

300 Northfield Road Bedford, OH 44146

Telephone: (440) 232-3320

-or- (800) 562-4797

#### MATERIAL SAFETY DATA SHEET

### **Section I - IDENTITY**

**Common/Trade Name:** Adenosine Injection (3 mg/ml, 2 and 4 ml/vial)

**Chemical Names:** 9-beta-D-Ribofuranosyl-9H-purine **Synonyms:** Adenocard IV; Nucleocardyl; beta-Adenosine.

Manufacturer's Name: BEN VENUE LABORATORIES, INC.

**Address:** 300 NORTHFIELD ROAD BEDFORD, OH 44146

Emergency Telephone Number: Chemtrec: 1(800)424-9300 Telephone Number for Info.: (440)232-3320 -or- (800)562-4797 Medical Emergency: Professional Services 1(800)521-5169

**Date Prepared:** June 10, 2004 **Date Revised:** June 11, 2007

### Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

Component	<u>%</u>	CAS#	OSHA PEL	ACGIH TLV	Other Limits Recommended
Adenosine	0.3	58-61-7	NONE	NONE	$6 \text{ ug/m}^3$
Sodium Chloride	0.9	7647-14-5	NONE	NONE	NONE
Water for Injection	98.8	7732-18-5	NONE	NONE	NONE

Adenosine Injection is a sterile injectable liquid drug provided in a vial.

### **Section III - HEALTH HAZARD DATA**

**Routes of Entry:** Adenosine Injection may be absorbed via contact with skin or eyes; inhalation of aerosols or accidentally ingested. Under normal use with supervision of a physician, Adenosine Injection presents little hazard.

**Health Hazard (Acute & Chronic):** Adenosine Injection is an anti-arrhymic cardiac depressant that is used in treating certain heart conditions. Minimal adverse effect should occur from routine use with this product. Acute signs and symptoms of exposure may include dizziness, nausea, vomiting, flushing of skin, irregular heartbeat, pain in chest, fluctuation in blood pressure and numbness or tingling in arms. May cause irritation to eyes, skin, and respiratory tract. Product may cause allergic reaction if inhaled or absorbed through the skin. Adenosine has low chronic toxicity.

**Medical Conditions Generally Aggravated by Exposure:** Adenosine is a mild bronchoconstrictor and should be used with caution in asthmatic patients. Adenosine is contraindicated in patients with second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, except where a pacemaker has been placed. See package insert for additional information.

Carcinogenicity: NTP? NO IARC Monographs? NONE OSHA Regulated? NO

Signs & Symptoms of Exposure: Exposure can cause dilation of the blood vessels and an increase in

contraction of some smooth muscles.

**BVL Hazard Category: 3** 

### **Section IV - FIRST AID MEASURES**

**Eye Exposure:** Flush eyes with large volumes of water for 15 or more minutes. Get medical attention if

irritation or signs of exposure are noted.

**Skin Exposure:** Remove contaminated clothing, wash skin with water and soap for 15 minutes. Get

medical attention if irritation or signs of exposure are noted.

**Ingestion:** If ingestion occurs, flush mouth with water and seek medical attention immediately.

Never give anything by mouth to an unconscious person.

**Injection:** In cases of accidental injection, wash and disinfect area, get medical attention.

**Inhalation:** If difficulty with breathing, remove from exposure, administer oxygen. Seek attention

of a physician immediately. When appropriate and trained in CPR, provide artificial

respiration.

## Section V - FIRE AND EXPLOSION HAZARD DATA

Flash Point (Method Used): Not Applicable LEL: Not Applicable UEL: Not Applicable

Flammable Limits: Not Applicable

**Extinguishing Media:** Use water or an ABC multi-purpose extinguisher.

**Special Fire Fighting Procedures:** As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke. Product is aqueous-

based and is not expected to present a fire hazard concern.

Unusual Fire/Explosion Hazards: Heat of the fire could cause vials or syringes to burst.

### Section VI - ACCIDENTAL RELEASE INFORMATION

**Release to Land:** Absorb Adenosine Injection with absorbent materials and dispose according to local, state, and federal guidelines.

**Release to Air:** If aerosolized, reduce exposures by ventilating area.

**Release to Water:** Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

### **Section VII - PRECAUTIONS FOR SAFE HANDLING AND USE**

Steps to be taken in case material is released or spilled: See Section VI above.

Wear latex or nitrile gloves and safety glasses when cleaning spills. A dust/mist respirator (N95) may be necessary if excessive aerosols are generated.

**Waste Disposal Method:** Incineration in an approved incinerator is recommended. Refer to local, state, and federal rules.

**Precautions to be taken in handling and storing:** Store at controlled room temperature 15°-30°C (59°-86°F). Follow instructions provided in packaging.

Other Precautions: None identified.

### Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

**Respiratory Protection:** Under normal use, respirators are not required. If aerosols are generated, a disposable dust/mist respirator (N95) may be used. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.

**Ventilation:** Handle product in a well-ventilated area.

**Protective Gloves:** Latex or nitrile **Eye Protection:** Safety glasses

Other Protective Clothing or Equipment: Lab Coat

Work/Hygienic Practices: Wash hands following use. No eating, drinking, or smoking while

handling this product.

### Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical State: Liquid

Appearance and Odor: Clear solution

Boiling Point: Not available

Specific Gravity: Approx. to water

Melting Point: Approx. 234 °C

Evaporation Rate: Approx. to water

Vapor Pressure: Not available Solubility in Water: Soluble

vapor ressure. Not available Solubility in water

**Vapor Density:** Not available **pH:** 5.5 - 7.0

### Section X - STABILITY AND REACTIVITY DATA

Stability: Stable

Incompatibility (Materials to Avoid): None identified.

Hazardous Decomposition or Byproducts: Decomposition products of this compound may include

potentially hazardous byproducts such as oxides of carbon and nitrogen.

**Hazardous Polymerization:** Will not occur **Conditions to Avoid:** None identified.

### Section XI - TOXICOLOGICAL INFORMATION

For Adenosine Injection (active ingredient) RTECS Number AU7175000

 $TD_{LO}$  Human, Intravenous = 200 ug/kg

 $LD_{50}$  mouse, Intraperitoneal = 500 mg/kg

LD<sub>50</sub> mouse, Oral >20 gm/kg

 $LD_{50}$  mouse, Subcutaneous = 39.6 ug/kg

Additional reproductive health data is available from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS).

### Section XII - ENVIRONMENTAL IMPACT INFORMATION

Information is currently not available on the environmental impact of Adenosine Injection. Handle in a manner to prevent spills or releases to the environment.

### **Section XIII - DISPOSAL INFORMATION**

Dispose of by incineration at an approved/permitted incinerator.

Review local, state, and federal regulations for your regulatory area.

### **Section XIV - TRANSPORTATION INFORMATION**

Adenosine Injection is not a DOT hazardous material.

Adenosine Injection is not a DOT Marine Pollutant.

### **Section XV - REGULATORY INFORMATION**

SARA 313 listed?: NO CERCLA listed?: NO RCRA listed?: NO

TSCA Inventory YES, TSCA Section 8(b) Chemical Inventory

### **Section XVI - OTHER DATA**

1. Use of this product should be through or under the direction of a physician. This MSDS does not address therapeutic use of this material.

- 2. Persons administering this drug to patients must be careful to avoid needle sticks to syringes and other sharps used in the administration. All needle sticks must be reported to your company management.
- 3. BVL Hazard Category Definitions (internal hazard ranking used by Ben Venue Laboratories):
  - 1 = Low Toxicity
  - 2 = Moderate Toxicity
  - 3 = Potent or Toxic
  - 4 = Highly Potent or Toxic
  - 5 = Extremely Potent or Toxic
- 4. OEL=Occupational Exposure Limit. An internal limit set by Ben Venue Laboratories for the recommended limit of employee exposure to airborne dusts or aerosols that should not be exceeded over an eight-hour time-weighted average.
- 5. Adenosine may be considered a Hazardous Drug as described in the NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings. Employees who prepare or administer hazardous drugs or who work in areas where these drugs are used should follow specific handling guidelines in order to prevent exposure to these agents in the air or on work surfaces, clothing, or equipment.

# 6. The Following Guidance Information is excerpted from the NIOSH Alert:

Elements of a Hazardous Drug Handling Program include:

- Establishment and implementation of written policies and protocols to ensure the safe handling of oncolytic and/or potent drugs, including receipt of product.
- Training and education of employees on the recognition, evaluation and control of Hazardous Drugs
- Effective Planning and design of the workplace
- Use of best practice control measures and specialized equipment such as ventilated cabinets or isolators designed for worker protection
- Wearing recommended personal protective equipment
- An integrated health surveillance program that: includes the assessment and counseling of prospective employees before they commence any work involving oncolytic and/or potent drugs and related waste

### 7. Published guidance on the handling and transport of cytotoxic drugs:

NIOSH Alert – Preventing occupational exposures to antineoplastic and other hazardous drugs in health care settings

http://www.cdc.gov/niosh/docs/2004-165/

National Study Commission on Cytotoxic Exposure: Recommendation for handling Cytotoxic Agents:

http://www.nih.gov/od/ors/ds/pubs/cyto/index.htm

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