Glyceryl Monostearate

1 Nonproprietary Names

BP: Glyceryl monostearate 40–55
JP: Glyceryl monostearate
PhEur: Glyceroli monostearas 40–55
USPNF: Glyceryl monostearate

2 Synonyms

Capmul GMS-50; *Cutina GMS*; 2,3-dihydroxypropyl octadecanoate; glycerine monostearate; glycerin monostearate; glycerol monostearate; glycerol stearate; glyceryl stearate; GMS; *Imwitor 191* and *900*; *Kessco GMS*; *Lipo GMS 410*, *450* and *600*; monoester with 1,2,3-propanetriol; monostearin; *Myvaplex 600P*; *Myvatex*; 1,2,3-propanetriol octadecanoate; *Protachem GMS-450*; stearic acid, monoester with glycerol; stearic monoglyceride; *Rita GMS*; *Stepan GMS*; *Tegin*; *Tegin 503* and *515*; *Tegin 4100*; *Tegin M*; *Unimate GMS*.

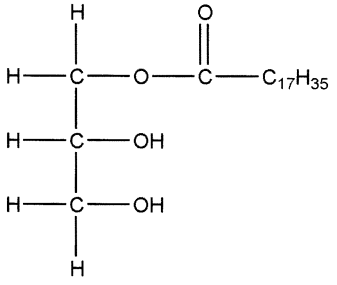
3 Chemical Name and CAS Registry Number

Octadecanoic acid, monoester with 1,2,3-propanetriol [31566-31-1]

4 Empirical Formula and Molecular Weight

Empirical Formula	Molecular Weight
$C_{21}H_{42}O_4$	358.6

5 Structural Formula



6 Functional Category

Emollient; emulsifying agent; solubilizing agent; stabilizing agent; sustained-release ingredient; tablet and capsule lubricant.

7 Applications in Pharmaceutical Formulation or Technology

Glyceryl monostearate is used as a nonionic emulsifier, stabilizer, emollient, and plasticizer in a variety of food, pharmaceutical, and cosmetic applications. It acts as an effective stabilizer, that is, as a mutual solvent for polar and nonpolar compounds that may form water-in-oil or oil-in-water emulsions.[1,2] These properties also make it useful as a dispersing agent for pigments in oils or solids in fats, or as a solvent for phospholipids, such as lecithin.

Glyceryl monostearate has also been used in a novel fluidized hot-melt granulation technique for the production of granules and tablets.[3]

Glyceryl monostearate is a lubricant for tablet manufacturing and may be used to form sustained-release matrices for solid dosage forms.[4–6] Sustained-release applications include the formulation of pellets for tablets[7] or suppositories[8] and the preparation of a veterinary bolus.[9] Glyceryl monostearate has also been used as a matrix ingredient for a biodegradable, implantable, controlled-release dosage form.[10]

8 Description

The USPNF 20 describes glyceryl monostearate as consisting of not less than 90% of monoglycerides, chiefly glyceryl monostearate ($C_{21}H_{42}O_4$) and glyceryl monopalmitate ($C_{19}H_{38}O_4$). The PhEur 2002 describes glyceryl monostearate 40–55 as a mixture of monoacylglycerols, mostly monostearoylglycerol, together with quantities of di- and triacylglycerols. It contains 40–55% of monoacylglycerols, 30–45% of diacylglycerols, and 5–15% of triacylglycerols.

The commercial product is a mixture of variable proportions of glyceryl monostearate and glyceryl monopalmitate.

Glyceryl monostearate is a white to cream-colored, waxlike solid in the form of beads, flakes, or powder. It is waxy to the touch and has a slight fatty odor and taste.

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for glyceryl monostearate.

Test	JP 2001	PhEur 2002	USPNF 20
Identification	+	+	—
Characters	+	+	—
Acid value	≤15.0	≤3.0	≤6.0
Iodine value	≤3.0	≤3.0	≤3.0
Hydroxyl value	—	—	300–330
Saponification value	157–170	158–177	155–165
Melting point	≥55°C	—	≥55°C
Residue on ignition	≤0.10%	—	≤0.5%
Acidity or alkalinity	+	—	—
Free glycerol	—	≤6.0%	—
Composition of fatty acids	—	+	—
Heavy metals	—	—	≤0.001%
Nickel	—	≤1 ppm	—
Water	—	≤1.0%	—
Organic volatile impurities	—	—	+
Total ash	—	≤0.10%	—
Assay	—	+	+

10 Typical Properties

A wide variety of glyceryl monostearate grades are commercially available, including self-emulsifying grades that contain

small amounts of soap or other surfactants. Most grades are tailored for specific applications or made to user specifications and therefore have varied physical properties.
HLB value: 3.8
Flash point: ≈240°C
Melting point: 55–60°C
Solubility: soluble in hot ethanol, ether, chloroform, hot acetone, mineral oil, and fixed oils. Practically insoluble in water, but may be dispersed in water with the aid of a small amount of soap or other surfactant.
Specific gravity: 0.92

11 Stability and Storage Conditions

If stored at warm temperatures, glyceryl monostearate increases in acid value upon aging owing to the saponification of the ester with trace amounts of water. Effective antioxidants may be added, such as butylated hydroxytoluene and propyl gallate.

Glyceryl monostearate should be stored in a tightly closed container in a cool, dry place, and protected from light.

12 Incompatibilities

The self-emulsifying grades of glyceryl monostearate are incompatible with acidic substances.

13 Method of Manufacture

Glyceryl monostearate is prepared by the reaction of glycerol with triglycerides from animal or vegetable sources, producing a mixture of monoglycerides and diglycerides. The diglycerides may be further reacted to produce the 90% monoglyceride grade. Another process involves reaction of glycerol with stearoyl chloride.

The starting materials are not pure substances and therefore the products obtained from the processes contain a mixture of esters, including palmitate and oleate. Consequently, the composition, and therefore the physical properties, of glyceryl monostearate may vary considerably depending on the manufacturer.

14 Safety

Glyceryl monostearate is widely used in cosmetics, foods, and oral and topical pharmaceutical formulations and is generally regarded as a nontoxic and nonirritant material.

LD_{50} (mouse, IP): 0.2 g/kg[11]

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; ophthalmic, otic, rectal, topical, transdermal, and vaginal preparations). Included in nonparenteral medicines licensed in the UK.

If gylceryl monostearate is produced from animal fats (tallow), there may be additional regulatory requirements that the source be free of contamination from bovine spongiform encephalopathy.

17 Related Substances

Glyceryl monooleate; glyceryl palmitostearate; self-emulsifying glyceryl monostearate.

Self-emulsifying glyceryl monostearate

Synonyms: *Aracel 165*; *Arlatone 983*; *Cithol MS S/E*; glyceryl stearate SE; GMS SE; *Hodag GMS-D*.
Acid value: <6
Alkalinity: pH = 8.0–10.0
Assay (for monogylcerides): 40.0–50.0%
Free glycerol: <7.0%
Heavy metals: <10 ppm
Iodine value: <3
Melting point: 54–64°C
Moisture content: <2.0%
Soap (as sodium oleate): <6.0%
Comments: self-emulsifying glyceryl monostearate is a grade of glyceryl monostearate to which an emusifying agent has been added. The emulsifier may be a soluble soap, a salt of a sulfated alcohol, a nonionic surfactant, or a quaternary compound. It is used primarily as an emulsifying agent for oils, fats, solvents, and waxes. Aqueous preparations should contain an antimicrobial preservative.

18 Comments

Glyceryl monostearate and other fatty acid monoesters are not efficient emulsifiers. However, they are useful emollients that are readily emulsified by common emulsifying agents and by incorporation of other fatty materials into the formulation. Addition of the monoester materials provides the creams with smoothness, fine texture, and improved stability.

In topical applications, glyceryl monostearate is less drying than straight stearate creams, and is not drying when used in protective applications.

19 Specific References

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20 General References

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21 Author

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22 Date of Revision

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