

2. Oiso N, *et al.* Concomitant allergic reaction to cetyl alcohol and crotamiton. *Contact Dermatitis* 2003; **49**: 261.
3. Soga F, *et al.* Contact dermatitis due to lanocanazole, cetyl alcohol and diethyl sebacate in lanocanazole cream. *Contact Dermatitis* 2004; **50**: 49–50.
4. Kiec-Swierczynska M, *et al.* Photoallergic and allergic reaction to 2-hydroxy-4-methoxybenzophenone (sunscreens) and allergy to cetyl alcohol in cosmetic cream. *Contact Dermatitis* 2005; **53**: 170–1.

Preparations

Proprietary Preparations (details are given in Part 3)

Arg.: Lactopan†.

Multi-ingredient: Arg.: Caien; **Hong Kong:** Ego Skin Cream; **Malaysia:** Ego Skin Cream; **NZ:** Ego Skin Cream; **Philipp.:** Dermalin; Sebo Fluid; **Singapore:** Ego Skin Cream.

Cetyl Esters Wax

Cera Cetyla; Cera de ésteres cetílicos; Cera de ésteres del alcohol cetílico; Esperma de ballena sintético; Spermaceti Wax Replacement; Synthetic Spermaceti.

Воск Сложных Цетиловых Эфиров

CAS — 85566-24-1.

Pharmacopoeias. In *Int.* Also in *USNF*.

USNF 26 (Cetyl Esters Wax). A mixture consisting primarily of esters of saturated fatty alcohols (C₁₄ to C₁₈) and saturated fatty acids (C₁₄ to C₁₈). White to off-white somewhat translucent flakes with a crystalline structure and a pearly lustre when caked; it has a faint odour and is free from rancidity. M.p. 43° to 47°. Insoluble in water; practically insoluble in cold alcohol; soluble in boiling alcohol, in chloroform, in ether, and in fixed and volatile oils; slightly soluble in cold petroleum spirit. Store in a dry place at a temperature not exceeding 40°.

Profile

Cetyl esters wax is used mainly as a stiffening agent and emollient in creams and ointments. It is also used in the coating of some oral dosage forms. It is a synthetic replacement for natural spermaceti obtained from the sperm whale and the bottle-nosed whale.

Preparations

USP 31: Rose Water Ointment.

Proprietary Preparations (details are given in Part 3)

Multi-ingredient: Arg.: Cold Cream Nature†.

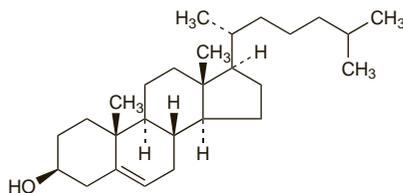
Cholesterol

Cholesterin; Cholestérol; Cholesterolis; Cholesterolium; Colesterina; Colesterol; Kolesterol; Kolesteroli; Koleszterin; Koleszterin. Cholest-5-en-3 β -ol.

Холестерин; Холестерол

C₂₇H₄₆O = 386.7.

CAS — 57-88-5.



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

Ph. Eur. 6.2 (Cholesterol). A white or almost white, crystalline powder. It is sensitive to light. M.p. 147° to 150°. Practically insoluble in water; sparingly soluble in alcohol and in acetone. Protect from light.

USNF 26 (Cholesterol). White or faintly yellow, practically odourless, pearly leaflets, needles, powder, or granules. It acquires a yellow to pale tan colour on prolonged exposure to light. M.p. 147° to 150°. Insoluble in water; slowly soluble 1 in 100 of alcohol; soluble 1 in 50 of dehydrated alcohol; soluble in acetone, in chloroform, in dioxan, in ether, in ethyl acetate, in petroleum spirit, and in vegetable oils. Protect from light.

Profile

Cholesterol imparts water-absorbing power to pharmaceutical preparations and is used as an emulsifying agent. It has emollient activity and is used mainly in topical preparations. It is also used in ophthalmic and vaginal formulations, and in preparations for parenteral use.

Cholesteryl benzoate has been used as an ingredient in dermatological preparations.

Preparations

Proprietary Preparations (details are given in Part 3)

Fr.: Senophile†.

Multi-ingredient: Arg.: Liposomas; **Belg.:** Senophile; **Chile:** Perfungol.

Coconut Oil

Aceite de coco; Coco (huile de) raffinée; Cocos oleum raffinaturn; Coconut Butter; Copra Oil; Finomított kókuszolaj; Hindistancévi Yağ; Kokosolja, raffinerad; Kokosový olej čistěný; Kokosų aliejus, rafinuotas; Kookosölj, puhdistettu; Oleum Cocos; Oleum Cocos Raffinatum; Oleum Cocosis.

Кокосовое Масло

CAS — 8001-31-8.

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

Ph. Eur. 6.2 (Coconut Oil, Refined). The refined fatty oil obtained from the dried, solid part of the endosperm of *Cocos nucifera*. A white or almost white, unctuous mass. M.p. 23° to 26°. Practically insoluble in water; very slightly soluble in alcohol; freely soluble in dichloromethane and in petroleum spirit (b.p. 65° to 70°). Store in well-filled containers. Protect from light.

USNF 26 (Coconut oil). The refined fixed oil obtained from the seeds of *Cocos nucifera*. A clear, white to light yellow-tan, viscous liquid. Practically insoluble in water; very slightly soluble in alcohol; freely soluble in dichloromethane and in light petroleum. M.p. 23° to 26°. Store in airtight, well-filled containers. Protect from light.

Profile

Coconut oil is used as a basis for topical creams and ointments, in rectal and vaginal suppositories, and in solid dosage forms. It is also used in food manufacturing. Topical preparations have been used for pediculosis.

Fractionated coconut oil (thin vegetable oil) is used as a source of medium-chain triglycerides (p.1956).

Hypersensitivity. Sensitivity reactions to coconut products, including coconut oil,¹ have been reported rarely. Cases of anaphylaxis have been reported.^{2,3}

1. Couturier P, *et al.* Un cas d'allergie à l'huile de noix de coco chez un nourrisson: responsabilité des laits maternelisés. *Allerg Immunol (Paris)* 1994; **26**: 386–7.
2. Rosado A, *et al.* Anaphylaxis to coconut. *Allergy* 2002; **57**: 182–3.
3. Nguyen SA, *et al.* Cross-reactivity between coconut and hazelnut proteins in a patient with coconut anaphylaxis. *Ann Allergy Asthma Immunol* 2004; **92**: 281–4.

Preparations

Proprietary Preparations (details are given in Part 3)

Ger.: Aesculo Gel L; **UK:** Nitlotion.

Multi-ingredient: Arg.: Tersoderm Cabellos Grasos†; **Cz.:** Nutralipid MCT†; **Fr.:** Biostop; **Indon.:** Minyak Telon; Minyak Telon Cap Tiga Anak Yanthi Baby Oil; **Mex.:** Nutegen G†; **NZ:** Mr Nits; **Turk.:** Kataljin.

Emulsifying Wax

Anionic Emulsifying Wax; Cera emulgente; Cera Emulsificans; Cera emulsionante; Cetylanum; Emulsif. Wax.

Эмульгирующий Воск

CAS — 8014-38-8.

Pharmacopoeias. In *Br.* Also in *USNF*.

BP 2008 (Emulsifying Wax). It is prepared from 9 parts of ceto-stearyl alcohol and 1 part of sodium laurilsulfate or sodium salts of similar sulfated higher primary aliphatic alcohols. An almost white or pale yellow, waxy solid or flakes, becoming plastic when warmed, with a faint characteristic odour. Practically insoluble in water, forming an emulsion; partly soluble in alcohol.

USNF 26 (Emulsifying Wax). It is prepared from ceto-stearyl alcohol containing a polyoxyethylene derivative of a fatty acid ester of sorbitan. M.p. 50° to 54°. It is a creamy-white, wax-like solid, with a mild characteristic odour. Insoluble in water; soluble in alcohol; freely soluble in chloroform, in ether, in most hydrocarbon solvents, and in aerosol propellants.

Profile

Emulsifying wax added to fatty or paraffin bases facilitates the preparation of oil-in-water emulsions which are absorbed and are nongreasy when rubbed into the skin. It is a constituent of many hydrophilic ointment bases for so-called 'washable' ointments, and is also used in rectal preparations, and in cosmetics.

Sunscreens activity. Emulsifying ointment, which contains emulsifying wax with white soft paraffin and liquid paraffin, was found to have major sunscreen activity in clinically normal skin.¹ It should not be used before phototherapy or in phototesting procedures.

1. Cox NH, Sharpe G. Emollients, salicylic acid, and ultraviolet erythema. *Lancet* 1990; **335**: 53–4.

Preparations

BP 2008: Aqueous Cream; Emulsifying Ointment.

Proprietary Preparations (details are given in Part 3)

Multi-ingredient: UK: Epaderm; Hydromol.

Hard Fat

Adeps Neutralis; Adeps solidus; Glicéridos semisintéticos sólidos; Glicéridos hémi-synthétiques solides; Glicéridos Semi-synthétiques Solides; Grasa sólida; Hãrdfett; Hartfett; Kietieji riebalai; Kovarvasa; Massa Estearífnica; Neutralfett; Szilárd zsír; Tuk ztužený; Tłuszcz objętą.

Твёрдый Жир

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

Ph. Eur. 6.2 (Hard Fat). A mixture of triglycerides, diglycerides, and monoglycerides obtained either by esterification of fatty acids of natural origin with glycerol or by transesterification of natural fats. A white or almost white, waxy, brittle mass. M.p. 30° to 45°; it does not differ by more than 2° from the nominal value. Practically insoluble in water; slightly soluble in dehydrated alcohol. When heated to 50°, it melts giving a colourless or slightly yellowish liquid. Protect from light and heat.

USNF 26 (Hard Fat). A mixture of glycerides of saturated fatty acids. A white mass, almost odourless and free from rancid odour, and greasy to the touch. M.p. is between 27° and 44° and does not differ by more than 2° from the nominal value. The melted substance is colourless or slightly yellowish and forms a white emulsion when shaken with an equal amount of hot water. Practically insoluble in water; slightly soluble in alcohol; freely soluble in ether. Store in airtight containers at a temperature 5° or more below the melting-point.

Profile

The name Hard Fat is applied to a range of bases with varying degrees of hardness and differing melting ranges used for the preparation of suppositories and vaginal pessaries. Hard fat is also used in some topical preparations.

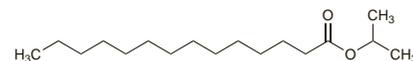
Isopropyl Myristate (USAN)

Isopropyl myristát; Isopropyle, myristate d'; Isopropylis myristas; Isopropylmyristat; Isopropylmyristaatti; Isopropil-mirisztát; Izopropilo miristata; Izopropylu mirystynian; Miristato de isopropilo. Tetradecanoic acid 1-methylethyl ester; Isopropyl tetradecanoate.

Изопропилимиристант

C₁₇H₃₄O₂ = 270.5.

CAS — 110-27-0.



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

Ph. Eur. 6.2 (Isopropyl Myristate). A clear, colourless, oily liquid. Relative density about 0.853. Immiscible with water; miscible with alcohol, with dichloromethane, with fatty oils, and with liquid paraffin. Protect from light.

USNF 26 (Isopropyl Myristate). A clear practically colourless, almost odourless, oily liquid; congeals at about 5°. Insoluble in water, in glycerol and in propylene glycol; freely soluble in alcohol. Miscible with most organic solvents and with fixed oils. Store in airtight containers. Protect from light.

Incompatibility. Isopropyl myristate is incompatible with hard paraffin.

Profile

Isopropyl myristate is resistant to oxidation and hydrolysis and does not become rancid. It is absorbed fairly readily by the skin and is used as a basis for relatively nongreasy emollient ointments and creams. It is also used as a penetration enhancer for many substances applied externally as creams, sprays, or transdermal patches.

Other isopropyl fatty acid esters, including di-isopropyl adipate, isopropyl laurate, isopropyl linoleate, and isopropyl palmitate (below) have similar properties and are used for similar purposes to those of isopropyl myristate.

Hypersensitivity. A case of sensitivity to isopropyl myristate has been reported¹ in a 64-year-old woman. She developed a rash after using a sunscreen containing isopropyl myristate for 3 days, and patch testing confirmed a sensitivity both to this substance and to isohexadecane (a mixture of C₁₆ paraffins).

1. Bharati A, King CM. Allergic contact dermatitis from isohexadecane and isopropyl myristate. *Contact Dermatitis* 2004; **50**: 256–7.

Preparations

Proprietary Preparations (details are given in Part 3)

Spain: Nucoa.

Multi-ingredient: Hong Kong: Hydromol†; **Ir.:** Emulsiderm; Hydromol†; **Israel:** Emulsiderm; **UK:** Dermal; Diprobath; Doublebase; Emulsiderm; Full Marks Solution; Hydromol.

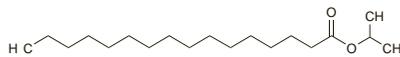
Isopropyl Palmitate

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.

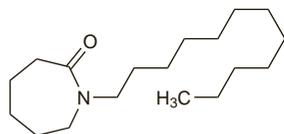
Laurocapram (*USAN, INN*)

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 microcristallinum; 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.

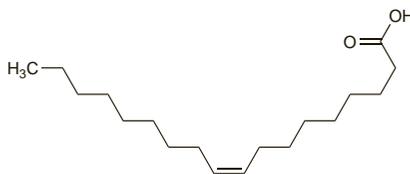
Oleic Acid

Acide oléique; Acidum oleicum; Elaic 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 choleric.

Preparations

BP 2008: Chloroxyleneol Solution; White Liniment.

Proprietary Preparations (details are given in Part 3)

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

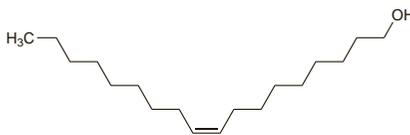
Oleyl Alcohol

Alcohol oleico; Alcohol oleicus; cis-9-Octadecen-1-ol; Oleic Alcohol; Oleilo alkoholis; Olélique (alcohol); Oleo Alcohol; Oleol; Oleylalkohol; Oleylialkoholi. (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, kiinteä; 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 ciekka; 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.