Triacetin

Nonproprietary Names

BP: Triacetin

PhEur: Glycerolum tricacetas

USP: Triacetin

2 Synonyms

Captex 500; E1518; glycerol triacetate; glyceryl triacetate; triacetyl glycerine.

Chemical Name and CAS Registry Number

1,2,3-Propanetriol triacetate [102-76-1]

Empirical Formula

Molecular Weight

 $C_9H_{14}O_6$

218.21

Structural Formula

Functional Category

Humectant; plasticizer; solvent.

Applications in Pharmaceutical Formulation or Technology

Triacetin is mainly used as a hydrophilic plasticizer in both aqueous and solvent-based polymeric coating of capsules, tablets, beads, and granules; typical concentrations used are 10-35% w/w. (1,2)

Triacetin is used in cosmetics, perfumery, and foods as a solvent and as a fixative in the formulation of perfumes and flavors.

Description

Triacetin is a colorless, viscous liquid with a slightly fatty odor.

Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for triacetin.

Test	PhEur 2002	USP 25
Appearance	+	_
Characters	+	
Identification	+	+
Specific gravity	1.159-1.164	1.152-1.158
Refractive index	1.429-1.432	1.429-1.430
Acidity	+	+
Water	≤0.2%	≤0.2%
Assay (anhydrous basis)	97.0-100.5%	97.0-100.5%

10 **Typical Properties**

Autoignition temperature: 432 °C

Boiling point: 258 °C

Density: 1.16 g/cm³ at 25 °C

Explosive limits:

1.05% at 189°C lower limit 7.73% at 215 °C upper limit

Flash point: 153 °C (open cup)

Freezing point: 3.2 °C (supercools to about -70 °C)

Melting point: $-78 \,^{\circ}\text{C}$ Refractive index: $n_{\text{D}}^{2.5} = 1.4296$

Solubility: see Table II.

Table II: Solubility of triacetin.

Solvent	Solubility at 20 °C	
Carbon disulfide	Miscible	
Chloroform	Miscible	
Ethanol	Miscible	
Ethanol (95%)	Miscible	
Ether	Miscible	
Toluene	Miscible	
Water	1 in 14	

Vapor density (relative): 7.52 (air = 1)

Vapor pressure: 133 Pa (1 mmHg) at 100 °C

Viscosity (dynamic):

 $1111 \,\mathrm{mPa}\,\mathrm{s}$ (1111 cP) at $-17.8\,^{\circ}\mathrm{C}$

 $107 \, \text{mPa} \, \text{s} \, (107 \, \text{cP}) \, \text{at} \, 0 \, ^{\circ}\text{C}$

 $17.4 \,\mathrm{mPa}\,\mathrm{s}\,(17.4 \,\mathrm{cP})$ at $25\,^{\circ}\mathrm{C}$

1.8 mPa s (1.8 cP) at 100 °C

Stability and Storage Conditions

Triacetin is stable and should be stored in a well-closed, nonmetallic container, in a cool, dry place.

12 Incompatibilities

Triacetin is incompatible with metals and may react with oxidizing agents. Triacetin may destroy rayon fabric.

13 Method of Manufacture

Triacetin is prepared by the esterification of glycerin with acetic anhydride.

14 Safety

Triacetin is used in oral pharmaceutical formulations and is generally regarded as a relatively nontoxic and nonirritant material at the levels employed as an excipient.

LD₅₀ (dog, IV): 1.5 g/kg⁽³⁾ LD₅₀ (mouse, IP): 1.4 g/kg LD₅₀ (mouse, IV): 1.6 g/kg LD₅₀ (mouse, oral): 1.1 g/kg LD₅₀ (mouse, SC): 2.3 g/kg LD₅₀ (rabbit, IV): 0.75 g/kg LD₅₀ (rat, IP): 2.1 g/kg LD₅₀ (rat, oral): 3 g/kg LD₅₀ (rat, SC): 2.8 g/kg

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Triacetin may be irritant to the eyes; eye protection and gloves are recommended.

16 Regulatory Status

GRAS listed. Accepted in Europe as a food additive in certain applications. Included in the FDA Inactive Ingredients Guide (oral capsules and tablets and gels). Included in nonparenteral medicines licensed in the UK.

17 Related Substances

18 Comments

The EINECS number for triacetin is 203-051-9.

19 Specific References

- 1 Shah PS, Zatz JL. Plasticization of cellulose esters used in the coating of sustained release solid dosage forms. *Drug Dev Ind Pharm* 1992; 18: 1759–1772.
- Williams RO, Wheatley TA, Liu J. Influence of plasticization and curing conditions on the mechanical properties of aqueous based cellulose acetate films. STP Pharma Sci 1999; 9(6): 545–553.
- 3 Lewis RJ, ed. Sax's Dangerous Properties of Industrial Materials, 10th edn. New York: Wiley, 2000: 3503.

20 General References

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- Johnson K, Hathaway R, Leung P, Franz R. Effect of triacetin and polyethylene glycol 400 on some physical properties of hydroxypropyl methylcellulose free films. *Int J Pharm* 1991; 73: 197– 208.
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22 Date of Revision

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