

A hard, waxy mass or powder, or white or almost white, unctuous flakes. Practically insoluble in water; partly soluble in hot alcohol; soluble in dichloromethane. M.p. 50° to 60° (types I and II) or 50° to 70° (type III).

**USNF 26** (Glyceryl Distearate). A mixture of diglycerides, mainly glyceryl distearate, together with variable quantities of monoglycerides and triglycerides. It contains 8 to 22% of monoglycerides, 40 to 60% of diglycerides, and 25 to 35% of triglycerides. It is obtained by partial glycerolysis of vegetable oil that consists mainly of triglycerides of palmitic or stearic acid or by esterification of glycerol with stearic acid. The fatty acids may be of vegetable or animal origin.

Hard, waxy mass or powder, or white or almost white flakes. Insoluble in water; partly soluble in hot alcohol; soluble in dichloromethane and in tetrahydrofuran. Store in airtight containers.

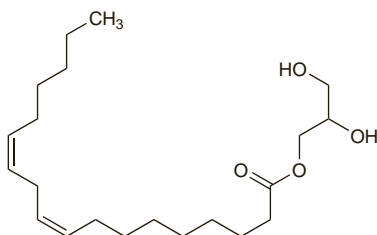
#### Profile

Glyceryl distearate is used as an emulsifying and/or solubilising agent.

### Glyceryl Monolinoleate

Glicerol-monolinoleát; Glicerol, monolinoleato de; Glicerolio monolinoleatas; Glycerol Monolinoleate; Glycérol, monolinoléate de; Glyceroli monolinoleas; Glycerol-monolinolát; Glycerolmonolinoleat; Glycerolmonolinoleaatti; Monolinolein.

Глицерилмонолинлеат  
CAS — 26545-74-4.



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

**Ph. Eur. 6.2** (Glycerol Monolinoleate). A mixture of monoacylglycerols, mainly mono-oleoylglycerol and monolinoleoylglycerol, together with variable quantities of di- and triacylglycerols. It contains 32 to 52% of monoacylglycerols, 40 to 55% of diacylglycerols, and 5 to 20% of triacylglycerols, obtained by partial glycerolysis of vegetable oils mainly containing triacylglycerols of linoleic acid. A suitable antioxidant may be added.

Amber, oily liquids which may be partially solidified at room temperature. Practically insoluble in water; freely soluble in dichloromethane. Store in airtight containers. Protect from light.

**USNF 26** (Glyceryl Monolinoleate). A mixture of monoglycerides, mainly glyceryl mono-oleate and glyceryl monolinoleate, together with variable quantities of diglycerides and triglycerides. It is obtained by partial glycerolysis of vegetable oil that consists mainly of triglycerides of linoleic acid. It contains 32 to 52% of monoglycerides, 40 to 55% of diglycerides, and 5 to 20% of triglycerides. A suitable antioxidant may be added.

Amber, oily liquids that may be partially solidified at room temperature. Practically insoluble in water; freely soluble in dichloromethane; soluble in tetrahydrofuran. Store in airtight containers.

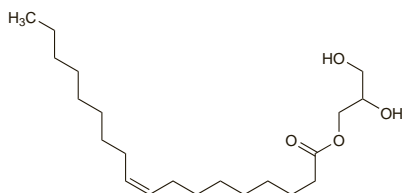
#### Profile

Glyceryl monolinoleate is used as an emulsifying and/or solubilising agent.

### Glyceryl Mono-oleate

Glicerol, monooleato de; Glycérol, mono-oléate de; Glyceroli mono-oleas; Monoolein.

Глицерилмоноолеат  
CAS — 25496-72-4.



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

**Ph. Eur. 6.2** (Glycerol Mono-oleates). Mixtures of monoacylglycerols, mainly mono-oleoylglycerol, together with variable quantities of di- and triacylglycerols. They are defined by the

nominal content of monoacylglycerols and obtained by partial glycerolysis of vegetable oils mainly containing triacylglycerols of oleic acid, or by esterification of glycerol by oleic acid. A suitable antioxidant may be added.

Amber, oily liquids which may be partially solidified at room temperature. Practically insoluble in water; freely soluble in dichloromethane. Store in airtight containers. Protect from light.

**USNF 26** (Glyceryl Monooleate). A mixture of monoglycerides, mainly glyceryl mono-oleate, together with variable quantities of di- and triglycerides. It is obtained by partial glycerolysis of vegetable oil that consists mainly of triglycerides of oleic acid, or by esterification of glycerol with oleic acid of vegetable or animal origin. It is defined by the nominal content of monoglycerides. A suitable antioxidant may be added.

Amber, oily liquids that may be partially solidified at room temperature. Practically insoluble in water; freely soluble in dichloromethane; soluble in tetrahydrofuran. Store in airtight containers.

#### Profile

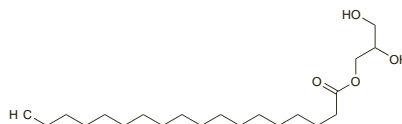
Glyceryl mono-oleate has similar properties to glyceryl monostearate or self-emulsifying glyceryl monostearate (below).

### Glyceryl Monostearate

Gliceril, monoestearato de; Glicerol-monostearát; Glicerolio monostearatas; Glicerolu monostearanyian; Glycérol, monostéarate de; Glyceroli monostearas; Glycerolmonostearat; Glycerolmonostearát; Glycerolmonostearaatti; GMS; Monostearin.

Глицерилмоностеарат

CAS — 31566-31-1 (glyceryl monostearate); 26657-96-5 (glyceryl monopalmitate).



**Pharmacopoeias.** In *Eur.* (see p.vii), *Int.*, and *Jpn.* Also in *US-NF*.

**Ph. Eur. 6.2** (Glycerol Monostearate 40-55). A mixture of monoacylglycerols, mainly monostearoylglycerol, together with variable quantities of di- and triacylglycerols. It contains 40 to 55% of monoacylglycerols, 30 to 45% of diacylglycerols, and 5 to 15% of triacylglycerols, obtained by partial glycerolysis of vegetable oils mainly containing triacylglycerols of palmitic or stearic acid, or by esterification of glycerol with stearic acid. The fatty acids may be of vegetable or animal origin.

A white or almost white, hard, waxy mass or unctuous powder or flakes. Practically insoluble in water; soluble in alcohol at 60°. M.p. 54° to 66°.

**USNF 26** (Glyceryl Monostearate). It contains not less than 90% of monoglycerides of saturated fatty acids, chiefly glyceryl monostearate (C<sub>21</sub>H<sub>42</sub>O<sub>4</sub> = 358.6) and glyceryl monopalmitate (C<sub>19</sub>H<sub>38</sub>O<sub>4</sub> = 330.5). It may contain a suitable antioxidant.

A white to yellowish wax-like solid, beads, flakes, or powder with a slight, agreeable, fatty odour. M.p. not below 55°. Insoluble in water but may be dispersed in hot water with the aid of a small amount of soap or other suitable surfactant; soluble 1 in 10 of chloroform, 1 in 100 of ether and of methyl alcohol, 1 in 33 of isopropyl alcohol; dissolves in hot organic solvents such as alcohol, acetone, mineral or fixed oils, and benzene. Store in airtight containers. Protect from light.

### Self-emulsifying Glyceryl Monostearate

Glicerol autoemulsionable, monoestearato de; Monostearato de glicerilo autoemulsionable; Monostearin Emulsificans; Self-emulsifying Mono- and Diglycerides of Food Fatty Acids; Self-emulsifying Monostearin.

Глицерилмоностеарат Самоэмульгирующий

**Pharmacopoeias.** In *Br.*

**BP 2008** (Self-emulsifying Glyceryl Monostearate). A mixture consisting principally of mono-, di-, and triglycerides of stearic and palmitic acids, and of minor proportions of other fatty acids; it may also contain free fatty acids, free glycerol, and soap. It contains not less than 30% of monoglycerides, not more than 7% of free glycerol, and not more than 6% of soap, calculated as sodium oleate, all calculated with reference to the anhydrous substance.

A white to cream-coloured, hard, waxy solid with a faint fatty odour. Dispersible in hot water; soluble in hot dehydrated alcohol and in hot liquid paraffin; soluble in hot vegetable oils, but may give turbid solutions at concentrations below 20%.

**Incompatibility.** Because of the presence of soap, self-emulsifying glyceryl monostearate is incompatible with acids and high concentrations of ionisable salts, hard water, calcium compounds, zinc oxide, and oxides of heavy metals.

#### Profile

Glyceryl monostearate is a poor water-in-oil emulsifying agent but it is a useful stabiliser of water-in-oil and oil-in-water emulsions in preparations for internal and external use. It has emollient properties. Glyceryl monostearate is also used in the food and cosmetic industries.

It is usual to add a small amount of soap, sulfated fatty alcohol, or other surfactant, to glyceryl monostearate, which has the effect of making the product self-emulsifying and capable of producing satisfactory oil-in-water emulsions. Self-emulsifying glyceryl monostearate is used as an emulsifying agent for oils, fats, solvents, and waxes in the preparation of bases of the non-emulsified, emulsified, and vanishing-cream types. It is not intended for inclusion in preparations for internal use.

Aqueous preparations containing self-emulsifying glyceryl monostearate should contain a preservative to prevent fungal or bacterial growth.

### Macrogol Cetostearyl Ethers

Ceteareth Compounds; Macrogol, éteres cetoestearílicos de; Macrogol, ether cétostéarylique de; Macrogoli aether cetoestearylicus; Makrogol-cetil-sztearil-éter; Makrogolcetoestearyl-eter; Makrogolio cetoestearilo eteris; Makrogolisetostearylieetteri.

Полиэтиленгликоля и Цетостеарилового Спирта Эфиры  
CAS — 68439-49-6.

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

**Ph. Eur. 6.2** (Macrogol Cetostearyl Ether). A mixture of ethers of mixed macrogols with linear fatty alcohols, mainly cetostearyl alcohol. It may contain some free macrogols and it contains various amounts of free cetostearyl alcohol. The amount of ethylene oxide reacted with cetostearyl alcohol is from 2 to 33 units per molecule (nominal value). White or yellowish-white waxy, unctuous mass, pellets, microbeads, or flakes. Macrogol cetostearyl ether with low numbers of ethylene oxide units per molecule is practically insoluble in water; soluble in alcohol and in dichloromethane. Macrogol cetostearyl ether with higher numbers of ethylene oxide units per molecule is dispersible or soluble in water; soluble in alcohol and in dichloromethane. Macrogol cetostearyl ether solidifies at 32° to 52°. Store in airtight containers. The labelling states the amount of ethylene oxide reacted with cetostearyl alcohol (nominal value).

### Cetomacrogol 1000

Cétomacrogol 1000; Cetomacrogolum 1000; Éter monocétílico de polietilenglicol 1000; Polyethylene Glycol 1000 Monocetyl Ether; Polyoxoethylene Glycol 1000 Monocetyl Ether.

Кетомакрогол 1000; Цетомакрогол 1000  
CAS — 9004-95-9 (macrogol cetyl ethers); 68439-49-6 (macrogol cetostearyl ethers).

**Description.** Cetomacrogol 1000 is a macrogol ether containing 20 to 24 oxoethylene groups in the polyoxoethylene chain. It may be prepared from either cetyl alcohol or from cetostearyl alcohol. It is represented by the formula CH<sub>3</sub>[CH<sub>2</sub>]<sub>m</sub>[OCH<sub>2</sub>CH<sub>2</sub>]<sub>n</sub>OH, where *m* may be 15 or 17 and *n* may be 20 to 24. The more specific term macrogol cetostearyl ether (22), representing such an ether in which *n* = 22, has replaced cetomacrogol 1000 in BP formulations. Macrogol cetyl ethers are also sometimes termed ceteth compounds.

**Pharmacopoeias.** In *Int.*

**Incompatibility.** Cetomacrogol has been reported to be incompatible with phenols and to reduce the antibacterial activity of quaternary ammonium compounds. Cetomacrogol may separate from solutions in the presence of a high concentration of electrolytes.

### Polyoxyl 20 Cetostearyl Ether

Polióxil 20, éter cetoestearílico de.

Полиоксиэтилендиола 20 и Цетостеариловой Кислоты Эфир  
CAS — 68439-49-6.

**Pharmacopoeias.** In *USNF*.

**USNF 26** (Polyoxyl 20 Cetostearyl Ether). A mixture of the monocetostearyl (mixed hexadecyl and octadecyl) ethers of mixed macrogols, the average polymer length being equivalent to 17.2 to 25.0 oxoethylene units. A cream-coloured waxy unctuous mass, melting, when heated, to a clear brownish-yellow liquid. Soluble in water, in alcohol, and in acetone; insoluble in petroleum spirit. A 10% solution in water has a pH of 4.5 to 7.5. Store at a temperature of 8° to 15° in airtight containers.

#### Profile

Macrogol cetostearyl ethers are used as surfactants and emulsifiers. Macrogol cetostearyl ether (22) is used with cetostearyl alcohol (for example, in the form of Cetomacrogol Emulsifying Wax BP 2008) as an emulsifying agent for making oil-in-water emulsions that are unaffected by moderate concentrations of electrolytes and that are stable over a wide pH range. It is also used to disperse volatile oils in water to form transparent sols.