



**** MATERIAL SAFETY DATA SHEET ****

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

COMMON NAME: ZINECARD(R) INJECTION

SYNONYMS: Dexrazoxane
4,4'-propylenedi-2,6-piperazinedione, (+)
24584-09-6 - CAS NUMBER
dexrazoxane for injection
0013-8715-62 - NDC NUMBER
0013-8725-89 - NDC NUMBER
PNU-167523 - PHARMACIA & UPJOHN PNU#
(S)-4,4'-(1-methyl-1,2-ethanediyl)bis-2,6-piperazinedione

MOLECULAR FORMULA: C11-H16-N4-O4

CHEMICAL FAMILY: Piperazine

USE: Human drug used as a cardioprotective agent.

MANUFACTURER/SUPPLIER: PHARMACIA & UPJOHN CO., A SUBSIDIARY OF
PHARMACIA CORP.
7171 PORTAGE RD
KALAMAZOO, MI 49001-0199

TELEPHONE NUMBERS: (616) 833-5122 - (24 HOURS)
(616) 833-7555 - (8:00 a.m. - 4:30 p.m.)

2. COMPOSITION/INFORMATION ON INGREDIENTS

INGREDIENT 1

COMMON NAME: ZINECARD(R) Injection
% BY WEIGHT: > 99 %
CAS NUMBER: 24584-09-6
EXPOSURE LIMIT(S): Not established.

INGREDIENT 2

COMMON NAME: Hydrochloric Acid
% BY WEIGHT: < 1 %
CAS NUMBER: 7647-01-0
EXPOSURE LIMIT(S):
OSHA PEL-CEILING: 5 PPM
OSHA PEL-CEILING (TRANSITIONAL LIMIT): 5 PPM
ACGIH TLV-CEILING: 5 PPM

EXPOSURE LIMIT(S) FOR THE MATERIAL: Not established.

3. HAZARDS IDENTIFICATION

PRIMARY ROUTE(S) OF EXPOSURE: Skin contact, eye contact, ingestion and inhalation.
EFFECTS OF OVEREXPOSURE: Dexrazoxane has caused adverse reproductive effects in animals.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Not established.



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4. FIRST AID MEASURES

EYES: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
SKIN: Wash off with soap and water. Take off all contaminated clothing immediately.
INHALATION: Remove from exposure.
INGESTION: Contact a physician or poison control center.

5. FIRE FIGHTING MEASURES

FLASH POINT: Not applicable (solid).
LOWER EXPLOSION LIMIT (LEL): Not applicable.
UPPER EXPLOSION LIMIT (UEL): Not applicable.
EXTINGUISHING MEDIA: Water, carbon dioxide, or dry chemical.
FIRE-FIGHTING PROCEDURES: Wear self-contained breathing apparatus and full body protective equipment.
UNUSUAL FIRE OR EXPLOSION HAZARDS: As with all finely divided organic powders, it is advisable to eliminate explosion hazards by methods such as grounding mechanical equipment in contact with the material to prevent the buildup of static electricity, inerting the atmosphere or controlling dust levels.
HAZARDOUS COMBUSTION PRODUCTS: Carbon monoxide. Carbon dioxide. Nitrogen oxides.

6. ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED: Remove all sources of ignition. Control the generation of dust/vapors. Ensure adequate ventilation. Provide respiratory, skin, and eye protection to prevent overexposure. Do not let product enter drains. Do not flush into surface water. Do not flush to groundwater and soil. Vacuum with HEPA-filtered and explosion-proof equipment. Shovel into suitable container for disposal.

7. HANDLING AND STORAGE

PRECAUTIONS FOR HANDLING AND STORING: Avoid generating dust/vapors and contact with skin, eyes and clothing. Use with adequate ventilation. Wash thoroughly after handling. Launder contaminated clothing before reuse. Store at room temperature. Do not get in eyes, on skin or clothing. Avoid breathing dust or mist. Use adequate dust/vapor control.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

RESPIRATORY PROTECTION: Approved respirator.
VENTILATION: Local exhaust at point of manufacture or use.
PROTECTIVE GLOVES: Rubber.
EYE PROTECTION: Safety glasses with side-shields.
OTHER PROTECTIVE EQUIPMENT: Protective covering for exposed areas of skin.



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9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE/PHYSICAL STATE: White lyophilized cake.
MELTING POINT: 191 - 197 C (376 - 387 F) (of Dexrazoxane active drug substance)
MOLECULAR WEIGHT: 268.27
OTHER PROPERTIES:
REACTIVITY IN WATER: Hydrolyzes slowly.
SOLUBILITY IN WATER: 10 - 12 MG/ML (slightly soluble)

10. STABILITY AND REACTIVITY

STABILITY: Stable.
PHYSICAL CONDITIONS TO AVOID: None known.
INCOMPATIBILITY WITH OTHER MATERIALS: None known.
HAZARDOUS DECOMPOSITION PRODUCTS: None known.
HAZARDOUS POLYMERIZATION: Does not occur.

11. TOXICOLOGICAL INFORMATION

ACUTE STUDIES:
INTRAVENOUS LD50 (DOG): > 250 MG/KG
INTRAVENOUS LD50 (RAT): > 500 MG/KG
INTRAVENOUS LD50 (MOUSE): > 1,000 MG/KG
OTHER STUDIES:
GENOTOXICITY: Dexrazoxane was not mutagenic in the Ames Assay, but was found to be clastogenic to human lymphocytes In Vitro and to mouse bone marrow erythrocytes In Vivo (micronucleus test).
REPRODUCTION/FERTILITY: Testicular atrophy was seen with dexrazoxane administration at 1/3 the equivalent human dose (on a mg/M (squared) basis) for 6 weeks in rats and at the equivalent human dose (on a mg/M (squared) basis) for 13 weeks in dogs.
TERATOGENICITY: Dexrazoxane was maternotoxic at 1/40 the human dose (on a mg/M (squared) basis) and embryotoxic and teratogenic at 1/10 the human dose (on a mg/M (squared) basis) when given daily to pregnant rats during the period of organogenesis.
CARCINOGENICITY: Ingredient(s) are not listed as carcinogenic by IARC, NTP or OSHA.

12. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Deactivate with dilute sodium hydroxide solution. Dispose of by incineration in accordance with applicable international, national, state, and/or local waste disposal regulations.

13. SHIPPING REGULATIONS

Not regulated for transportation by the United States Department of Transportation (DOT), International Maritime Organization (IMO), or International Air Transport Association (IATA). May be subject to state and/or local transportation requirements.



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14. OTHER INFORMATION

REVIEWED BY: Environment and Safety.

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15. LABELING

This drug is subject to FDA labeling requirements; therefore, it is exempt from the labeling requirements of the OSHA Hazard Communication Standard.