

Monothioglycerol

1 Nonproprietary Names

USPNF: Monothioglycerol

2 Synonyms

1-Mercaptoglycerol; 1-mercapto-2,3-propanediol; monothioglycerin; α -monothioglycerol; thioglycerin; 1-thioglycerol.

3 Chemical Name and CAS Registry Number

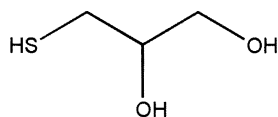
3-Mercapto-1,2-propanediol [96-27-5]

4 Empirical Formula Molecular Weight

$C_3H_8O_2S$

108.16

5 Structural Formula



6 Functional Category

Antimicrobial preservative; antioxidant.

7 Applications in Pharmaceutical Formulation or Technology

Monothioglycerol is used as an antioxidant in pharmaceutical formulations, mainly in parenteral preparations.⁽¹⁾ Monothioglycerol is reported to have some antimicrobial activity.⁽²⁻⁴⁾ It is also widely used in cosmetic formulations such as depilating agents.

Therapeutically, monothioglycerol has been used in a 0.02% w/w aqueous solution to stimulate wound healing, and as a 0.1% w/w jelly in atrophic rhinitis.

8 Description

Monothioglycerol occurs as a colorless or pale-yellow colored, viscous, hygroscopic liquid with a slight odor of sulfide.

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for monothioglycerol.

Test	USPNF 20
Identification	+
Specific gravity	1.241–1.250
Refractive index	1.521–1.526
pH (10% aqueous solution)	3.5–7.0
Water	≤5.0%
Residue on ignition	≤0.1%
Selenium	≤0.003%
Heavy metals	≤0.002%
Organic volatile impurities	+
Assay (anhydrous basis)	97.0–101.0%

10 Typical Properties

Acidity/alkalinity: pH = 3.5–7.0 (10% w/v aqueous solution)

Boiling point: 118 °C

Flash point: 110 °C

Refractive index: $n_D^{25} = 1.521–1.526$

Solubility: miscible with ethanol (95%); freely soluble in water; practically insoluble in ether.

Specific gravity: 1.241–1.250

11 Stability and Storage Conditions

Monothioglycerol is unstable in alkaline solutions. Monothioglycerol should be stored in a well-closed container in a cool, dry place.

12 Incompatibilities

Monothioglycerol can react with oxidizing materials.

13 Method of Manufacture

Monothioglycerol is prepared by heating an ethanolic solution of 3-chloro-1,2-propanediol with potassium bisulfide.

14 Safety

Monothioglycerol is generally regarded as a relatively nontoxic and nonirritant material at the concentrations used as a pharmaceutical excipient. It is used in topical and injectable preparations.

Undiluted monothioglycerol is considered a poison by the IP and IV routes; it has also been reported to be mutagenic.⁽⁵⁾

LD₅₀ (cat, IV): 0.22 g/kg⁽⁵⁾

LD₅₀ (mouse, IP): 0.34 g/kg

LD₅₀ (rabbit, IV): 0.25 g/kg

LD₅₀ (rat, IP): 0.39 g/kg

15 Handling Precautions

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

flammable when exposed to heat or flame; when heated to decomposition it emits toxic fumes of SO_x.

16 Regulatory Status

Included in the FDA Inactive Ingredients Guide (IM, IV and other injections).

17 Related Substances

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18 Comments

The EINECS number for monothioglycerol is 202-495-0.

19 Specific References

- 1 Kasraian K, Kuzniar AA, Wilson GG, Wood JA. Developing an injectable formula containing an oxygen sensitive drug: case study of danofloxacin injectable. *Pharm Dev Technol* 1999; 4(4): 475-480.
- 2 Jensen KK, Javor GT. Inhibition of *Escherichia coli* by thioglycerol. *Antimicrob Agents Chemother* 1981; 19: 556-561.

- 3 Javor GT. Depression of adenosylmethionine content of *Escherichia coli* by thioglycerol. *Antimicrob Agents Chemother* 1983; 24: 860-867.
- 4 Javor GT. Inhibition of respiration of *Escherichia coli* by thioglycerol. *Antimicrob Agents Chemother* 1983; 24: 868-870.
- 5 Lewis RJ, ed. *Sax's Dangerous Properties of Industrial Materials*, 10th edn. New York: Wiley, 2000: 2576.

20 General References

Nealon DA, Pettit SM, Henderson AR. Diluent pH and the stability of the thiol group in monothioglycerol, N-acetyl-L-cysteine, and 2-mercaptoethanol. *Clin Chem* 1981; 27(3): 505-506.

21 Authors

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22 Date of Revision

10 June 2002.