name 'Vaseline' is a trade-mark.

Ph. Eur. 6.2 (Paraffin, White Soft). Purified and wholly or nearly decolorised mixture of semi-solid hydrocarbons, obtained from petroleum. It may contain a suitable antioxidant. It is not suitable for oral use. A white or almost white, translucent, soft unctuous mass, slightly fluorescent in daylight when melted. Drop point 35° to 70°. Practically insoluble in water, in alcohol, and in glycerol; slightly soluble in dichloromethane. Protect from light.

The BP 2008 gives White Petroleum Jelly as an approved synonym.

USP 31 (White Petrolatum). A purified mixture of semisolid hydrocarbons obtained from petroleum, and wholly or nearly decolorised. It may contain a suitable stabiliser. A white or faintly yellowish unctuous mass, transparent in thin layers even after cooling to 0°. Insoluble in water; slightly soluble in cold or hot alcohol and in cold dehydrated alcohol; freely soluble in chloroform, in benzene, and in carbon disulfide; soluble in ether, in petroleum spirit, and in most fixed and volatile oils.

Yellow Soft Paraffin

Keltavaseiliini; Minkštasis geltonas parafinas; Paraff. Moll. Flav.; Paraffinum Molle Flavum; Petrolatum; Petroleum Jelly; Sárga vazelín; Vaseline, gult; Vaseline Amarella; Vaseline amarilla; Vaseline filante amarilla; Vaseline jaune; Vaselinum flavum; Vazelina žlutá; Wazelina zółta; Yellow Petrolatum; Yellow Petroleum Jelly.

Жёлтый Вазелин

CAS — 8009-03-8.

Pharmacopoeias. In *Chin.*, *Eur.* (see p.vii), *Int.*, *Jpn.*, and *US*. Many pharmacopoeias use the title Vaselinum Flavum; in some countries the name 'Vaseline' is a trade-mark.

Ph. Eur. 6.2 (Paraffin, Yellow Soft). A purified mixture of semi-solid hydrocarbons obtained from petroleum. A yellow, translucent, unctuous mass, slightly fluorescent in daylight when melted. It has a drop point of 40° to 60°. Practically insoluble in water, in alcohol, and in glycerol; slightly soluble in dichloromethane. Protect from light.

USP 31 (Petrolatum). A purified mixture of semi-solid hydrocarbons obtained from petroleum. It may contain a suitable stabiliser. It is an unctuous yellowish to light amber mass, having not more than a slight fluorescence even after being melted. It is transparent in thin layers. It is free or practically free from odour. M.p. 38° to 60°. Insoluble in water; practically insoluble in cold or hot alcohol and in cold dehydrated alcohol; freely soluble in benzene, in carbon disulfide, in chloroform, and in turpentine oil; soluble in ether, in petroleum spirit, and in most fixed and volatile oils.

Adverse Effects

Adverse effects of soft paraffin are rare when used in topical preparations, but sensitivity reactions and acne have been reported after topical use. Granulomatous reactions after absorption or injection and lipoid pneumonia after aspiration have occurred.

Fire risk. Burns to the scalp, face, and hands have been reported¹ in 5 patients who accidentally ignited their hair after the application of paraffin-based hair grease. Four patients suffered inhalation injury, 2 of whom required intubation. The death of a patient who, while smoking, ignited bandages covering a paraffin-based ointment for psoriasis,² prompted the *BNF* to recommend that patients should be told not to smoke and to keep away from flames when using paraffin-based emollients.

- Bascom R, *et al.* Inhalation injury related to use of petrolatum-based hair grease. *J Burn Care Rehabil* 1984; **5**: 327–30.
- National Patient Safety Agency. Skin treatment fire risk. *Patient Safety Bulletin* 2007 (Jan.); 4. Available at: <http://www.npsa.nhs.uk/EasySiteWeb/GatewayLink.aspx?allid=6341> (accessed 29/08/08)

Hypersensitivity. The allergenicity of soft paraffin products has been investigated.^{1–4} Considering their widespread use there are very few reports of sensitivity;³ of nearly 80 000 patients patch tested with white soft paraffin, only 29 showed a positive reaction. White soft paraffin is generally less sensitising than yellow soft paraffin, although allergenicity differs from product to product. The allergenic components are probably polycyclic aromatic hydrocarbons present as impurities and quantities found in a particular paraffin depend on the source and purification method. Only the purest forms should be used in pharmaceuticals, cosmetics, and for patch testing, and highly purified white soft paraffin is preferred to yellow soft paraffin.

- Dooms-Gossens A, Degreef H. Contact allergy to petrolatums (I). Sensitising capacity of different brands of yellow and white petrolatums. *Contact Dermatitis* 1983; **9**: 175–85.
- Dooms-Gossens A, Degreef H. Contact allergy to petrolatums (II). Attempts to identify the nature of the allergens. *Contact Dermatitis* 1983; **9**: 247–56.
- Dooms-Gossens A, Dooms M. Contact allergy to petrolatums (III). Allergenicity prediction and pharmacopoeial requirements. *Contact Dermatitis* 1983; **9**: 352–9.
- Schnuch A, *et al.* White petrolatum (Ph. Eur.) is virtually non-sensitizing: analysis of IVDK data on 80 000 patients tested between 1992 and 2004 and short discussion of identification and designation of allergens. *Contact Dermatitis* 2006; **54**: 338–43.

Lipoid pneumonia. Various uses of soft paraffin have been associated with lipoid pneumonia, including topical facial use to treat psoriasis,¹ long-term intranasal application for a dry nose,² and use as a lubricant during nasogastric intubation.³

- Cohen MA, *et al.* Exogenous lipoid pneumonia caused by facial application of petrolatum. *J Am Acad Dermatol* 2003; **49**: 1128–30.
- Brown AC, *et al.* Exogenous lipoid pneumonia due to nasal application of petroleum jelly. *Chest* 1994; **105**: 968–9.
- Bernabeu Mora R, *et al.* Neumonía lipoidea aguda debida a la aspiración accidental de vaselina utilizada en un sondaje nasogástrico. *Arch Bronconeumol* 2000; **36**: 485–7.

Uses and Administration

Soft paraffin is used as an ointment basis and as an emollient in the management of skin disorders. It is not readily absorbed by the skin. Sterile dressings containing soft paraffin are used for wound dressing and as a packing material. Soft paraffin is also included in ointments used as ophthalmic lubricants in the management of dry eye (p.2140). Application of soft paraffin has been used for the eradication of pubic lice from the eyelashes (see Pediculosis, p.2034). It has been used as a contact medium to reduce pain during extracorporeal shock wave lithotripsy. Soft paraffin is also used in food manufacturing.