

**SAFETY DATA SHEET****SECTION 1 – IDENTIFICATION OF THE PRODUCT & THE COMPANY**

- a) **Product Name** : Dexrazoxane for Injection (500mg/Vial)
- b) **Common/Trade Name** : Dexrazoxane for Injection (500mg/Vial)
Chemical Names : (S)-4,4'-(1-methyl-1,2-ethanediyl)bis-2,6piperazinedione
Chemical Family : Cardioprotective agent
- c) **Product Use** : It is a cardioprotective agent for use in conjunction with doxorubicin
Product Type : Regulated Prescription Drug
Container Information : Vial (50mL vial)
- d) **Manufacturers Name & Address** : **Gland Pharma Limited**
: Survey No.: 143–148, 150&151
: Near Gandimaisamma Cross Roads,
: D.P.Pally, Quthubullapur Mandal
: Ranga Reddy District
: Hyderabad- 500043
: Telangana, India
- e) **Telephone Number for Info** : +91-40-30510999

SECTION 2 – HAZARDS IDENTIFICATIONa) **Classification****NFPA Rating**

Health Hazard : 0

Fire Hazard : 1

Reactivity Hazard : 0

b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	c) Description of Hazards:
Signal Word: Warning	-Not Available
Suspected of causing genetic defects	

d) **Unknown Acute Toxicity:** N/A



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SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

a) Chemical Name	b) Common Name/Synonym	%Composition or other measure	c) CAS Number	d) Impurities / Stabilizing Additives
(S)-4,4'-(1-methyl-1,2-ethanediyl)bis-2,6 piperazinedione	Dexrazoxane	500 mg/Vial	24584-09-6	N/A
Hydrochloric Acid	Hydrochloric acid	0.17 mL/vial	128794-94-5	N/A
Water	Water for Injection	q.s.to 20 mL	7732-18-5	N/A

SECTION 4 – FIRST AID MEASURES

- Eye Exposure** : Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
- Skin Exposure** : 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.
- Notesto Physician** : See patient package insert in shipping carton for complete information

SECTION 5 – FIRE FIGHTING MEASURES

- a) Extinguishing Media** : Use carbon dioxide, dry chemical, or water spray..
- b) Hazardous Combustion Products** : Formation of toxic gases is possible during heating or fire. May emit toxic fumes of oxides of carbon and nitrogen.
- c) Special Protective Equipment / Precautions** : During all fire fighting activities, wear appropriate protective equipment, including self contained breathing apparatus.



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SECTION 6 – ACCIDENTAL RELEASE MEASURES

- Spill** : Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.
- Release to Environment** : Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

SECTION 7 – HANDLING AND STORAGE

- General Handling** : No special handling required for hazard control under conditions of normal product use.
- Storage Conditions** : Store at 20°C to 25°C (68°F to 77°F). Excursions to 15°C-30°C [See USP Controlled Room Temperature].

SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Dexrazoxane	OSHA	PEL	5 (TWA mg/m ³)
	ACGIH	TLV	10 (TWA mg/m ³)

b) Engineering Controls

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels within the OEB range.

(c) Individual Protection Measures

Refer to applicable national standards and regulations in the selection and use of personal Protective equipment (PPE).

- Respiratory Protection** : If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.
- Eye Protection** : Wear safety glasses or goggles if eye contact is possible.



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

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

a)	Appearance/Description	:	A white to off-white or pale pink lyophilized powder or cake.
b)	Odor	:	NA
c)	Odor Threshold	:	NA
d)	P ^H	:	3.5-5.5
e)	Melting Point	:	NA
f)	Initial Boiling Point	:	NA
g)	Flash Point	:	NA
h)	Evaporation Rate	:	NA
i)	Flammability	:	NA
j)	Upper Lower Flammability or Explosion Limits	:	NA
k)	Vapor Pressure:	:	NA
l)	Vapor Density	:	NA
m)	Relative Density	:	NA
n)	Solubility(ies)	:	Soluble in water
o)	Partition Coefficient: n-octanol/water	:	NA
p)	Auto-ignition Temperature	:	NA
q)	Decomposition Temperature	:	NA
r)	Viscosity	:	NA

SECTION 10 – STABILITY AND REACTIVITY

a)	Reactivity	Not determined.
b)	Chemical Stability	Stable under normal use and storage conditions.
c)	Possibility of Hazardous Reactions	Not determined
d)	Conditions to Avoid	Strong oxidizers
e)	Incompatible Materials	Not determined
f)	Hazardous Decomposition Products	Not determined



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SECTION 11 – TOXICOLOGICAL INFORMATION

a)	Likely Routes of Exposure	Inhalation, eye/skin contact, or ingestion
b)	Symptoms related to the physical, chemical and toxicological characteristics	Nausea, vomiting, impaired liver function tests, leukopenia, diarrhoea
c)	Delayed and immediate effects and also chronic effects from short and long term exposure	Dexrazoxane- investigated as a mutagen.

d) Acute Toxicity:

Component	Type	Route	Species	Dosage
Dexrazoxane	LD50	Intravenous	Rat	>500mg/kg
	LD50	Intravenous	Mouse	>1000mg/kg
	LD50	Intravenous	Dog	>250mg/kg

e) Hazardous Chemical Listings

NTP: Not Listed IARC: Not Listed OSHA: Not Listed

SECTION 12 – ECOLOGICAL INFORMATION

a)	Ecotoxicity	Avoid release into the environment. Runoff from fire control or dilution water may cause pollution.
b)	Persistence and degradability	Not established
c)	Bioaccumulative potential	Not established
d)	Mobility in soil	Not established
e)	Other Adverse Effects	Not established

SECTION 13 – DISPOSAL CONSIDERATIONS

Waste Disposal: All waste materials must be properly characterized. Further, disposal should be Performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal: Dispose of container and unused contents in accordance with federal, state and local regulations.



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SECTION 14 – TRANSPORTATION INFORMATION

a)	UN Number	Not available
b)	UN Proper Shipping Name	Not available
c)	Transport Hazard Class(es)	Not available
d)	Packing Group	Not available
e)	Environmental Hazards	Not available
f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not available
g)	Special Precautions	Not available

DOT: Not dangerous goods

ICAO/IATA: Not dangerous goods

IMDG: Not regulated

SECTION 15 – REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:

TSCA – Not on this list

SARA 302 - Not on this list

SARA 313 - Not on this list

Prop 65 (Calif.) – Not on this list

RCRA – Not on this list



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SECTION 16 – OTHER INFORMATION

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. **THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE).** In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.



SAFETY DATA SHEET

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)