

Glyceryl Monooleate

1 Nonproprietary Names

BP: Glycerol mono-oleates

PhEur: Glyceroli mono-oleates

2 Synonyms

Aldo MO; Arlacel 186; Atlas G-695; Capmul GMO; Cithrol GMO N/E; glycerol-1-oleate; glyceryl mono-oleate; GMO GE; Hodag GMO; Kessco GMO; Ligalub; monoolein; Monomuls 90-O18; mono-olein; α -mono-olein glycerol; Myverol 18-99; Peceol; Priolube 1408; Stepan GMO; Tegin.

3 Chemical Name and CAS Registry Number

9-Octadecenoic acid (Z), monoester with 1,2,3-propanetriol [25496-72-4]

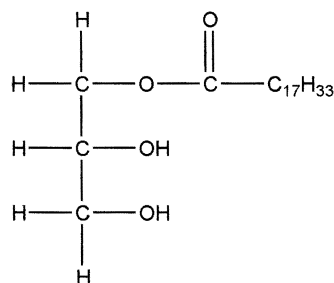
4 Empirical Formula Molecular Weight

C₂₁H₄₀O₄

356.55 (for pure material)

Glyceryl monooleate is a mixture of the glycerides of oleic acid and other fatty acids, consisting mainly of the mono-oleate; see Section 8.

5 Structural Formula



6 Functional Category

Nonionic surfactant.

7 Applications in Pharmaceutical Formulation or Technology

Glyceryl monooleate is a polar lipid that swells in water to give several phases with different rheological properties.⁽¹⁾ It is available in both nonemulsifying (n/e) and self-emulsifying (s/e) grades, the self-emulsifying grade containing about 5% of an anionic surfactant.

The nonemulsifying grade is used in topical formulations as an emollient and as an emulsifying agent for water-in-oil emulsions. It is also a stabilizer for oil-in-water emulsions. The self-emulsifying grade is used as a primary emulsifier for oil-in-water systems.

Glyceryl monooleate gels in excess water, forming a highly ordered cubic phase that can be used to sustain the release of various water-soluble drugs.⁽²⁻⁵⁾

Glyceryl monooleate is reported to enhance transdermal⁽⁶⁾ and buccal penetration.⁽⁷⁾

8 Description

The PhEur 2002 describes glyceryl monooleate as being a mixture of monoacylglycerols, mainly mono-oleoylglycerol, together with variable quantities of di- and triacylglycerols. They are defined by the nominal content of monoacylglycerols (see Table I) and obtained by partial glycerolysis of vegetable oils mainly containing triacylglycerols of oleic acid or by esterification of glycerol by oleic acid, this fatty acid being of vegetable or animal origin. A suitable antioxidant may be added.

Glyceryl monooleates occur as amber oily liquids, which may be partially solidified at room temperature and have a characteristic odor.

Table I: Nominal content of acylglycerols in glycerol monooleate defined in the PhEur 2002.

	Nominal content of acylglycerol (%)		
	40	60	90
Monoacylglycerols	32.0–52.0	55.0–65.0	90.0–101.0
Diacylglycerols	30.0–50.0	15.0–35.0	< 10.0
Triacylglycerols	5.0–20.0	2.0–10.0	< 2.0

9 Pharmacopeial Specifications

See Table II.

Table II: Pharmacopeial specifications for glyceryl monooleate.

Test	PhEur 2002
Identification	+
Characters	+
Acid value	≤ 6.0%
Iodine value	65.0–95.0
Peroxide value	≤ 12.0
Saponification value	150–170
Free glycerin	≤ 6.0%
Composition of fatty acids	+
Palmitic acid	≤ 12.0%
Stearic acid	≤ 6.0%
Oleic acid	≤ 60.0%
Linoleic acid	≤ 35.0%
Linolenic acid	≤ 2.0%
Arachidic acid	≤ 2.0%
Eicosenoic acid	≤ 2.0%
Content of acylglycerols	+
Water	≤ 1.0%
Total ash	≤ 0.1%

10 Typical Properties

Boiling point: 238–240°C

Density: 0.942 g/cm³

Flash point: 216°C

HLB value: 3.3 (n/e); 4.1 (s/e).

Melting point: 35°C (see also Section 13)

Refractive index: 1.4626

Solubility: soluble in chloroform, ethanol (95%), ether, mineral oil, and vegetable oils; practically insoluble in water. The self-emulsifying grade is dispersible in water.

Viscosity (kinematic): 100 m²/s (100 cSt) at 40°C

11 Stability and Storage Conditions

Glyceryl monooleate should be stored in an airtight container, protected from light in a cool, dry place.

12 Incompatibilities

Glyceryl monooleate is incompatible with strong oxidizing agents. The self-emulsifying grade is incompatible with cationic surfactants.

13 Method of Manufacture

Glyceryl monooleate is prepared by the esterification of glycerol with fatty acids, chiefly oleic acid. As the fatty acids are not pure substances, but rather a mixture of fatty acids, the product obtained from the esterification will contain a mixture of esters, including stearic and palmitic. Di- and tri-esters may also be present. The composition and, therefore, the physical properties of glyceryl monooleate may thus vary considerably from manufacturer to manufacturer; e.g., the melting point may vary from 10 to 35°C.

14 Safety

Glyceryl monooleate is used in oral and topical pharmaceutical formulations and is generally regarded as a relatively nonirritant and nontoxic excipient.

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled.

16 Regulatory Status

GRAS listed. Included in the FDA Inactive Ingredients Guide (oral capsules and tablets). Included in nonparenteral medicines licensed in the UK.

17 Related Substances

Glyceryl monostearate.

18 Comments

The EINECS number for glyceryl monooleate is 247-038-6.

19 Specific References

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20 General References

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22 Date of Revision

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