

Product Name: Iloprost trometamol salt, min. 70 % ethanol in solution

Product Number: -

Date: 25-Jan-07

Manufacturer: CYCLOLAB R&D. Ltd.,
Budapest, Hungary

Date of 25-Jan-07
Revision:

1. Product Identity/Ingredients and Manufacturer's Description:

1.1

Product Name:

Iloprost trometamol salt, in aqueous ethanol solution

CAS Number: 78919-13-8

Reference No.: 18215

Chemical Family: Prostaglandins

Synonyms: 6,9.alpha.-methylene-11alpha,15S-dihydroxy-16-methyl-prosta-5E,13E-dien-18-yn-1-oic acid trometamol salt

1.2.

Information about Manufacturer:

Cyclolab R&D. Ltd., Budapest, Hungary

H-1097 Budapest, IX. Illatos út 7, Hungary

Tel: (36-1)-347-60-60; Fax: (36-1)-347-60-68; email: cyclolab@cyclolab.hu

2. Composition/Information on Ingredients:

Chemical Characteristics:

Product

Composition

Name: Iloprost Percentage: min. 1.5 %

Cas No.: 78919-13-9

OSHA PEL: No data ACGIH TLV No data

Name: Ethanol Percentage: min 70 %

Cas No.: 64-17-5

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3. Possible Hazards:

Emergency Overview:

Flammable

Route(s) of Entry:

Inhalation:	Yes
Skin:	Yes
Eyes:	Yes
Ingestion:	Yes
Other:	Injection

4. First-Aid Instructions:

Emergency and First Aid Procedures

If inhaled remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.

If swallowed, wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. DO NOT induce vomiting unless directed to do so by medical personnel.

In case of contact with eyes, hold eyelids apart and flush eyes with plenty of water. After initial flushings, remove any contact lenses and continue flushing for at least 20 minutes. Have eyes examined and tested by medical personnel.

In case of skin contact, immediately wash skin with active chlorine containing ethanolic solution, then soap and plenty of water. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.

Note to Physician

Strong vasodilating effect. Apply rules of Ilomedin and/or Ventavis formulation. Compound decomposes *in vivo*.

Medical Conditions Generally Aggravated By Exposure

www.emea.eu.int/humandocs/PDFs/EPAR/ventavis/106603en6.pdf

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5. Fire Fighting Procedures

Apply relating information of Ethanol 96 %.

6. Procedures in Case of Spill/Leakage:

Steps to be taken in case Material is released or spilled

Absorb spill with inert material moisted with an active chlorine containing agent (e.g. dry sand or earth), then place in a chemical waste container.

After removal, ventilate contaminated area and flush thoroughly with water.

7. Handling and Storage:

Hazard Label Information:

Avoid contact with skin and eyes. Do not reuse this container.

Use with adequate ventilation. Wash thoroughly after handling with 1% hypo* in min. 70 % ethanol then with water.

Precautions to be taken in Handling

Avoid contact with eyes, skin and clothing.

Do not reuse this container.

Keep away from sources of ignition.

Use with adequate ventilation

Wash thoroughly after handling with 1% hypo in min. 70 % ethanol then with water.

Precautions to be taken in Storing

Store in refrigerator, less than 6 °C temperature.

Other Precautions

No data available.

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Work/Hygienic/Maintenance Practices

Do not take internally.

Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

Wash thoroughly after handling with 1% hypo in min. 70 % ethanol then with water.

* domestic sodium hypochlorite solution

8. Exposure Limits and Personal Protection:

Protective Equipment Summary – Hazard Label Information:

Eye wash station in work area, proper lab coat

Latex disposable gloves, safety glasses

Safety shower in work area

Work in fume hood only!

Respiratory Equipment (Specify Type):

No data available.

Eye Protection:

Safety Glasses.

Protective Gloves

Latex disposable gloves

Other Protective Clothing

Safety lab coat

Engineering Controls (Ventilation etc.)

Good general ventilation should be sufficient to control airborne levels.

On contact with the skin, the material may provoke long-lasting but painless erythema, redness. Suitable precautions should therefore be taken to avoid any form of the sample contact with the skin. In the event of such contact, the affected area should be washed immediately with copious amounts of water or saline containing active chlorine.

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9. Physical and Chemical Properties:

9.1.

Appearance:

Formula: $C_{22}H_{32}O_4$

Color: Clear, colorless solution

Odor: ethanolic

Physical States: Liquid

Molecular Weight: 360.50

9.2.

Safety Data:

pH-value: 7-9

Boiling Point: min. 78 °C

Melting point: N.A.

Density: min. 0.8 g/cm³

Solubility in Water: min. 1 mg/ml at 25.0 °C

Other solubility Notes: PBS pH 7.2 soln, in EtOH, DMSO, DMF

Percent Volatile: N.A.

Saturated Vapor Concentration: N.A.

Viscosity: N.A.

Vapor Pressure: max. 44.6 Hgmm at 20 °C (

9.3.

Miscellaneous:

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10. Stability and Reactivity:

Stability: Stable below room temperature.

Conditions to avoid – instability: Excess heat, direct light

Incompatibility – materials to avoid: Acids, oxidants, radical generators

Hazardous Decomposition or Byproducts: carbon dioxide, carbon monoxide

Hazardous Polymerization: Will not occur

Conditions to avoid – Hazardous polymerization: No data available.

11. Toxicity Data:

Potential Health Effects (Acute and Chronic)

Contact may cause skin or eye irritation. On contact with the skin, the material may provoke long-lasting but painless erythema, redness.

Material is irritating to the mucous membranes and upper respiratory tract.

May be harmful by inhalation, ingestion, or skin absorption.

May cause eye, skin, or respiratory system irritation.

Repeated exposure may cause skin dryness or cracking.

Vapors may cause drowsiness and dizziness, long-lasting but painless erythema.

The toxicological properties of this compound can be found at European Agency for the Evaluation of Medicinal Products (EMA)

(www.emea.eu.int/humandocs/PDFs/EPAR/ventavis/106603en6.pdf)

Carcinogenicity: Not listed by ACGIH, IARC, NIOSH, NTP, or OSHA

Signs and Symptoms of Exposure

Irritating to the skin, eyes, nose, throat, and respiratory tract. Skin redness.

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12. Ecological Data (Ecotoxicity):

Run off from fire control or dilution water may cause pollution.

13. Disposal Considerations:

Waste Disposal Method:

Dispose in accordance with local, state, and federal regulations.

14. Transport Regulations:

DOT Proper Shipping Name: Ethanol

DOT Hazard Class: 2

DOT Hazard Label: Flammable Liquid

UN Number: 1170

Additional Transport Information

Transport in accordance with local, state, and federal regulations.

15. Regulatory Information:

Regulatory information on this product is not available.

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16. Other Information

For research use only, not for human or veterinary clinical use.

The information contained herein is based on the present state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.

Users should make their own investigations to determine the suitability of the information for their particular purposes.