



# DEXRAZOXANE FOR INJECTION AND SODIUM LACTATE INJECTION, USP SAFETY DATA SHEET

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY

### Product Identifier

**Product name:** Dexrazoxane for Injection and Sodium Lactate Injection, USP

**Note:** *Dexrazoxane for Injection is supplied as a kit containing Dexrazoxane powder and a 0.167 M Sodium Lactate Solution, which is used as the diluent for injection. The 0.167 M Sodium Lactate solution is not considered hazardous in accordance with the 2012 US Hazard Communication Standard and Canada's Hazardous Products Act, and therefore does not require a Safety Data Sheet. This Safety Data Sheet applies only to the Dexrazoxane powder that is contained in the kit.*

### Intended Use of the Product

**Use of the substance/mixture:** Pharmaceutical. Intravenous. Use only as directed. Refer to product insert for usage instructions and product information.

### Name, Address, and Telephone of the Responsible Party

#### Supplier:

Mylan Institutional LLC  
1718 Northrock Court  
Rockford, IL 61103 USA  
1-888-258-4199

[www.mylan.com](http://www.mylan.com)

### Emergency Telephone Number

**Emergency number** : +1 877-446-3679

## 2. HAZARDS IDENTIFICATION

**Patients/Consumers:** Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions. Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk.

### Classification of the Substance or Mixture

#### Classification (GHS-US)

Skin Irrit. 2 H315  
Eye Irrit. 2A H319  
Muta. 2 H341  
Repr. 2 H361  
STOT SE 3 H335

### Label Elements

#### GHS-US labeling

**Hazard pictograms (GHS-US)** :



**Signal word (GHS-US)** :

Warning

**Hazard statements (GHS-US)** :

H315 - Causes skin irritation  
H319 - Causes serious eye irritation  
H335 - May cause respiratory irritation  
H341 - Suspected of causing genetic defects  
H361 - Suspected of damaging fertility or the unborn child

**Precautionary statements (GHS-US)** : P201 - Obtain special instructions before use.  
P261 - Avoid breathing dust.  
P264 - Wash hands, forearms, and exposed areas thoroughly after handling.  
P271 - Use only outdoors or in a well-ventilated area.  
P280 - Wear protective clothing, eye protection, protective gloves.  
P302+P352 - IF ON SKIN: Wash with plenty of soap and water.  
P304+P340 - IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.  
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P312 - Call a POISON CENTER/doctor/physician if you feel unwell.  
P362 - Take off contaminated clothing and wash before reuse.  
P403+P233 - Store in a well-ventilated place. Keep container tightly closed.  
P405 - Store locked up.  
P501 - Dispose of contents/container according to local, regional, national, territorial, provincial, and international regulations.

**Other Hazards** Not available

**Unknown acute toxicity (GHS-US)** Not available

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Substance

Name	Product identifier	% (w/w)	Classification (GHS-US)
Dexrazoxane	(CAS No) 24584-09-6	100*	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Muta. 2, H341 Repr. 2, H361 STOT SE 3, H335

Full text of H-phrases: see section 16

Additional information: Hydrochloric acid has been added for pH adjustment.

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### 4. FIRST AID MEASURES

#### Description of First Aid Measures

**General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice.

**Inhalation:** The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

**Skin Contact:** Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required) and seek medical advice.

**Eye Contact:** The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

**Ingestion:** Ingestion is not an anticipated route of exposure. If accidental ingestion occurs, flush mouth out with water and get medical attention.

#### Most Important Symptoms and Effects Both Acute and Delayed

**General:** Please refer to the package insert for more detailed information. Irritation to eyes, skin and respiratory tract.

**Inhalation:** May cause respiratory irritation.

**Skin Contact:** Causes skin irritation.

**Eye Contact:** Causes serious eye irritation.

**Ingestion:** Pharmaceutical. May be harmful if swallowed.

**Injection:** Common side effects include: diarrhea, difficulty with bowel movements, dizziness, mood changes, hair loss, headache, irritability, loss of appetite, loss of interest or pleasure, muscle pain, spasms, cramps, or stiffness, nausea, stomach pain, trouble concentrating, trouble sleeping, vomiting, weight loss.

**Chronic symptoms:** Suspected of causing genetic defects. Suspected of damaging fertility or the unborn child.

#### Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention.

### 5. FIREFIGHTING MEASURES

#### Extinguishing Media

**Suitable extinguishing media:** Not flammable. Use extinguishing media appropriate for surrounding fire.

**Unsuitable extinguishing media:** None known.

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### **Special Hazards Arising From the Substance or Mixture**

**Fire hazard:** Not flammable.

**Explosion hazard:** Product itself is not explosive but if dust is generated, dust clouds suspended in air can be explosive.

**Reactivity:** Hazardous reactions will not occur under normal conditions.

### **Advice for Firefighters**

**Precautionary measures fire:** Exercise caution when fighting any chemical fire.

**Firefighting instructions:** Use water spray or fog for cooling exposed containers.

**Protection during firefighting:** Do not enter fire area without proper protective equipment, including respiratory protection.

**Hazardous Combustion Products:** Carbon oxides (CO, CO<sub>2</sub>). Nitrogen compounds.

**Other information:** Refer to Section 9 for flammability properties.

<b>6. ACCIDENTAL RELEASE MEASURES</b>
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### **Personal Precautions, Protective Equipment and Emergency Procedures**

**General measures:** Avoid generating dust. Avoid all contact with skin, eyes, or clothing. Do not breathe dust.

#### **For Non-Emergency Personnel**

**Protective equipment:** Use appropriate personal protection equipment (PPE).

**Emergency procedures:** Evacuate unnecessary personnel.

#### **For Emergency Personnel**

**Protective equipment:** Equip cleanup crew with proper protection.

### **Environmental Precautions**

Prevent entry to sewers and public waters.

### **Methods and Material for Containment and Cleaning Up**

**For containment:** Avoid generation of dust during clean-up of spills. Use only non-sparking tools.

**Methods for cleaning up:** For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, after absorption with inert material, collect spillage by sweeping up spilled material and place in a labeled, sealed container for proper disposal.

### **Reference to Other Sections**

See heading 8, Exposure Controls and Personal Protection.

<b>7. HANDLING AND STORAGE</b>
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### **Precautions for Safe Handling**

**Patients/Consumers:** Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

**Hygiene measures:** This SDS is for a pharmaceutical agent - Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.

### **Conditions for Safe Storage, Including Any Incompatibilities**

**Storage conditions:** Store in a dry, cool and well-ventilated place. Protect from heat and direct sunlight.

### **Specific End Use(s)**

Pharmaceutical. Intravenous. Use only as directed. Refer to product insert for usage instructions and product information.

<b>8. EXPOSURE CONTROLS/PERSONAL PROTECTION</b>
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### **Control Parameters**

No Occupational Exposure Limits (OELs) have been established for this product or its chemical components.

### **Exposure Controls**

**Appropriate engineering controls:** Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

**Personal protective equipment:** Not generally required. The use of personal protective equipment may be necessary as conditions warrant. Dust formation: dust mask. Protective clothing. Gloves. Safety glasses.

**Hand protection:** Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.

**Eye protection:** In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended.

**Skin and body protection:** In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.

**Respiratory protection:** When manufacturing or handling product in large quantities and dusts or particulates may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

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**9. PHYSICAL AND CHEMICAL PROPERTIES****Information on Basic Physical and Chemical Properties**

Physical state	: Solid
Appearance	: Not available
Odor and Odor Threshold	: Not available
pH	: Not available
Relative evaporation rate (butyl acetate=1)	: Not available
Melting/Freezing point	: Not available
Boiling point	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition Temperature	: Not available
Flammability (solid, gas)	: Not available
Upper and Lower flammable limits	: Not available
Vapor pressure	: Not available
Relative vapor density at 20 °C	: Not available
Relative density/Specific gravity	: Not available
Solubility	: Not available
Log Pow/Kow	: Not available
Viscosity	: Not available
Explosion data	: Not available

**10. STABILITY AND REACTIVITY**

**Reactivity** Hazardous reactions will not occur under normal conditions.

**Chemical Stability** Stable under normal conditions.

**Possibility of Hazardous Reactions** Hazardous polymerization will not occur.

**Conditions to Avoid** Direct sunlight. Extremely high or low temperatures. Avoid creating or spreading dust.

**Incompatible Materials** Strong oxidizers. Strong bases. Strong acids.

**Hazardous Decomposition Products** Carbon oxides (CO, CO<sub>2</sub>). Nitrogen compounds.

**11. TOXICOLOGICAL INFORMATION****Information on Toxicological Effects - Product**

**Acute toxicity:** Not classified

**LD50 and LC50 Data:** Not available

**Skin Corrosion/Irritation:** Causes skin irritation.

**Serious Eye Damage/Irritation:** Causes serious eye irritation.

**Respiratory or Skin Sensitization:** Not classified

**Germ Cell Mutagenicity:** Suspected of causing genetic defects.

**Teratogenicity:** Not available

**Carcinogenicity:** Not classified

**Specific Target Organ Toxicity (Repeated Exposure):** Not classified

**Reproductive Toxicity:** Suspected of damaging fertility or the unborn child.

**Specific Target Organ Toxicity (Single Exposure):** May cause respiratory irritation.

**Aspiration Hazard:** Not classified

**Information on Toxicological Effects - Ingredient(s)**

**LD50 and LC50 Data:** Not available

**12. ECOLOGICAL INFORMATION**

**Toxicity** Not available

**Persistence and Degradability** Not available

**Bioaccumulative Potential** Not available

**13. DISPOSAL CONSIDERATIONS**

**Sewage disposal recommendations:** Do not dispose of waste into sewer.

**Waste disposal recommendations:** Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations.

**14. TRANSPORT INFORMATION**

**In Accordance With ICAO/IATA/DOT/TDG**

**UN Number** Not regulated for transport

**UN Proper Shipping Name** Not regulated for transport

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**REGULATORY INFORMATION****US Federal Regulations****Dexrazoxane for Injection and Sodium Lactate Injection, USP**

SARA Section 311/312 Hazard Classes

Immediate (acute) health hazard  
Delayed (chronic) health hazard**US State Regulations**

Neither this product nor its chemical components appear on any US state lists.

**Canadian Regulations****Dexrazoxane for Injection and Sodium Lactate Injection, USP**

WHMIS Classification

Class D Division 2 Subdivision A - Very toxic material causing other toxic effects  
Class D Division 2 Subdivision B - Toxic material causing other toxic effects

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all of the information required by CPR.

16.

**OTHER INFORMATION**

- Revision date** : 10/13/2014
- Data sources** : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.
- Other information** : This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warnings included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

**GHS Full Text Phrases:**

Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Muta. 2	Germ cell mutagenicity Category 2
Repr. 2	Reproductive toxicity Category 2
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H341	Suspected of causing genetic defects
H361	Suspected of damaging fertility or the unborn child

**Party Responsible For The Preparation Of This Document:**

Mylan Global Environmental, Health, and Safety Department  
Phone Number: 304-599-2595

*This MSDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product. Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions.*

*To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.*

North America Mylan Pharmaceuticals