



MSN Laboratories Private Limited
R&D Center, Formulation Division.

SAFETY DATA SHEET

Product Name	Clofarabine Injection 20mg/20 mL (1mg/mL)
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1. Identification

Product Name: Clofarabine Injection 20mg/20 mL (1mg/mL)

Chemical Family: Mixture

Intended use: Clofarabine injection is a nucleoside metabolic inhibitor indicated for the treatment of paediatric patients 1 to 21 years old with the relapsed or refractory acute lymphoblastic leukaemia after at least two prior regimens.

Details of the manufacturer:

MSN Laboratories Private Limited.
Formulation Division, Unit - II,
Sy No 1277 & 1319 to 1324
Nandigama Village & Mandal
Ranga Reddy Dist
Telangana State, India.
PIN 509228
Phone: +91 40 3044 9200

2. Hazard(s) Identification

Handling should only be performed by personnel trained and familiar with handling of potent active pharmaceutical ingredients Moderate to severe irritant to the skin and eyes.

3. Composition/Information on Ingredients

C.A.S. No: : 123318-82-1
Molecular Formula : $C_{10}H_{11}ClFN_5O_3$
Molecular Weight : 303.68g/mol
Chemical Name : [2-Chloro-9-(2'-deoxy-2'-fluoro- β -D-arabinofuranosyl)-9H-purine-6-amine]

4. First Aid Measures

Inhalation: If inhaled, move from exposure area to fresh air. Seek immediate medical attention if breathing becomes difficult or if cough or other symptoms develop.

Eye Contact: Immediately flush eyes with plenty of tepid water for 15 minutes while separating eyelids with fingers. Remove contact lenses if worn. Obtain medical attention if needed or if symptoms, such as redness or irritation persist.

Skin Contact: In case of contact, immediately flush skin with copious amounts of cool water and remove contaminated clothing. Obtain medical attention if needed or if irritation or other symptoms develop.

Ingestion: In case of ingestion, contact a poison control center and seek immediate medical attention.

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5. Fire Fighting Measures

Flammable Properties: Dilute aqueous solution not considered a fire hazard.

Suitable Extinguishing Media: Use extinguishing media suitable for surrounding fire, such as carbon dioxide, chemical foam, dry chemical or water spray.

Unsuitable Extinguishing Media: Unknown.

Specific Hazards Arising from the Chemical: None known.

Standard Protective Equipment and Precautions for Firefighters: Firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and full protective gear.

6. Accidental Release Measures

Personal Precautions: Wear Personal Protective Equipment (PPE) as indicated in Section 8. Avoid physical contact with material and avoid aerosol inhalation.

Environmental Precautions: No information available.

Methods and Materials for Containment and Clean-Up: Absorb spill with inert material/sorbent. Decontaminate the spill site following standard procedures. Dispose of materials in accordance with all applicable federal, state, local and provincial environmental regulations, as per Section 13.

7. Handling and Storage

Handling: Follow good laboratory hygiene practices for the handling and use of cytotoxic drugs. See Section 8, Engineering Controls. Wash hands thoroughly after handling.

Storage Conditions: Stored at 25 °C (77°F) ; excursions permitted to 15-30°C (59-86°F). Do not freeze

8. Exposure Controls/Personal Protection

Exposure Guidelines: There are no ACGIH, NIOSH, OSHA or country-specific occupational exposure limits currently established for components present in this preparation at concentrations equal to or greater than 1% (0.1% if carcinogen). The Genzyme occupational exposure limit (OEL) for clofarabine is 0.2 µg/m³ as an 8-hour TWA. The Genzyme OEL is based upon the best scientific information available at this time.

Engineering Controls: Follow cytotoxic drug handling procedures.

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

Personal Protective Equipment (PPE):

Respiratory : Respiratory protection should not be necessary under normal work conditions and if appropriate engineering controls are in place.

Eye/Face : Wear appropriate protective chemical safety glasses.

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Skin : Wear lab coat or other protective garments. Remove contaminate clothing promptly.

Gloves : Wear chemical resistant protective gloves. Change gloves regularly or immediately if they are contaminated, torn or punctured.

General : Follow company-specific safety procedures.

9. Physical and Chemical Properties

Appearance: Clear colorless solution free from visible particulate matter in 20 mL tubular USP Type – I clear glass vial with 20 mm bromobutyl rubber stopper and sealed with aluminium seal having polypropylene disc

10. Stability and Reactivity

Chemical Stability: Stable under ordinary conditions of use and storage. See Section 7.

Incompatible Materials: Unknown.

Hazardous Decomposition Products: None expected under normal conditions of use.

Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

11. Toxicological Information

Acute Effects: Clofarabine was nonirritating to the skin and eyes in rabbit models.

Lethal Dose Finding Studies in Animals for Clofarabine:

LD10 (mouse): 75 mg/kg/day for 7 days by intraperitoneal injection.

LD (rat): 50 mg/kg/day for 5 days by intravenous injection.

LD (dog) 3.0 mg/kg/day for 5 days by intravenous injection.

Single daily dose oral toxicity (rats), 21 day study: LLD 30 mg/kg/day with LOAEL of 3 mg/kg/day.

Chronic Effects: Clofarabine can cause myelosuppression.

12. Ecological Information

Persistence and degradability: No data available

Toxicity: No data available

Bio accumulative potential: No data available

Mobility in soil: No data available

PBT and vPvB assessment: No data available

Other adverse effects: No data available

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13. Disposal Considerations

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Dispose of unused product, spilled material and waste in accordance with all applicable federal, state, local and provincial environmental and hazardous waste regulations. Unused, expired, and waste product, as well as contaminated waste should be handled as hazardous, cytotoxic waste.

14. Transport Information

Basic Shipping Description: Not classified as dangerous goods. Not regulated per IATA and DOT regulations

15. Regulatory Information

US Federal Regulations: This pharmaceutical preparation is regulated by the U.S. FDA.

International Regulations: This preparation is intended for use as a medicinal product. If approved for use in the EU, it is regulated under the Medicinal Products Directive (2001/83/EC) and is exempt from classification under the Dangerous Substances Directive (67/548/EC).

Canadian Hazardous Products: WHMIS Status Exempt European Communities Dangerous Substances/Preparations: EC Hazard Class Risk Phrases None Safety Phrases None

16. Other Information

While the information herein is believed to be reliable, it is furnished without warranty of any kind. It shall be used only as a guide. We assume no liabilities from the use of this product or information contained herein.

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