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]

LD_{50} (cat, IV): 0.22 g/kg[5]
LD_{50} (mouse, IP): 0.34 g/kg
LD_{50} (rabbit, IV): 0.25 g/kg
LD_{50} (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 Database (IM, IV and other injections). Included in the Canadian Natural Health Products Ingredients Database.

17 Related Substances

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18 Comments

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.

The EINECS number for monothioglycerol is 202-495-0. The PubChem Compound ID (CID) for monothioglycerol includes 7291 and 447638.

19 Specific References

1 Kasraian K, *et al.* 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*, 12th edn. New York: Wiley, 2012; 3171.

20 General References

Modi S, *et al.* Determination of thio-based additives for biopharmaceuticals by pulsed electrochemical detection following HPLC. *J Pharm Biomed Anal* 2005; 37(1): 19–25.

Nealon DA, *et al.* 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.

Sherman F, Kuselman I. Water determination in drugs containing thiols. *Int J Pharm* 1999; 190(2): 193–196.

21 Author

PJ Sheskey.

22 Date of Revision

4 May 2017.

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Myristic Acid

1 Nonproprietary Names

USP–NF: Myristic Acid

2 Synonyms

Edenor C14 98-100; *n*-tetradecanoic acid; 1-tridecanecarboxylic acid.

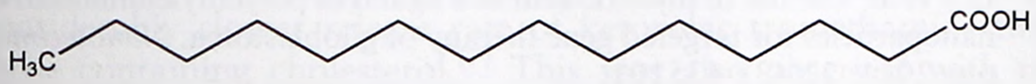
3 Chemical Name and CAS Registry Number

Tetradecanoic acid [544-63-8]

4 Empirical Formula and Molecular Weight

$C_{14}H_{28}O_2$ 228.37

5 Structural Formula



6 Functional Category

Emulsifying agent; penetration enhancer; tablet and capsule lubricant.

7 Applications in Pharmaceutical Formulation or Technology

Myristic acid is used in oral and topical pharmaceutical formulations as an emulsifying agent, penetration enhancer, and tablet and capsule lubricant.

Myristic acid has been evaluated as a penetration enhancer in melatonin transdermal patches in rats[1] and bupropion formulations on human cadaver skin.[2] Further studies have assessed the suitability of myristic acid in oxymorphone formulations,[3] clobetasol 17-propionate topical applications,[4] and diltiazem hydrochloride hydroxypropyl methylcellulose gel formulations.[5] Furthermore, polyvinyl alcohol substituted with myristic acid (as well as other fatty acids) at different substitution degrees has been studied for the preparation of biodegradable microspheres containing progesterone or indomethacin.[6] Myristic acid has also been investigated for use in solid lipid nanoparticles for enhanced oral bioavailability of low molecular weight heparins,[7] and for colon-specific delivery of peptide drugs.[8]

8 Description

Myristic acid occurs as an oily white crystalline solid with a faint odor.