

17 *Food Chemicals Codex*. [online] Bethesda, MD: United States Pharmacopeia. <http://publications.usp.org> (accessed 31 March 2017).

20 General References

Sigma-Aldrich. Material safety data sheet: Ethyl acetate, June 2014.

21 Author

ME Quinn.

22 Date of Revision

4 May 2017.

E Ethyl Lactate

1 Nonproprietary Names

None adopted.

2 Synonyms

Actylol; *Acytol*; *Dermol EL*; ethyl α -hydroxypropionate; ethyl-2-hydroxypropanoate; ethyl-2-hydroxypropionate; ethyl-S-(-)-2-hydroxypropionate; 2-hydroxypropanoic acid ethyl ester; lactic acid ethyl ester; propanoic acid 2-hydroxy-ethyl ester; *Purasolv EL*; *Solactol*.

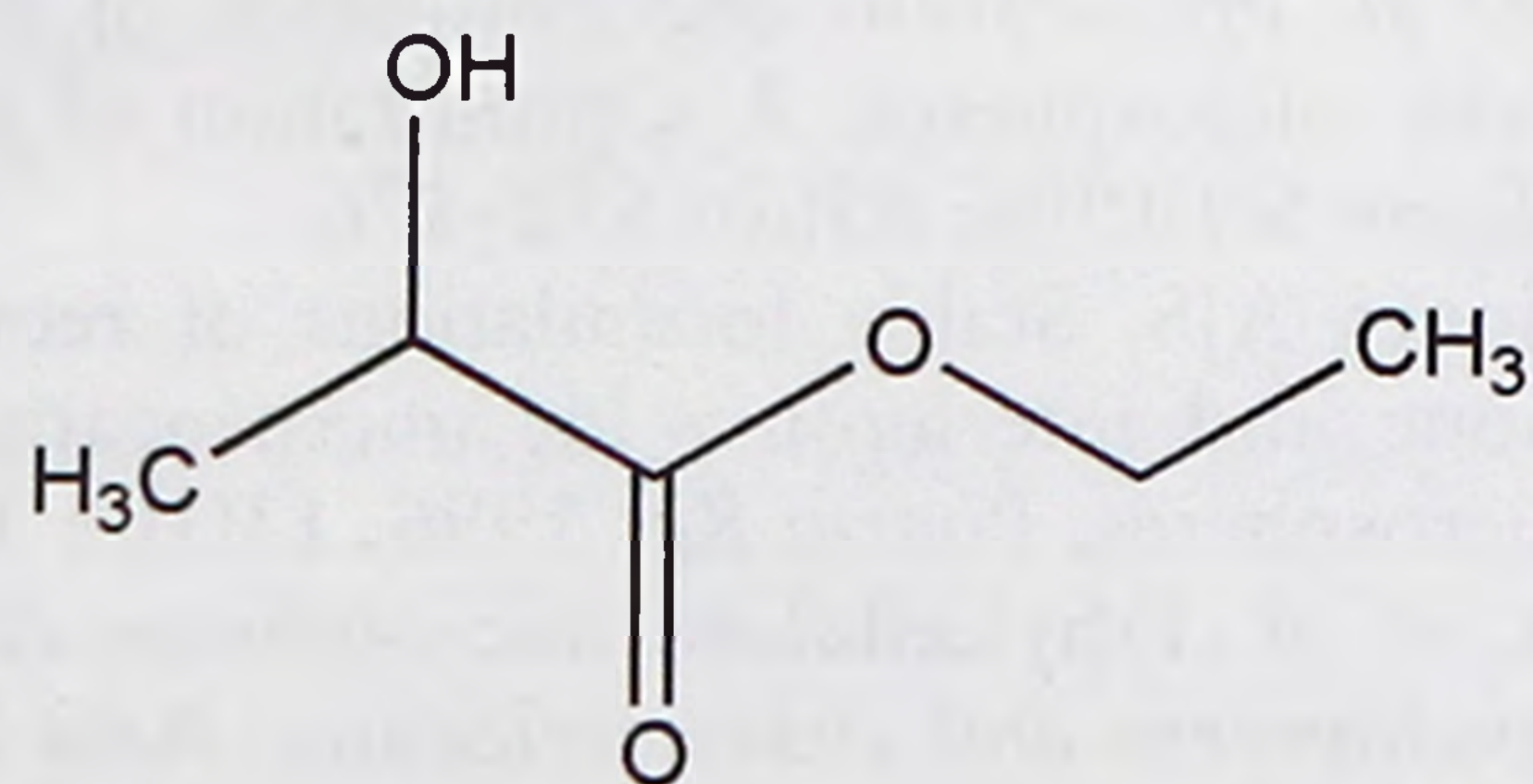
3 Chemical Name and CAS Registry Number

2-Hydroxy-propanoic acid ethyl ester [97-64-3]

4 Empirical Formula and Molecular Weight

C₅H₁₀O₃ 118.13

5 Structural Formula



6 Functional Category

Flavoring agent; solvent.

7 Applications in Pharmaceutical Formulation or Technology

Ethyl lactate is used as a solvent or co-solvent in liquid formulations⁽¹⁻³⁾ and as a co-solvent in emulsions, microemulsion, and liquid dispersion formulations.⁽⁴⁾ It has been investigated as a solvent to prepare biodegradable and biocompatible dosage forms as a safer and greener option.⁽⁵⁾ It has also been used as a solvent for nitrocellulose, cellulose acetate, cellulose ethers, polyvinyl and other resins.⁽⁶⁾

Ethyl lactate is also used as a flavoring agent in pharmaceutical preparations, and is found in food products.

8 Description

Ethyl lactate occurs as a clear colorless liquid with a sharp characteristic odor.

9 Pharmacopeial Specifications

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10 Typical Properties

Acidity/alkalinity pH = 7 (10% w/v aqueous solution)

Boiling point 154–155°C

Density 1.0328 g/cm³ at 20°C

Explosion limits 1.5–11.4%

Flash point 46°C

Heat of combustion 6.5 kcal/g

Melting point -26.0°C

Refractive index n_D^{20} = 1.412–1.414

Solubility Miscible with water (with partial decomposition), ethanol (95%), ether, chloroform, ketones, esters, and hydrocarbons.

Viscosity (dynamic) 0.0261 mPa s (0.0261 cP) at 20°C

Vapor density 4.07 (air = 1)

Vapor pressure 0.732 kPa at 30°C

11 Stability and Storage Conditions

Stable at normal temperature and pressure. Ethyl lactate is a flammable liquid and vapor. Store in a cool, dry, and well-ventilated location away from any fire hazard area, in a tightly closed container.

12 Incompatibilities

Incompatible with bases or strong alkalis and may cause fire or explosion with strong oxidizing agents.

13 Method of Manufacture

Ethyl lactate is produced by the esterification of lactic acid with ethanol in the presence of a little mineral oil, or by combination of acetaldehyde with hydrocyanic acid to form acetaldehyde cyanhydrin. This is followed by treatment with ethanol (95%) and hydrochloric or sulfuric acid. Purification is achieved using fractional distillation. The commercial product is a racemic mixture.

14 Safety

Ethyl lactate is used as a flavoring agent in pharmaceutical preparations, and is found in food products. The estimated acceptable daily intake for lactic acid is 12.5 mg/kg body-weight.

In general, lactate esters have an oral LD₅₀ > 2000 mg/kg; and the inhalation LC₅₀ is generally above 5000 mg/m³. They have the potential of causing eye and skin irritation (on prolonged contact), but not sensitization.⁽⁷⁾ Ethyl lactate is moderately toxic by intraperitoneal, subcutaneous, and intravenous routes. There is low oral and skin contact toxicity; although ingestion may cause