TECHNICAL INFORMATION

Dimercaprol / BAL

Ph. Eur.

1. MANUFACTURER OF THE FINAL SUBSTANCE

Evonik Operations GmbH
Gutenbergstrasse 2
69221 Dossenheim
Germany

2. PRODUCT

- Nomenclature

  Recommended International Non-proprietary name (INN):

  Dimercaprol
  British Anti-Lewisite (BAL)

  Chemical name(s):

  2,3-Dimercapto-1-propanol
  2,3-Bis-sulfanyl-propan-1-ol (IUPAC)
  1,2-Dithioglycerin
  1-Propanol, 2,3-dimercapto- (CAS)
  2,3-Dimercaptopropanol
  2,3-Dimercaptopropan-1-ol
  1,2-Thioglycerol

  CAS No.: 59-52-9

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- Structure

Molecular formula:	$C_3H_8OS_2$
Molecular mass:	124.2 g/mol

- General Properties

Description:	Colorless or yellowish liquid with characteristic odor of mercaptans.
Solubility:	Soluble in water (87 g/L) and peanut oil, miscible with benzyl benzoate.
Refractive index:	$\mathbf{n_D^{20}}$ = 1.568 - 1.574

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3. SPECIFICATION

Table 1: Specification

Test Items	Test Methods	References	Acceptance Criteria	Frequencies
Appearance	Visual	Ph. Eur. monograph 0389	Clear, colorless to slightly yellow liquid	Each batch
Identity	De-colorization of iodine solution		conforms	
	Copper sulfate precipitation		conforms	
	Sodium Bismuthate-colorization		conforms	
Assay	Titration		98.5 - 101.5%	
Clarity	Turbidity	Ph. Eur. 2.2.1	< 3 NTU (clear)	
Color	Colorimetry	Ph. Eur. monograph 0389	not more intensely colored than reference solution B_6 or BY_6	
Acidity or alkalinity	---		nmt. 0.5 mL 0.01 N NaOH per 200 mg sample	
Refractive index	---		n_D^{20} = 1.568 - 1.574	
Halogenides (Halides)	Titration		≤ 1.0 mL 0.1 N NH_4SCN difference per 2 g sample	

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Table 1: Specification (cont.)

Test Items	Test Methods	References	Acceptance Criteria	Frequencies
Impurities:				
Impurity RRT 0.57	Gas Chromatography (GC-1)	Ph. Eur. 2.2.28	nmt. 0.5%	Each batch
Impurity RRT 0.60			nmt. 0.2%	
Impurity RRT 0.91			nmt. 0.5%	
Impurity 2,3-Dibromo-1-propanol			nmt. 0.5%	
Impurity 1,2,3-Trimercaptopropane			nmt. 1.5%	
Impurity RRT 1.43			nmt. 0.2%	
Impurity RRT 1.44			nmt. 0.2%	
Impurity RRT 1.82			nmt. 0.2%	
Impurity RRT 1.85			nmt. 0.2%	
Other impurities, each			nmt. 0.1%	
Others impurities, sum of all			nmt. 0.5%	
Residual solvants:				
Chloroform	Gas Chromatography (GC-2)	Ph. Eur. 2.2.28	nmt. 60 ppm	Each batch
Methanol			nmt. 3000 ppm	
Acetone			nmt. 5000 ppm	
Dimethyl formamide (DMF)	Gas Chromatography (GC-3)		nmt. 880 ppm	

- nmt. = not more than

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4. PACKAGING

- Container Closure System I

  In narrow-neck bottles or jerry cans, depending on the amount and customer request. Generally, 5 L jerry cans or 0.1 L and 1 L narrow neck bottles are used.

  Narrow-neck bottles: 0.1 L or 1 L

  High Density Polyethylene (HDPE)

  Jerry cans: 5 L

  Inner layer: High Density Polyethylene (HDPE)

  Outer layer: Ethylene – Vinyl alcohol co-polymer, EVOH (antistatic coating)

- Container Closure System II

  Fiber drums

  Compliance

  The packaging is certified according to directives of EU and FDA, it conforms to the "Food Contact Regulations".
  Material conforms to EU-framework on materials and articles intended for food contact: (EC) No. 1935/2004.
  Raw material conforms to
  - Regulation (EU) No. 10/2011 and amendments
  - Commodities regulation of 10.04.1992 and amendments

  All applied packaging systems have an “UN”-approval for transport of dangerous goods.

5. STORAGE AND STABILITY

Based on stability data, a re-test period of 36 months, if stored at 2 – 8 °C in the original HDPE containers, is defined.

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6. GENERAL INFORMATION

- GMP certificate: available.
- CEP No.: CEP 2007-330
- Residual solvents

  The residual organic solvents are controlled in the final drug substance. The acceptance criteria are compliant with the guideline ICH Q3C.

Table 2: Residual solvents

Solvent Class 1	**Acceptance criterion**	**Tested in routine**	**Method used**
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Solvent Class 2	**Acceptance criterion**	**Tested in routine**	**Method used**
Chloroform	nmt. 60 ppm	yes	GC
Methanol	nmt. 3000 ppm		
Dimethyl formamide	nmt. 880 ppm		
Solvent Class 3	**Acceptance criterion**	**Tested in routine**	**Method used**
Acetone	nmt. 5000 ppm	yes	GC

- nmt. = not more than