

**SAFETY DATA SHEET**

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Product Name Dexrazoxane for injection 250 mg/Vial and 500 mg/Vial**1. Product Information****Product Name :** Dexrazoxane for injection 250 mg/Vial and 500 mg/Vial**Chemical Family:** Mixture**Intended use:** Cardioprotective agent**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. Hazards Identification**

Classification of the Substance or Mixture

GHS - Classification

Germ Cell Mutagenicity: Category 2

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

Label Elements

Signal Word: Warning

Hazard Statements: H341 - Suspected of causing genetic defects

Precautionary Statements: P201 - Obtain special instructions before use

P202 - Do not handle until all safety precautions have been read and understood

P281 - Use personal protective equipment as required

P308 +P313 - IF exposed or concerned: Get medical attention/advice

P405 - Store locked up

P501 - Dispose of contents/container in accordance with all local and national regulations

3. Composition/Information on Ingredients

C.A.S. No : 24584-09-6

Molecular Formula : C₁₁H₁₆N₄O₄

Formula Weight : 268.31

Chemical Name : (S)-4,4'-(1-methyl-1,2-ethanediyl)bis-2,6-piperazinedione

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4. First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately

5. Fire Fighting Measures

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire. May emit toxic fumes of oxides of carbon and nitrogen.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

6. Accidental Release Measures

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections:

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. Handling and Storage

General Handling: Minimize dust generation and accumulation. Avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

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Product Name

Dexrazoxane for injection 250 mg/Vial and 500 mg/Vial

Storage Conditions: Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

8. Exposure Controls/Personal Protection

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. Physical and Chemical Properties

Appearance :

White to off white lyophilized cake

10. Stability and Reactivity

Stability: Stable under normal conditions of use.

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: None known

11. Toxicological Information

General Information: The information included in this section describes the potential hazards of the active ingredient.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system.

Known Clinical Effects: Adverse effects most commonly reported in clinical use include bone marrow suppression,

changes in liver function, abnormal kidney function tests, loss of hair, nausea, and malaise.

Acute Toxicity: (Species, Route, End Point, Dose)

Dexrazoxane :

Rat Intravenous LD50 > 500 mg/kg

Mouse Para-periosteal LD50 > 1000mg/kg

Dog Intravenous LD50 > 250 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**Dexrazoxane**

6 Week(s) Rat 30 mg/kg/day LOAEL Male reproductive system

13 Week(s) Dog 20 mg/kg/day LOAEL Male reproductive system

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Embryo / Fetal Development Rat 2 mg/kg/day LOAEL Maternal toxicity

Embryo / Fetal Development Rabbit 5 mg/kg/day LOAEL Maternal Toxicity

2 Generation Reproductive Toxicity Rat 8 mg/kg/day LOAEL Fertility, (F1)

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Bacterial Mutagenicity (Ames) : Salmonella , E. coli Negative

In Vitro Chromosome Aberration Human Lymphocytes Positive

In Vivo Micronucleus Mouse Bone Marrow Positive

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.**12. Ecological Information****Environmental Overview:** Environmental properties have not been investigated. Releases to the environment should be avoided**Persistence and degradability:** No data available**Toxicity:** No data available**Bioaccumulative potential:** No data available**Partition Coefficient: (Method, pH, Endpoint, Value)****Mobility in soil:** No data available**PBT and vPvB assessment:** No data available**Other adverse effects:** No data available**13. Disposal Considerations****Waste Treatment Methods:** Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.**14. Transport Information****DOT (US):** Not dangerous goods.**IMDG:** Not dangerous goods.**IATA:** Not dangerous goods.**EUADR :** Not dangerous goods.

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15. Regulatory Information

CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 - Not Listed
EU EINECS/ELINCS List - Not Listed

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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