

10. A clear, colourless or light yellow, viscous liquid. Miscible with water, with alcohol, and with vegetable oils. Store in airtight containers.

Profile

Octoxinols have surface active properties and may be used as solubilising agents. They are also used as spermicides.

Preparations

Proprietary Preparations (details are given in Part 3)

Austral.: Ortho-Gynol; **NZ:** Ortho-Gynol; **USA:** Ortho-Gynol†.

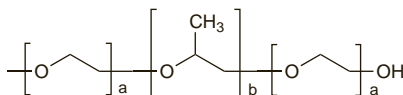
Multi-ingredient: **Austral.:** Summers Eve Feminine; **Chile:** Summer's Eve Hierbast†.

Poloxamers

Polioxietilen-propilenglicol; Poloksamerit; Poloksamerai; Poloxamera; Poloxamerek; Poloxamerer; Poloxamères; Poloxameros; Poloxamery; Polyethylene-polypropylene glycol. α -Hydro- ω -hydroxypropyl(oxyethylene)poly(oxypropylene)poly(oxyethylene) block copolymer.

Полюксамеры

CAS — 9003-11-6.



Nomenclature. Poloxamer is *BAN* and *rINN*. The name is followed by a figure, the first 2 digits of which, when multiplied by 100, correspond to the approximate average molecular weight of the polyoxypropylene portion and the third digit, when multiplied by 10, corresponds to the percentage by weight of the polyoxyethylene portion. *USAN* specifies Poloxamer 182D, Poloxamer 182LF, Poloxamer 188, Poloxamer 188LF, and Poloxamer 331.

Poloxalene (*BAN*, *USAN*, *rINN*) is also a poloxamer.

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

Ph. Eur. 6.2 (Poloxamers). A synthetic block copolymer of ethylene oxide and propylene oxide represented by the general formula: $\text{HO}(\text{C}_2\text{H}_4\text{O})_a(\text{C}_3\text{H}_6\text{O})_b(\text{C}_2\text{H}_4\text{O})_a\text{H}$. It may contain a suitable antioxidant. Poloxamer 124 is a colourless or almost colourless liquid. Poloxamer 237 and poloxamer 338 are white or almost white, waxy powders, microbeads or flakes; m.p. about 50°. Poloxamers 124, 237, and 338 are very soluble in water and in alcohol; practically insoluble in petroleum spirit (50° to 70°). pH of a 10% solution in water is 5.0 to 7.5. Store in airtight containers.

USNF 26 (Poloxamer). A synthetic block copolymer of ethylene oxide and propylene oxide with the general formula $\text{HO}(\text{C}_2\text{H}_4\text{O})_a(\text{C}_3\text{H}_6\text{O})_b(\text{C}_2\text{H}_4\text{O})_a\text{H}$. It may contain a suitable antioxidant. Poloxamer 124 is a colourless liquid with a mild odour. Poloxamers 237 and 338 are white, prilled or cast solids, odourless or with a mild odour. All poloxamers are freely soluble in water and in alcohol. Poloxamer 124 is freely soluble in isopropyl alcohol and in propylene glycol; poloxamer 237 is sparingly soluble in isopropyl alcohol and in xylene; poloxamer 338 is sparingly soluble in propylene glycol; poloxamer 124 is freely soluble in xylene. A 2.5% solution in water has a pH of 5.0 to 7.5. Store in airtight containers.

Incompatibility. Poloxamers have been reported to be incompatible with hydroxybenzoates and phenols.

Poloxalene (*BAN*, *USAN*, *rINN*)

Poloxalène; Poloxaleno; Poloxalenum; SKF-18667.

Полюксален

CAS — 9003-11-6.

Pharmacopoeias. In *US* for veterinary use only.

USP 31 (Poloxalene). A synthetic block copolymer of ethylene oxide and propylene oxide. A colourless or pale yellow liquid. Soluble in water, in chloroform, and in ethylene dichloride. A 2.5% solution in water has a pH of 5.0 to 7.5. Store in airtight containers at a temperature of 8° to 15°. Protect from light.

Poloxamer 188 (*BAN*, *USAN*, *rINN*)

Poloxalkol; Poloxamère 188; Poloxámero 188; Poloxamerum 188.

Полюксамер 188

NOTE. Compounded preparations of poloxamer 188 may be represented by the following names:

- Co-danthramer *x/y* (*BAN*)—where *x* and *y* are the strengths in milligrams of dantron and poloxamer respectively.

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

Ph. Eur. 6.2 (Poloxamers). Poloxamer 188 is a poloxamer in which *a* in the general formula given above is 75 to 85 and *b* is 25 to 30; it has an average molecular weight of 7680 to 9510. It is a white or almost white, waxy powder, microbeads, or flakes. M.p. about 50°. Very soluble in water and in alcohol; practically

insoluble in petroleum spirit (50° to 70°). pH of a 10% solution is 5.0 to 7.5. Store in airtight containers.

USNF 26 (Poloxamer). Poloxamer 118 is a poloxamer in which *a* in the general formula averages 80 and *b* averages 27; it has an average molecular weight of 7680 to 9510. A white prilled or cast solid, odourless or with a very mild odour. M.p. about 52°. Freely soluble in water and in alcohol. Store in airtight containers.

Poloxamer 407 (*BAN*, *rINN*)

Poloxamère 407; Poloxámero 407; Poloxamerum 407.

Полюксамер 407

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

Ph. Eur. 6.2 (Poloxamers). Poloxamer 407 is a poloxamer in which *a* in the general formula given above is 95 to 105 and *b* is 54 to 60; it has an average molecular weight of 9840 to 14 600. It is a white or almost white, waxy powder, microbeads, or flakes. M.p. about 50°. Very soluble in water and in alcohol; practically insoluble in petroleum spirit (50° to 70°). pH of a 10% solution in water is 5.0 to 7.5. Store in airtight containers.

USNF 26 (Poloxamer). Poloxamer 407 is a poloxamer in which *a* in the general formula averages 101 and *b* averages 56; it has an average molecular weight of 9840 to 14 600. A white, prilled or cast solid, odourless or with a very mild odour. M.p. about 56°. Freely soluble in water, in alcohol, and in isopropyl alcohol. Store in airtight containers.

Precautions

Poloxamers may increase the absorption of liquid paraffin and other fat-soluble substances.

Uses and Administration

Poloxamers are used as emulsifying agents for intravenous fat emulsions, as solubilising agents to maintain clarity in elixirs and syrups, and as wetting agents for antibacterials. They may also be used in ointment or suppository bases and as tablet binders or coaters.

Poloxamer 188 is used as a wetting agent in the treatment of constipation. It is usually given with a laxative such as dantron. It has also been used as an emulsifying agent in fluorocarbon blood substitutes. Poloxamer 188 has been investigated for its ability to improve blood flow in sickle-cell crisis; it has also been tried in myocardial infarction. Other investigational uses include the treatment of burns.

Poloxamer 407 is used in solutions for contact lens care, as is poloxamer 338.

Poloxalene is used as a defoaming agent in the treatment of bloat in ruminants.

References

- Orringer EP, *et al.* Purified poloxamer 188 for treatment of acute vaso-occlusive crisis of sickle cell disease: a randomized controlled trial. *JAMA* 2001; **286**: 2099–2106.
- Gibbs WJ, Hagemann TM. Purified poloxamer 188 for sickle cell vaso-occlusive crisis. *Ann Pharmacother* 2004; **38**: 320–4.
- Dumortier G, *et al.* A review of poloxamer 407 pharmaceutical and pharmacological characteristics. *Pharm Res* 2006; **23**: 2709–28.

Preparations

Proprietary Preparations (details are given in Part 3)

Austral.: Coloxyl; **Plagel†**; **Canad.:** Clerz†; **Fr.:** Alkenide†; **NZ:** Coloxyl; **S.Afr.:** Plagel.

Multi-ingredient: **Ir.:** Ailax; **Codalax**; **Cotron**; **NZ:** Codalax†; **Conthram†**; **Thai:** Siduol; **UK:** Ailax†; **Codalax**; **Danlax**; **USA:** Baby Orajel Tooth and Gum Cleanser; **ControlRx**.

Polyoxyl Castor Oils

Aceites de ricino polioxietilenados; Macroglylglycerol Ricinoleate; Macroglylgcérol, ricinoléate de; Macroglylgcérol ricinoleas; Makrogol-glicerín-éter-ricinoléat; Makroglylgcérol ricinoleatas; Makroglylgcérol ricinoleat; Makroglylgcérol ricinoleaatti; Makroglylgcérolu ricynolealin; Polyethoxylated Castor Oils; Polyoxethylene Castor Oils.

Полиэтиленгликоля Касторовые Масла

Pharmacopoeias. In *Eur.* (see p.vii).

Ph. Eur. 6.2 (Macroglylglycerol Ricinoleate; Polyoxyl Castor Oil BP 2008). It contains mainly ricinoleyl glycerol ethoxylated with 30 to 50 molecules of ethylene oxide (nominal value), with small amounts of macrogol ricinoleate and of the corresponding free glycols. It results from the reaction of castor oil with ethylene oxide. A clear, yellow, viscous liquid or semi-solid. Relative density about 1.05; viscosity, at 25°, 500 to 800 mPa s. Freely soluble in water and in alcohol; very soluble in dichloromethane. Protect from light.

Polyoxyl 35 Castor Oil

Aceite de ricino polioxil 35.

Полиэтиленгликоля 35 Касторовое Масло

Pharmacopoeias. In *USNF*.

USNF 26 (Polyoxyl 35 Castor Oil). A mixture of the tri-ricinoleate ester of ethoxylated glycerol with smaller amounts of macrogol ricinoleate and the corresponding free glycols. It is

produced by reacting 1 mole of glycerol ricinoleate with about 35 moles of ethylene oxide.

A yellow oily liquid with a faint characteristic odour. Sp. gr. 1.05 to 1.06; viscosity, at 25°, 650 to 850 mPa s. Very soluble in water, producing a practically odourless and colourless solution; soluble in alcohol and in ethyl acetate; insoluble in mineral oils. Store in airtight containers.

Incompatibility. Polyoxyl castor oils are reported to affect polyvinyl chloride containers and apparatus adversely.

Adverse Effects

Polyoxyl castor oils (such as *Cremophor EL*) used as vehicles in intravenous injections have been associated with severe anaphylactoid reactions, hyperlipidaemias, alterations in blood viscosity, and erythrocyte aggregation. They may also lead to adverse effects due to alterations in the pharmacokinetics of the formulated drug.

References

- Bagnarello AG, *et al.* Unusual serum lipoprotein abnormality induced by the vehicle of miconazole. *N Engl J Med* 1977; **296**: 497–9.
- Forrest ARW, *et al.* Long-term Althesin infusion and hyperlipidaemia. *BMJ* 1977; **2**: 1357–8.
- Dye D, Watkins J. Suspected anaphylactic reaction to Cremophor EL. *BMJ* 1980; **280**: 1353.
- Howrie DL, *et al.* Anaphylactoid reactions associated with parenteral cyclosporine use: possible role of Cremophor EL. *Drug Intell Clin Pharm* 1985; **19**: 425–7.
- Chapuis B, *et al.* Anaphylactic reaction to intravenous cyclosporine. *N Engl J Med* 1985; **312**: 1259.
- Siddall SJ, *et al.* Anaphylactic reactions to teniposide. *Lancet* 1989; **i**: 394.
- ten Tije AJ, *et al.* Pharmacological effects of formulation vehicles: implications for cancer chemotherapy. *Clin Pharmacokinet* 2003; **42**: 665–85.
- Hennenfent KL, Govindan R. Novel formulations of taxanes: a review. Old wine in a new bottle? *Ann Oncol* 2006; **17**: 735–49.

Uses

Polyoxyl castor oils are macrogol esters used as emulsifying and solubilising agents. Polyoxyl 35 castor oil has been used as a solvent in vehicles for various intravenous injections.

Polyoxyl Hydrogenated Castor Oils

Aceites de ricino hidrogenados y polioxietilenados; Macroglylglycerol Hydroxystearate; Macroglylgcérol, hydroxystéarate de; Macroglylgcérolu hydroxystearas; Makrogol-glicerín-éter-hidroxiszterát; Makroglylgcérolu hidroksisteratas; Makroglylgcérolu hydroxistearat; Makroglylgcérolu hidroksistearaatti.

Полиэтиленгликоля Касторовые Масла

Гидрогенизированные

Pharmacopoeias. In *Eur.* (see p.vii).

Ph. Eur. 6.2 (Macroglylglycerol Hydroxystearate; Hydrogenated Polyoxyl Castor Oil BP 2008). It contains mainly trihydroxystearyl glycerol ethoxylated with 7 to 60 molecules of ethylene oxide (nominal value), with small amounts of macrogol hydroxystearate and of the corresponding free glycols. It results from the reaction of hydrogenated castor oil with ethylene oxide. Polyoxyl hydrogenated castor oil with less than 10 units of ethylene oxide per molecule is a yellowish, turbid, viscous liquid. Practically insoluble in water; dispersible in alcohol; soluble in acetone. Polyoxyl hydrogenated castor oil with more than 20 units of ethylene oxide per molecule is a white or yellowish, semi-liquid or pasty mass. Freely soluble in water, in alcohol, and in acetone; practically insoluble in petroleum spirit.

Polyoxyl 40 Hydrogenated Castor Oil

Aceite de ricino hidrogenado polioxil 40.

Полиэтиленгликоля 40 Касторовое Масло

Гидрогенизированное

Pharmacopoeias. In *USNF*.

USNF 26 (Polyoxyl 40 Hydrogenated Castor Oil). A mixture of mainly the trihydroxystearate ester of ethoxylated glycerol, with smaller amounts of macrogol trihydroxystearate and the corresponding free glycols. It is produced by reacting 1 mole of glycerol trihydroxystearate with about 40 to 45 moles of ethylene oxide.

A white to yellowish paste or pasty liquid with a faint odour. Congealing range 20° to 30°. Very soluble in water, producing an odourless, colourless solution; soluble in alcohol and in ethyl acetate; insoluble in liquid paraffin. Store in airtight containers.

Profile

Polyoxyl hydrogenated castor oils are used as surfactants.

Polysorbates

Polisorbatos.

Полисорбаты

Description. A series of mixtures of fatty acid esters of sorbitol and its anhydrides copolymerised with about 20 moles of ethylene oxide for each mole of sorbitol and its anhydrides.

Incompatibility. Polysorbates have been reported to be stable with electrolytes and weak acids and bases although saponification may occur in the presence of strong acids and bases. Discoloration or precipitation may occur with phenolic substances. The oleic acid esters are sensitive to oxidation. For reference to the possible incompatibility of polysorbate 80 with hydroxybenzoates, see p.1649.

Polysorbate 20 (BAN, USAN, *INN*)

E432; Monolaurato de polietileno 20 sorbitano; Monolaurato de polioxietileno 20 sorbitano; Polisorbat 20; Polisorbatas 20; Polisorbato 20; Polisorbát 20; Polyoxyethylene 20 Sorbitan Monolaurate; Polysorbaatti 20; Polysorbát 20; Polysorbat 20; Polysorbatum 20; Sorbimacrogol Laurate 300; Sorboxaethenum Laurinum.

Полисорбат 20

$C_{58}H_{114}O_{26}$ (approximate).
CAS — 9005-64-5.

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

Ph. Eur. 6.2 (Polysorbate 20). A mixture of partial esters of fatty acids, mainly lauric acid, with sorbitol and its anhydrides ethoxylated with about 20 moles of ethylene oxide for each mole of sorbitol and its anhydrides. A clear or slightly opalescent yellowish to brownish-yellow oily liquid. Relative density about 1.10. Soluble in water, in dehydrated alcohol, in ethyl acetate, and in methyl alcohol; practically insoluble in liquid paraffin and in fatty oils. Store in airtight containers. Protect from light.

USNF 26 (Polysorbate 20). A laurate ester of sorbitol and its anhydrides copolymerised with approximately 20 moles of ethylene oxide for each mole of sorbitol and its anhydrides. A lemon to amber liquid with a faint characteristic odour. Soluble in water, in alcohol, in dioxan, in ethyl acetate, and in methyl alcohol; insoluble in liquid paraffin. Store in airtight containers.

Polysorbate 40 (BAN, USAN, *INN*)

E434; Monopalmitato de polietileno 20 sorbitano; Monopalmitato de polioxietileno 20 sorbitano; Polisorbatas 40; Polisorbato 40; Polisorbát 40; Polyoxyethylene 20 Sorbitan Monopalmitate; Polysorbaatti 40; Polysorbát 40; Polysorbat 40; Polysorbatum 40; Sorbimacrogol Palmitate 300.

Полисорбат 40

$C_{62}H_{122}O_{26}$ (approximate).
CAS — 9005-66-7.

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

Ph. Eur. 6.2 (Polysorbate 40). Mixture of partial esters of fatty acids, mainly palmitic acid, with sorbitol and its anhydrides ethoxylated with about 20 moles of ethylene oxide for each mole of sorbitol and sorbitol anhydrides. An oily, viscous, yellowish or brownish-yellow liquid. Relative density about 1.10. Miscible with water, with dehydrated alcohol, with ethyl acetate, and with methyl alcohol; practically insoluble in fatty oils and in liquid paraffin. Store in airtight containers. Protect from light. The BP 2008 gives Polyoxyethylene 20 Sorbitan Monopalmitate as an approved synonym.

USNF 26 (Polysorbate 40). A palmitate ester of sorbitol and its anhydrides copolymerised with about 20 moles of ethylene oxide for each mole of sorbitol and its anhydrides. A yellow liquid with a faint characteristic odour. Soluble in water and in alcohol; insoluble in liquid paraffin and in vegetable oils. Store in airtight containers.

Polysorbate 60 (BAN, USAN, *INN*)

E435; Monoestearato de polietileno 20 sorbitano; Monoestearato de polioxietileno 20 sorbitano; Polisorbat 60; Polisorbatas 60; Polisorbato 60; Polisorbát 60; Polyoxyethylene 20 Sorbitan Monostearate; Polysorbaatti 60; Polysorbát 60; Polysorbat 60; Polysorbatum 60; Sorbimacrogol Stearate 300; Sorboxaethenum Stearinum.

Полисорбат 60

$C_{64}H_{126}O_{26}$ (approximate).
CAS — 9005-67-8.

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

Ph. Eur. 6.2 (Polysorbate 60). A mixture of partial esters of fatty acids, mainly stearic acid 50, with sorbitol and its anhydrides ethoxylated with about 20 moles of ethylene oxide for each mole of sorbitol and its anhydrides. A yellowish-brown gelatinous mass which becomes a clear liquid at temperatures above 25°. Relative density about 1.10. Soluble in water, in dehydrated alcohol, in ethyl acetate, and in methyl alcohol; practically insoluble in liquid paraffin and in fatty oils. Store in airtight containers. Protect from light.

USNF 26 (Polysorbate 60). A mixture of stearate and palmitate esters of sorbitol and its anhydrides copolymerised with approximately 20 moles of ethylene oxide for each mole of sorbitol and its anhydrides. A lemon to orange-coloured oily liquid or semi-gel with a faint characteristic odour. Soluble in water, in ethyl acetate, and in toluene; insoluble in liquid paraffin and in vegetable oils. Store in airtight containers.

The symbol † denotes a preparation no longer actively marketed

Polysorbate 80 (BAN, USAN, *INN*)

E433; Monooleato de polietileno 20 sorbitano; Monooleato de polioxietileno 20 sorbitano; Olethyan 20; Polisorbat 80; Polisorbatas 80; Polisorbato 80; Polisorbát 80; Polyäthylenglykol-Sorbitanoleat; Polyoxyethylene 20 Sorbitan Mono-oleate; Polysorbaatti 80; Polysorbát 80; Polysorbat 80; Polysorbatum 80; Polysorbitanum 80 Oleinatum; Sorbimacrogol Oleate 300; Sorboxaethenum Oleinicum; Sorethyan 20 Mono-oleate.

Полисорбат 80

$C_{64}H_{128}O_{26}$ (approximate).
CAS — 9005-65-6.

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

Ph. Eur. 6.2 (Polysorbate 80). A mixture of partial esters of fatty acids, mainly oleic acid, with sorbitol and its anhydrides ethoxylated with about 20 moles of ethylene oxide for each mole of sorbitol and its anhydrides. An oily, yellowish or brownish-yellow, clear or slightly opalescent liquid. Relative density about 1.10. Dispersible in water, in dehydrated alcohol, in ethyl acetate, and in methyl alcohol; practically insoluble in liquid paraffin and in fatty oils. Store in airtight containers. Protect from light.

USNF 26 (Polysorbate 80). An oleate ester of sorbitol and its anhydrides copolymerised with about 20 moles of ethylene oxide for each mole of sorbitol and its anhydrides. A lemon to amber-coloured oily liquid with a faint characteristic odour. Sp. gr. between 1.06 and 1.09; viscosity, at 25°, between 300 and 500 mPa.s. Very soluble in water, producing an odourless and practically colourless solution; soluble in alcohol and in ethyl acetate; insoluble in liquid paraffin. Store in airtight containers.

Polysorbate 85 (BAN, USAN, *INN*)

Polisorbatas 85; Polisorbato 85; Polisorbát 85; Polyoxyethylene 20 Sorbitan Trioleate; Polysorbaatti 85; Polysorbat 85; Polysorbát 85; Polysorbatum 85; Sorbimacrogol Trioleate 300; Trioleato de polietileno 20 sorbitano; Trioleato de polioxietileno 20 sorbitano.

Полисорбат 85

$C_{100}H_{188}O_{28}$ (approximate).
CAS — 9005-70-3.

Description. A mixture of mainly trioleate esters of sorbitol and its anhydrides copolymerised with about 20 moles of ethylene oxide for each mole of sorbitol and its anhydrides.

Adverse Effects and Precautions

Polysorbates may increase the absorption of fat-soluble substances.

There have been occasional reports of hypersensitivity after topical application of preparations containing polysorbates.

For discussion of fatalities in low-birth-weight infants associated with the injection of a polysorbate-containing preparation, see below.

Polysorbates used as excipients may also lead to adverse effects due to alterations in the pharmacokinetics of the formulated drug.

References

- ten Tije AJ, *et al.* Pharmacological effects of formulation vehicles: implications for cancer chemotherapy. *Clin Pharmacokinet* 2003; **42**: 665–85.

Effects in infants. After the introduction in the USA of an intravenous preparation of vitamin E (*E-Ferol*) there were a number of reports of unusual liver and kidney disorders, with 38 deaths being reported among treated low-birth-weight infants. Affected infants had unexplained hypotension, thrombocytopenia, renal dysfunction, hepatomegaly, cholestasis, ascites, and metabolic acidosis.^{1–3} The preparation was subsequently withdrawn from the market in April 1984 about 5 months after it was introduced. *In-vitro* evidence was produced showing that *E-Ferol* suppressed the response of human lymphocytes to phytohaemagglutinin. However, it was the mixture of polysorbates, polysorbate 20 and in particular polysorbate 80, that was shown to be responsible for this suppression rather than the α -tocopherol acetate component. Despite this *in-vitro* data, overwhelming infection was not a feature in the affected infants.² Large doses of polysorbates were unavoidably injected when *E-Ferol* was used and it was suggested that polysorbates may accumulate as a result of an alteration in the metabolism by low-birth-weight infants; polysorbate-induced alteration of membrane fluidity in cells of vessel walls may have led to changes in structure and function.²

- Alade SL, *et al.* Polysorbate 80 and E-Ferol toxicity. *Pediatrics* 1986; **77**: 593–7.
- Balistreri WF, *et al.* Lessons from the E-Ferol tragedy. *Pediatrics* 1986; **78**: 503–6.
- Golightly LK, *et al.* Pharmaceutical excipients: adverse effects associated with inactive ingredients in drug products. *Med Toxicol* 1988; **3**: 128–65 and 209–240.

Hypersensitivity. Local inflammatory reactions after intramuscular injection of a vitamin A preparation were considered¹ to be due to a hypersensitivity reaction to polysorbate 80, included as an excipient. Anaphylactoid reactions which occurred in 2 patients after treatment with omalizumab for 27 and 13 months respectively, were likely to be due to the polysorbate excipient and not to the monoclonal antibody itself.² The presence of polysorbate 80 in the injection may also contribute to hypersen-

sitivity reactions to docetaxel (see Adverse Effects of Docetaxel, p.710).

- Shelley WB, *et al.* Polysorbate 80 hypersensitivity. *Lancet* 1995; **345**: 1312–13.
- Price KS, Hamilton RG. Anaphylactoid reactions in two patients after omalizumab administration after successful long-term therapy. *Allergy Asthma Proc* 2007; **28**: 313–19.

Uses

Polysorbates are hydrophilic nonionic surfactants that are used as emulsifying agents for the preparation of stable oil-in-water emulsions in pharmaceutical products; they are frequently used with a sorbitan ester in varying proportions to produce products with a range of texture and consistency. Polysorbates have also been used in the formulation of insecticide and herbicide sprays, industrial detergents, and cosmetic products. They are also used as emulsifiers in the food industry.

Polysorbates are used as solubilising agents for a variety of substances including essential oils and oil-soluble vitamins such as vitamins A, D, and E, and as wetting agents in the formulation of oral and parenteral suspensions. However, hypersensitivity reactions have been attributed to the presence of polysorbates, see Hypersensitivity, above.

Polysorbates may also be used for their surfactant properties in preparations for the removal of ear wax, and for the management of dry eyes and upper respiratory-tract disorders.

Preparations

Proprietary Preparations (details are given in Part 3)

Arg.: Sinroncar; **Belg.:** Oleosorbate; **Canad.:** Dioptears; Tears Encore; **Fr.:** Cerumenol; **USA:** OptiZen; Viva-Drops.

Multi-ingredient: **Arg.:** Balsan†; Otodean; Gotas Oticas; **Fin.:** Expigen; **Fr.:** Ceruspray; Fluisedal; Fluisedal sans promethazine; Paroplak; Prorhinel; **S.Afr.:** Expigen; **Switz.:** Prorhinel; Rhinocure; Rhinocure simplex; **Turk.:** Kanslak; Libalaks; **UK:** Asonor; **USA:** Refresh Dry Eye Therapy; Soothe; Soothe XR.

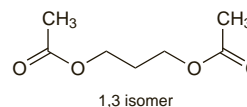
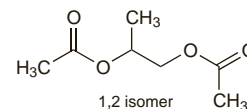
Propylene Glycol Diacetate

Propilenglicol, diacetato de. Propenediol diacetate.

Диацетат Пропиленгликоля

$C_7H_{12}O_4$ = 160.2.

CAS — 623-84-7 (1,2-isomer); 628-66-0 (1,3-isomer).



Profile

Propylene glycol diacetate is an emulsifying and/or solubilising agent, and a solvent. It is included in some external preparations for ear infection.

Preparations

Proprietary Preparations (details are given in Part 3)

Multi-ingredient: **Canad.:** VoSol HC†; **NZ:** VoSol; **USA:** Acetasol; Acetasol HC; VoSol HC†; VoSol†.

Propylene Glycol Laurates

E477 (propylene glycol esters of fatty acids); Propilenglicol, laurato de.

Пропиленгликоля Лаураты

Propylene Glycol Dilaurate

E477 (propylene glycol esters of fatty acids); Propilenglicol, dilaurato de; Propilenglikolio dilauratas; Propyleeniglykolidilauraatti; Propylene Dilaurate; Propylenglycol, dilaurate de; Propylenglycoli dilauras; Propylenglykoldilaurat; Propylenglykol-dilaurát.

Пропиленгликоля Дилаурат

CAS — 22788-19-8.

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

Ph. Eur. 6.2 (Propylene Glycol Dilaurate). A mixture of the propylene glycol mono- and di-esters of lauric acid. It contains a minimum of 70% of di-esters and a maximum of 30% of mono-esters. The content of free propylene glycol is not more than 2%. A colourless or slightly yellow, clear oily liquid at 20°. Practically insoluble in water; very soluble in alcohol, in methyl alcohol, and in dichloromethane. Protect from moisture.

USNF 26 (Propylene Glycol Dilaurate). A mixture of the propylene glycol mono- and di-esters of lauric acid. It contains not less than 70.0% of di-esters and not more than 30.0% of mono-esters. Protect from moisture.