

Material Safety Data Sheet

Material Name: Dexrazoxane for Injection

*** Section 1 - Chemical Product and Company Identification ***

Manufacturer Information

Mylan Institutional LLC
4901 Hiawatha Drive
Rockford, IL 61103

Phone: 1-888-258-4199

Emergency # 1-888-875-1671

*** Section 2 - Hazards Identification ***

Emergency Overview

None anticipated under normal product use conditions. May cause eye, skin and respiratory tract irritation from accidental exposure.

Potential Health Effects: Eyes

May cause eye irritation from accidental exposure.

Potential Health Effects: Skin

May cause skin irritation from accidental exposure.

Potential Health Effects: Ingestion

Not considered a likely route of exposure under normal product use.

Potential Health Effects: Inhalation

None anticipated under normal product handling conditions.

HMIS Ratings: Health: 1 Fire: 0 HMIS Reactivity 0

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe * = Chronic hazard

*** Section 3 - Composition / Information on Ingredients ***

CAS #	Component
24584-09-6	Dexrazoxane

*** Section 4 - First Aid Measures ***

First Aid: Eyes

Flush eye(s) immediately with plenty of water. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

First Aid: Skin

Rinse immediately with plenty of water for at least 15 minutes.

First Aid: Ingestion

If swallowed wash mouth with water provided person is conscious. Treat symptomatically and supportively. Get medical attention immediately.

First Aid: Inhalation

Remove the person from the exposed area to fresh air immediately. Get medical attention immediately.

*** Section 5 - Fire Fighting Measures ***

General Fire Hazards

See Section 9 for Flammability Properties.

Hazardous Combustion Products

Thermal decomposition or combustion may generate toxic and hazardous fumes.

Extinguishing Media

Use dry powder, CO2, water spray or regular foam.

Material Safety Data Sheet

Material Name: Dexrazoxane for Injection

Fire Fighting Equipment/Instructions

Firefighters should wear full protective gear.

NFPA Ratings: Health: 1 Fire: 0 Reactivity: 0

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe

*** Section 6 - Accidental Release Measures ***

Containment Procedures

Do not let the product enter drainage system, surface and ground-water and soil.

Clean-Up Procedures

Soak up with inert absorbent material, and clean with plenty of water. Dispose according to applicable regulations.

Evacuation Procedures

Isolate area. Keep unnecessary personnel away.

Special Procedures

Wear appropriate personal protective equipment.

*** Section 7 - Handling and Storage ***

Handling Procedures

Wear suitable protective clothing, gloves and eye/face protection. Do not eat, drink or smoke in work areas.

Storage Procedures

Store at 25°C (77°F). Excursions permitted to 15°C to 30°C (59°F to 86°F).

*** Section 8 - Exposure Controls / Personal Protection ***

A: Component Exposure Limits

ACGIH, OSHA, and NIOSH have not developed exposure limits for any of this product's components.

Engineering Controls

Ensure adequate ventilation, especially in confined areas.

PERSONAL PROTECTIVE EQUIPMENT

Personal Protective Equipment: Eyes/Face

Safety glasses with side-shields

Personal Protective Equipment: Skin

Use impervious gloves.

Personal Protective Equipment: Respiratory

Breathing apparatus only if aerosol or dust is formed.

Personal Protective Equipment: General

Eye wash fountain is recommended.

*** Section 9 - Physical & Chemical Properties ***

Appearance: White or off-white or pale pink

Physical State: Lyophilized powder or cake

Vapor Pressure: ND

Boiling Point: ND

Solubility (H2O): Slightly Soluble

Evaporation Rate: ND

Octanol/H2O Coeff.: ND

Flash Point Method: ND

Lower Flammability Limit (LFL): ND

Odor: None

pH: 3.5-5.5 (when reconstituted)

Vapor Density: ND

Melting Point: NA

Specific Gravity: ND

VOC: ND

Flash Point: ND

Upper Flammability Limit (UFL): ND

Burning Rate: ND

Material Safety Data Sheet

Material Name: Dexrazoxane for Injection

Auto Ignition: ND

*** Section 10 - Chemical Stability & Reactivity Information ***

Chemical Stability

This is a stable material at the recommended storage conditions.

Chemical Stability: Conditions to Avoid

Avoid heat

Incompatibility

Strong oxidizing agents

Hazardous Decomposition

Thermal decomposition or combustion may include toxic and hazardous fumes.

Possibility of Hazardous Reactions

Will not occur.

*** Section 11 - Toxicological Information ***

Acute Dose Effects

A: General Product Information

No information available for the product.

B: Component Analysis - LD50/LC50

Dexrazoxane (24584-09-6)

LD₅₀, intraperitoneal, mouse 500 mg/kg

LD₅₀, intravenous, dog 2 gm/kg

TD₁₀, intraperitoneal, rat 100 mg/kg

TD₁₀, intravenous, dog 1250 mg/kg/5D-I

TD₁₀ intravenous, man 383 mg/kg

Carcinogenicity

A: General Product Information

No information available for the product.

B: Component Carcinogenicity

None of this product's components are listed by ACGIH, IARC, OSHA, NIOSH, or NTP.

Mutagenicity

Dexrazoxane was positive in genetic toxicity tests. Mutagenicity testing studies indicate Dexrazoxane was not mutagenic in the Ames test but was found to be clastogenic to human lymphocytes in vitro and to mouse bone marrow erythrocytes in vivo (micronucleus test). It may cause fetal harm in pregnant women. Additional reproductive health and toxicity data from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS).

*** Section 12 - Ecological Information ***

Ecotoxicity

A: General Product Information

No information available for the product.

B: Component Analysis - Ecotoxicity - Aquatic Toxicity

No ecotoxicity data are available for this product's components.

Material Safety Data Sheet

Material Name: Dexrazoxane for Injection

*** Section 13 - Disposal Considerations ***

US EPA Waste Number & Descriptions

Component Waste Numbers

No EPA Waste Numbers are applicable for this product's components.

Disposal Instructions

All wastes must be handled in accordance with local, state and federal regulations.

See Section 7 for Handling Procedures. See Section 8 for Personal Protective Equipment recommendations.

*** Section 14 - Transportation Information ***

US DOT Information

Shipping Name: Not Regulated

IATA Information

Shipping Name: Not Regulated

ICAO Information

Shipping Name: Not Regulated

IMDG Information

Shipping Name: Not Regulated

*** Section 15 - Regulatory Information ***

US Federal Regulations

Component Analysis

None of this product's components are listed under SARA Section 302 (40 CFR 355 Appendix A), SARA Section 313 (40 CFR 372.65), or CERCLA (40 CFR 302.4).

State Regulations

Component Analysis - State

None of this product's components are listed on the state lists from CA, MA, MN, NJ, PA, or RI.

Component Analysis - WHMIS IDL

No components are listed in the WHMIS IDL.

Additional Regulatory Information

None

Component Analysis - Inventory

Component	CAS #	TSCA	CAN	EEC
Dexrazoxane	24584-09-6	No	No	No

*** Section 16 - Other Information ***

Other Information

The information herein is presented in good faith and believed to be accurate as of the effective date given. However, no warranty, expressed or implied, is given. It is the buyer's responsibility to ensure that its activities comply with Federal, State or provincial, and local laws.

Material Safety Data Sheet

Material Name: Dexrazoxane for Injection

Key/Legend

EPA = Environmental Protection Agency; TSCA = Toxic Substance Control Act; ACGIH = American Conference of Governmental Industrial Hygienists; IARC = International Agency for Research on Cancer; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration., NJTSR = New Jersey Trade Secret Registry; NA = Not Applicable; ND = Not Determined.

End of Sheet