

## 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; Parafin 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.:** Alcoderm; 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; Nutradirect†; 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†; Parapsyl; **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; **Dennm.:** 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; Vasetalum; **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; Dermo; 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 Officinale; Vaselinum album; Vazelina bílá; Vazelina 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 żółta; 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 reported<sup>1</sup> 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,<sup>2</sup> 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.<sup>1–4</sup> Considering their widespread use there are very few reports of sensitivity;<sup>3</sup> 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,<sup>1</sup> long-term intranasal application for a dry nose,<sup>2</sup> and use as a lubricant during nasogastric intubation.<sup>3</sup>

- 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 lipóidea 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.

## Preparations

**BP 2008:** Cetomacrogol Emulsifying Ointment; Cetrimide Emulsifying Ointment; Emulsifying Ointment; Paraffin Ointment; Simple Eye Ointment; Simple Ointment; Wool Alcohols Ointment;  
**USP 31:** Bland Lubricating Ophthalmic Ointment; Hydrophilic Ointment; Hydrophilic Petrolatum; Petrolatum Gauze; White Ointment; Yellow Ointment.

**Proprietary Preparations** (details are given in Part 3)

**Austral.:** Jelonet; Uni-Salvet; Unittulle†; **Braz.:** Vaselina; **Canad.:** Preveex; Vaseline; **Fr.:** Cuticren; Jelonet; Tulle Gras; Vaseline; **Ger.:** Oleo Tull; **Gr.:** Vaseline Pur; **Irl.:** Dermamist; **Ital.:** Adaptic; Jelonet; Lomatuell H; **Mex.:** Formula Dermica; Lubrilin; **Philipp.:** Apolito; **Rus.:** Klotex (Клотекс); **S.Afr.:** Jelonet; **Spain:** Lacrilube; **Turk.:** Duratears; **UK:** Dermamist; Jelonet; Paratulle†; Vaseline; **USA:** Ocu-Lube.

**Multi-ingredient Arg.:** Alcon Lagrimas; Aqualane; Benzalcem; **Austral.:** DermaVeen Moisturising; Dermaze; E45; Gold Cross Skin Basics Zinc Cream†; Lacri-Lube; Poly-Visc; **Austria:** Tiroler Steinol; **Belg.:** Duratears; Lacrytulle; Tulle Vaseline†; **Canad.:** A & D Ointment; Akwa Tears; Chapstick Medicated Lip Balm†; Duolube; Duratears†; Hydrophil; Hypotears; Moisture; Optilube; Puralube†; Refresh Lacri-Lube; Tears Naturale PM; **Chile:** Chapstick Medicated; Durasorb; Duratears; Tears Naturale PM; Lassar; **Dennm.:** Ojensalve Neutral; **Fin.:** Lacri-Lube; **Fr.:** Cellosoib; Pasta Zinc; Dexery; Grassolid Neutral; Ictyane; Ictyane HD; Oilatium Cream†; Transulose; **Ger.:** Allergika†; Cellosoib; Coliquifilm; Sofra-Tull sine; Vita-POS; **Gr.:** Duratears; Vaseline Borique; Vaseline Oxide Zinc; **Hong Kong:** Balneum; Duratears; Dypotex†; Oilatium Cream; **India:** CetraBen; **Irl.:** Lacri-Lube; Oilatium Junior; **Israel:** Duratears; Kamil Blue; Lacrimol; **Ital.:** Lacri-Lube; Balneum; Duratears Naturale; Lacrilube†; Oilatium; **Neth.:** Duratears Z; Transulose; **Norw.:** Simplex; **NZ:** Lacrilube; Poly-Visc; **Philipp.:** Oilatium; **Pol.:** Amfobase; Diprobaze; E45; Unibasis; **Singapore:** Balneum; Duratears; Lacrilube; **Spain:** Lubrifilm; Tears Lubricante†; Vaselina Boricada; Vaselina Mentolada†; **Switz.:** Coliquifilm; **Thai.:** Balneum†; Duratears; Oilatium Cream; **Turk.:** Cinkos; **UK:** 50/50; CetraBen Emollient; Diprobaze; Emollin; Epaderm; Hewlett's Hydromol; Imuderm; Lacri-Lube; Lacri-Lube; Melrose; Oilatium Cream; Oilatium Junior; **USA:** Akwa Tears; Bodi Care Lotion; Bottom Better†; Chapstick Medicated Lip Balm; Destin Creamy; Diaper Guard; Dry Eyes; Duratears Naturale; Formulation R; Hemoid For Women; Hydrocort; Hypotears; Lacri-Gel; Lacri-Lube; Lubri-Fresh PM; LubriTears; Paladin; Puralube; Refresh PM; Styer; Tears Again; Tears Renewed; **Venez.:** Lacrimart†.

## Shea Butter

Manteca de Karité.

Карите; Масло Ши

## Profile

Shea butter is a natural fat obtained from the kernel of the fruit of *Vitellaria paradoxa* (*Butyrospermum parkii*) (Sapotaceae) indigenous to West Africa. It is used as an ointment and cream base. Shea butter is widely used in cosmetics. It is also used in cooking oil, and as a substitute for theobroma oil in chocolate manufacturing.

## Preparations

## Silicones

Siliconas.

Силиконы

ATC — A03AX13.

ATC Vet — QA03AX13.

**Description.** Silicones are polymers with a structure consisting of alternate atoms of silicon and oxygen, with organic groups attached to the silicon atoms. As the degree of polymerisation increases, the products become more viscous and the various grades are distinguished by a number, approximately corresponding to the viscosity of the particular grade. Silicones may be fluids, greases, waxes, resins, or rubbers depending on the degree of polymerisation.

## Cyclomethicone

Dimethylcyclopolsiloxane.

Циклометикон

(C<sub>2</sub>H<sub>5</sub>OSi)<sub>n</sub>.

CAS — 69430-24-6.

**Pharmacopoeias.** In *USNF*.

**USNF 26** (Cyclomethicone). A fully methylated cyclic siloxane containing repeating units of the formula  $[-(CH_3)_2SiO-]_n$ , in which *n* is 4, 5, or 6, or a mixture of them. Store in airtight containers.

## Dimeticone (BAN, rINN)

Dimethicone (*USAN*); Dimethyl Silicone Fluid; Dimethylpolysiloxane; Dimethylsiloxane; Dimeticona; Dimeticone; Dimeticonium; Dimetikon; Dimetikonas; Dimetikon; Dimetilpolisiloxano; Dimetykon; E900; Huile de Silicone; Methyl Polysiloxane; Metilpolisiloksan; Metilpolisiloxano; Permethylpolisiloxane; Polidimetilsiloxano; Silicone Oil; Siliconum Liquidum. Poly(dimethylsiloxane).

Диметикон

CH<sub>3</sub>[Si(CH<sub>3</sub>)<sub>2</sub>O]<sub>n</sub>Si(CH<sub>3</sub>)<sub>3</sub>.

CAS — 9006-65-9.

ATC — A03AX13.

ATC Vet — QA03AX13.

**Description.** Dimeticones are fluid silicones in which the organic group is a methyl radical.

Simeticone (activated dimeticone), a mixture of liquid dimeticones with silicon dioxide, is described on p.1770.

**Pharmacopoeias.** In *Chin.* and *Eur.* (see p.vii). Also in *USNF*. **Ph. Eur. 6.2** (Dimeticone). The degree of polymerisation is such that the kinematic viscosities are nominally between 20 and 1300 mm<sup>2</sup>/second; dimeticones with a nominal viscosity of 50 mm<sup>2</sup>/second or lower are intended for external use only. Dimeticones are clear, colourless, liquids of various viscosities. Practically insoluble in water; very slightly soluble to practically insoluble in dehydrated alcohol; miscible with ethyl acetate, with methyl ethyl ketone, and with toluene.

**USNF 26** (Dimeticone). A mixture of fully methylated linear siloxane polymers containing repeating units of the formula  $[-(CH_3)_2SiO-]_n$ , stabilised with trimethylsiloxy end-blocking units of the formula  $[(CH_3)_3SiO-]$ , wherein *n* has an average value such that the corresponding nominal viscosity is in a discrete range between 20 and 30 000 centistokes. It is a clear colourless, odourless liquid. Insoluble in water, in alcohol, in acetone, and in methyl alcohol; very slightly soluble in isopropyl alcohol; soluble in amyl acetate, in chlorinated hydrocarbons, in ether, in *n*-hexane, in petroleum spirit, in benzene, in toluene, and in xylene. Store in airtight containers.

## Adverse Effects and Precautions

Adverse effects from the clinical use of silicones appear to be rare. Foreign-body reactions have been reported after their use as joint implants. Other implants, notably breast implants used for reconstruction after mastectomy or for cosmetic purposes, carry the risk of migration of silicone with cyst formation and other complications; accidental intravascular injection has been fatal. Late adverse ocular effects can follow the intravitreal injection of liquid silicone in the management of retinal detachment (see below).

**Breast feeding.** Concern has been raised regarding the possible effects on infants of mothers with silicone breast implants who breast feed. Oesophageal dysfunction has been reported in a number of such children,<sup>1</sup> although this finding has not been confirmed by subsequent reports. The American Academy of Pediatrics therefore states<sup>2</sup> that the current evidence does not justify classifying silicone implants as a contra-indication to breast feeding.

- Levine JJ, Ilowite NT. Scleroderma-like esophageal disease in children breast-fed by mothers with silicone breast implants. *JAMA* 1994; **271**: 213–6. Correction. *ibid.*; **272**: 770.
- American Academy of Pediatrics. The transfer of drugs and other chemicals into human milk. *Pediatrics* 2001; **108**: 776–89. Correction. *ibid.*; 1029. Also available at: <http://aappolicy.aappublications.org/cgi/content/full/pediatrics%3b108/3/776> (accessed 20/11/07)

**Connective tissue disorders.** Since the introduction of silicone breast implants in the early 1960s there have been numerous anecdotal reports of connective tissue disorders in women who have undergone breast reconstruction or augmentation with these implants. Scleroderma has been the most frequently reported disorder; others have included SLE, rheumatoid arthritis, and inflammatory myopathies. A syndrome of vague musculoskeletal symptoms, fever, and fatigue has also been reported. These cases led the FDA to call for a moratorium in the USA on the use of silicone breast implants in January 1992. However, with the exception of one study of self-reported symptoms which showed only a small increase in risk,<sup>1</sup> large epidemiological studies,<sup>2-5</sup> meta-analyses,<sup>6-8</sup> and a review by the Medical Devices Agency in the UK have so far failed to show any association between silicone breast implants and connective tissue disorders. After conducting a review of the evidence, the FDA in 2006 re-approved the sale of silicone breast implants, for use in women of all ages for breast reconstruction, and for cosmetic use in women aged 22 years or more;<sup>9</sup> the approval obliges the manufacturers to conduct a 10-year post-approval safety study.

- Hennekens CH, *et al.* Self-reported breast implants and connective-tissue diseases in female health professionals: a retrospective cohort study. *JAMA* 1996; **275**: 616–21.
- Gabriel SE, *et al.* Risk of connective-tissue diseases and other disorders after breast implantation. *N Engl J Med* 1994; **330**: 1697–1702.
- Sánchez-Guerrero J, *et al.* Silicone breast implants and the risk of connective-tissue diseases and symptoms. *N Engl J Med* 1995; **332**: 1666–70.
- Silverman BG, *et al.* Reported complications of silicone gel breast implants: an epidemiologic review. *Ann Intern Med* 1996; **124**: 744–56.
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## Uses and Administration

Dimeticones and other silicones are water-repellent and have a low surface tension. They are used in topical barrier preparations for protecting the skin against water-soluble irritants. Creams, lotions, and ointments containing a dimeticone are used for the prevention of bedsores and napkin rash and to protect the skin

against trauma due to incontinence or stoma discharge. A 4% solution of dimeticone is used for the treatment of head pediculosis in adults and children aged over 6 months. Silicone preparations should not be applied where free drainage is necessary or to inflamed or abraded skin. Silicones, usually a dimeticone, are also used topically as wound dressings, and to reduce scar elevation and pigmentation. They are also used in oral solid dosage forms, including modified-release preparations.

Silicones have also been used for arthroplasty in rheumatic disorders, by intravitreal injection for retinal detachment, and by subcutaneous injection or implantation in reconstructive or cosmetic surgery.

Dimeticones, in particular simeticone (activated dimeticone) (p.1770), are used in the treatment of flatulence.

**Retinal detachment.** Retinal detachment is separation of the retina from the underlying retinal pigmented epithelium and usually requires surgical repair. Intravitreal injection of liquid silicone, either alone or with a gas,<sup>1</sup> is used for retinal tamponade with or after surgery in complicated or persistent detachment of the retina.<sup>2</sup> In most cases, the silicone fluid is later removed from the eye.<sup>3</sup> High-density silicone fluids are increasingly being used.<sup>4</sup> Use of silicone fluid is reported to trigger a local inflammatory response, which may persist after the fluid is removed.<sup>5</sup> Other late complications after its use may include cataract, glaucoma, and keratopathy.

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## Preparations

**Proprietary Preparations** (details are given in Part 3)

**Arg.:** Aerogal; Atoderm†; Euporel; Finescar; Kurapel; Skinderm SIL; **Austral.:** Dermatic; Egozite Protective Baby Lotion; Instru-Safe†; Rosken Skin Repair; Silic 15; **Canad.:** Barrier Cream†; Barriere; Dermatic Si; **Chile:** Cadinol†; Epi-Derm; Lomprax; Neogasil; Para; **Fr.:** Cic-Care; Dermatic; Ophthaloxane; **Ger.:** Dermatic; Jaikin N†; Mepiform; Mepilex; Mepitex; Symadal M†; **Hong Kong:** Egozite Protective Baby Lotion; Silic 15; Skin Repair; **Hung.:** Fomarex†; **Irl.:** Dermatic; **Israel:** Adato-Sil Oil†; **Ital.:** Cic-Care; Mepiform; Mepitex; **Malaysia:** Dermatic; Egozite Protective Baby Lotion; Silic 15; **Neth.:** SIL-1000; -5000; **NZ:** Aquim†; DP Barrier Cream; Egozite Protective Baby Lotion; Silicare†; **Philipp.:** Cic-Care; Dermatic; **Pol.:** Silol; **Singapore:** Baritex; Dermatic; Silic 15; Skin Repair; **UK:** Cic-Care; Dermatic; Hedrin; Mepiform; Silgel; **USA:** Mentholatum Softlips; Pro-Q.

**Multi-ingredient Arg.:** Sumo Full Contact; **Austral.:** Dermalife Plus; Dimethicream; Eczema Cream; Egozite Baby Cream; Hamilton Pine Tar with Menthol; Hamilton Skin Repair†; Nappy-Mate†; Silcon†; **Austria:** Ceoliat Compositum; Evalgan; **Braz.:** Balmeex; **Canad.:** Blistex Lip Balm; Blistex Ultra Protection Lip Balm; Complex 15†; Moisture; Zilactin-Lip; **Chile:** Aero Itan; Balsamo Analgesico con Fenilbutazona; Blistprotec; Neopankreo-flat; Ureadin 30; Xeragel; **Dennm.:** Silan; **Fr.:** Supro; **Hong Kong:** DS Emulsion; Dypotex†; Egozite Baby Cream; Hamilton Skin Repair; **India:** Siloderm; Tinidafyl Plus; **Irl.:** Conotranex†; Siopel†; Sprilon; Vasogen; **Israel:** Kamil Blue; Kelo-Cote†; **Ital.:** Angstrom Viso; Rikospray; **Malaysia:** Egozite Baby Cream; Palmer's Cocoa Butter Formula Scar Serum; **Mex.:** Hidribet†; **NZ:** Egozite; Egozite Baby; Karicare Barrier Cream†; Rosken Skin Repair; Silic; **S.Afr.:** Arola Rosebalm; Siopel; **Singapore:** Egozite Baby Cream; Egozite Protective Baby Lotion†; Scarfade†; **Spain:** Dermo Halibut; Proskin; Silidermil; **Swed.:** Silon; **UK:** Conotranex; Cymex; Full Marks Solution; Siopel; Sprilon; Vasogen; **USA:** Blistex Lip Balm; ControlRx; Diaper Guard; Dypotex; Gold Bond Medicated Triple Action Relief; Herpecin-L; Maxilube; Mentholatum Cherry Ice; Mentholatum Natural Ice; Mentholatum Softlips Lipbalm; Mentholatum Softlips Lipbalm (UV); Soothe & Cool; **Venez.:** Hidribet.

## Squalene

Cosbiol; Dodecahydrosqualene; Escualano; Perhidroescualeno; Perhydrosqualène; Skvalani; Skvalan; Skvalanas; Skvalan; Spinalcane; Squalanum; Szkalván. 2,6,10,15,19,23-Hexamethyltetra-cosane.

Сквалан

C<sub>30</sub>H<sub>62</sub> = 422.8.

CAS — 111-01-3.

