



TEVA PARENTERAL MEDICINES

## Material Safety Data Sheet

# Adenosine Injection, USP

### 1. PRODUCT IDENTIFICATION

**Product Name** Adenosine Injection, USP  
**Product Use** Antiarrhythmic drug; Sterile solution for rapid bolus intravenous injection  
**Manufacturer** Teva Parenteral Medicines, Inc.  
**Address** 11 Hughes  
 Irvine, CA 92618-1902

**Chemtrec Emergency No.** 1-800-424-9300 (United States)  
 1-202-483-7617 (International Collect)

**Business Phone** 1-800-729-9991  
**Website Address** <http://www.tevausa.com>

**Common Names** Innovator RLD Adenocard®  
**Chemical Name** 2-Amino-9-β-Dribofuranosyl-9H-purine

**Chemical Formula** C<sub>10</sub>H<sub>13</sub>N<sub>5</sub>O<sub>4</sub>  
**Chemical Family** Antiarrhythmic drug  
**How Supplied** 3 mg/mL in 2 mL, 5 mL, 20 mL & 30 mL vials,  
 3 mg/mL in 2 mL syringe

**Date of Preparation:** July 22, 2002

### 2. COMPOSITION AND INGREDIENTS

CHEMICAL NAME	CAS#	% by wt	EXPOSURE LIMITS IN AIR					
			ACGIH		OSHA		IDLH	OTHER
			TLV	STEL	PEL	STEL		
Adenosine	58-61-7	0.3	NE	NE	NE	NE	NE	NE
Sodium Chloride	7647-14-5	0.9	NE	NE	NE	NE	NE	NE
Water (for injection)	7732-18-5	Balance	NE	NE	NE	NE	NE	NE

NE - Not Established

C - Ceiling Limit

NOTE: All WHMIS required information is included. It is located in appropriate sections based on the ANSI Z400.1 – 1998 format  
 CHEMTREC NUMBER: Use only in the event of a chemical emergency involving a spill, leak, fire, exposure or accident involving this drug.

### 3. HAZARD IDENTIFICATION

**EMERGENCY OVERVIEW:** Material is a clear, colorless solution. Eye and skin irritant. Avoid contact with eyes, skin and clothing. Do not taste or swallow. Wash thoroughly after handling.



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Symptoms of Overexposure by Route of Exposure: This material is intended for intravenous injection under the supervision of physicians.

Inhalation: Inhalation of significant amounts of the product is not anticipated to occur because of the small size of individual containers. However, bronchospasms in asthmatic patients, but not in normal individuals has been reported.

Contact with Skin or Eyes: Adenosine is irritating to eyes and skin. Eye contact may cause stinging, watering, redness, and swelling. Skin contact may cause redness, itching, burning, and skin damage.

Ingestion: Although ingestion is not an anticipated route of occupational exposure, symptoms similar to those identified under acute injection may occur, including facial flushing, shortness of breath, chest pressure, tingling in the arms, numbness and blurred vision.

Injection: Local redness and pain are the primary symptoms of accidental injection in an occupational setting. Medical personnel are not anticipated to experience over-exposures to the therapeutic doses of this product. See package insert for adverse reactions associated with therapeutic doses of this product.

### Health Effects or Risks From Exposure (An explanation in lay terms):

Acute: The primary health effects anticipated in an occupational setting include irritation of eyes and skin as well as redness and local swelling after accidental injection. In case of over-exposure by injection, facial flushing, shortness of breath, chest pressure, nausea, headache/lightheadedness, hyperventilation, head pressure, dizziness, tingling in the arms, numbness, sweating, hypotension, apprehension, blurred vision, burning sensation, heaviness in arms, neck and back, metallic taste, tightness in throat and pressure in groin may occur.

Chronic: Adenosine has caused male reproductive effects in animal studies (see Section 11).

Target Organs: Adverse effects on organs have not been identified.

Other Comments: The use of Adenosine in patients receiving digitalis may be rarely associated with ventricular fibrillation. Appropriate resuscitative measures should be available. See package insert.

Pre-Existing Medical Conditions: Conditions aggravated by exposure may include skin and respiratory disorders.



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### 4. FIRST-AID MEASURES

Skin Exposure: Remove contaminated shoes and clothing and cleanse affected area(s) thoroughly by washing with mild soap and water. If irritation or redness develops and persists, seek medical attention.

Eye Exposure: Move victim away from exposure and into fresh air. If irritation or redness develops, flush eyes with clean water and seek immediate medical attention. For direct contact, hold eyelids apart and flush the affected eye(s) with clean water for at least 15 minutes. Seek medical attention.

Inhalation: If respiratory symptoms develop, move victim away from source of exposure and into fresh air. If symptoms persist, seek medical attention. If victim is not breathing, clear airway and immediately begin artificial respiration. If breathing difficulties develop, oxygen should be administered by qualified personnel. Seek immediate medical attention.

Ingestion: If swallowed, seek emergency medical attention. If victim is drowsy or unconscious and vomiting, place on the left side with the head down and DO NOT give anything by mouth. If not vomiting and professional advice is not available, DO NOT induce vomiting. If possible, do not leave victim unattended. Observe closely for adequacy of breathing.

Victims of chemical exposure must be taken for medical attention. Take a copy of the MSDS to the physician or health professional with victim. Physicians should refer to Section 11 (Toxicological Information) as well as the Physicians Desk Reference for additional treatment information.

### 5. FIRE-FIGHTING MEASURES

Flash Point: No data      Autoignition Temperature: No data

Flammable Limits (in air by volume, %): Lower: No data    Upper: No data

Fire Extinguishing Equipment: Use extinguishing agent suitable for type of surrounding fire.

Water Spray: OK    Carbon Dioxide: OK      Halon: OK  
Foam: OK      Dry Chemical: OK      Other: Any "ABC" Class

Unusual Fire and Explosion Hazards: No unusual fire or explosion hazards are expected.

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

Special Fire Fighting Procedures: For fires beyond the incipient stage, emergency responders in the immediate hazard area should wear bunker gear. When the potential chemical hazard is unknown, in enclosed or confined spaces, or when explicitly required by DOT, a self-contained breathing apparatus should be worn. In addition, wear other appropriate protective equipment as conditions warrant (see Section 8). Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Move undamaged containers from immediate hazard area if it can be done with minimal risk. Cool equipment exposed to fire with water, if it can be done with minimal risk.



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### 5. FIRE-FIGHTING MEASURES (cont.)

NFPA HAZARD CLASS:      Health:            2 (Moderate)  
   Flammability:    0 (Least)  
   Reactivity:       0 (Least)

### 6. ACCIDENTAL RELEASE MEASURES

#### Spill and Leak Response:

For small releases of this product, wear latex or nitrile gloves and safety glasses. Absorb spilled liquid and rinse area thoroughly with soap and water.

For large or uncontrolled releases, stay upwind and away from spill. Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Wear appropriate protective equipment including respiratory protection as conditions warrant (see Section 8). Prevent spilled material from entering sewers, storm drains, other unauthorized treatment drainage systems, and natural waterways. Dike far ahead of spill for later recovery or disposal. Spilled material may be absorbed into an appropriate absorbent material. Notify appropriate federal, state, and local agencies. Immediate cleanup of any spill is recommended.

### 7. HANDLING and STORAGE

Work and Hygiene Practices: As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling.

Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Precautions should be taken during the following activities:

- Withdrawal of needles from drug vials.
- Drug transfers using syringes and needles or filter straws.
- Expulsion of air from drug-filled syringes.

Storage and Handling Practices: Employees must be trained to properly use the product. Ensure vials are properly labeled. Store only in approved containers. Keep away from any incompatible materials or conditions (see Section 10). Store product between 15-30°C (59-86°F). Do not refrigerate. Protect from freezing. Product must not be used if it is discolored or contains a precipitate.

Protective Practices During Maintenance of Contaminated Equipment: When cleaning non-disposable equipment, wear latex or nitrile gloves (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. All needles, syringes, vials and other disposable items contaminated with this product should be disposed of properly.



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### 8. EXPOSURE CONTROLS - PERSONAL PROTECTION

Ventilation and Engineering Controls: Use with adequate ventilation. Follow standard medical product handling procedures.

Respiratory Protection: Not normally required for routine, medical administration of this product. A NIOSH certified air-purifying respirator with a type 95 filter may be used under conditions where airborne concentrations are expected to be excessive. Protection provided by air purifying respirators is limited (see manufacturer's respirator selection guide). Use a positive pressure air supplied respirator if there is potential for uncontrolled release, exposure levels are not known, or any other circumstances where air-purifying respirators may not provide adequate protection. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions warrant a respirator's use.

Eye Protection: The use of a face shield and/or chemical goggles to safeguard against potential eye contact, irritation, or injury is recommended.

Hand Protection: Use latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before and after using gloves.

Body Protection: No special body protection required for routine, medical administration of this product. Wear lab coat, gown, or smock, as appropriate for procedure.

Product Preparation Instructions for Medical Personnel: Follow standard procedure for handling pharmaceutical materials and recommendations presented on the Package Insert.

### 9. PHYSICAL and CHEMICAL PROPERTIES

Relative Vapor Density (air = 1):	ND	Evaporation Rate (n-BuAc=1):	<1
Specific Gravity (water = 1):	ND	Melting/Freezing Point:	234-235°C
Solubility in Water:	Soluble	Boiling Point:	100°C (212°F)
Vapor Pressure, mm Hg @ 25°C:	ND	pH:	4.5-7.5
Odor Threshold: Odorless			
Appearance and Color: Clear, Colorless Solution			

ND = No Data

### 10. STABILITY and REACTIVITY

Stability: Stable under normal conditions of storage and handling.

Materials With Which Substance is Incompatible: This product is generally compatible with other common materials in a medical facility.

Hazardous Polymerization: Will not occur.

Conditions To Avoid: Protect from refrigeration and freezing.



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### 11. TOXICOLOGICAL INFORMATION

Toxicity Data: The following information is for Adenosine

Oral LD50(mouse) >20 g/kg      IP LD50(mouse) = 500 mg/kg

Suspected Cancer Agent: This product has **NOT** been identified as a carcinogen by NTP, IARC or OSHA. Studies in animals have not been performed to evaluate the carcinogenic potential of Adenosine.

Irritancy of Product: This product may be irritating to eyes and other tissues.

Sensitization to the Product: This product is not expected to cause sensitization, although individual sensitivities may vary.

Reproductive Toxicity Information: Listed below is information concerning the effects of Adenosine Injection on human and animal reproductive systems. This material is classified as a Pregnancy Category C (Risk to Fetus Cannot be Ruled-Out).

Mutagenicity: Negative in the Ames *Salmonella* test system, and Mammalian Microsome Assay. Adenosine, however, like other nucleosides at millimolar concentrations present for several doubling times in cells in culture, is known to produce a variety of chromosomal alterations.

Embryotoxicity/Teratogenicity/Reproductive Toxicity: Altered sperm counts and morphology have been shown in rats and mice with intraperitoneal injection. Additional animal reproductive studies have not been conducted; nor have studies been performed in pregnant women. As a naturally occurring material, widely dispersed throughout the body, no fetal effects would be anticipated. However, since effects are not known, it should be used during pregnancy only if clearly needed.

ACGIH Biological Exposure Indices: Currently there are no Biological Exposure Indices (BEIs) associated with the components of this product.

### 12. ECOLOGICAL INFORMATION

All work practices must be aimed at eliminating environmental contamination.

Environmental Stability: This product will be relatively stable under ambient environmental conditions.

Effect of Materials on Plants or Animals: No specific information is available on the effect of Adenosine on plants or animals in the environment.

Effect of Chemicals on Aquatic Life: No specific information is available on the effect of Adenosine on plants or animals in the aquatic environment.

### 13. DISPOSAL CONSIDERATIONS

Preparing Wastes for Disposal: This material, if discarded as produced, is not a RCRA "listed" or "characteristic" hazardous waste. Use resulting in chemical or physical change or contamination may subject it to regulation as a hazardous waste. Along with properly characterizing all waste materials consult state and local regulations regarding the proper disposal of this material.

U.S. EPA Waste Number: None



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### 14. TRANSPORTATION INFORMATION

This Materials is not Hazardous as Defined by 49 CFR 172.101 by the U. S. Department of Transportation

Proper Shipping Name: Not applicable

Hazard Class Number and Description: Not applicable

UN Identification Number: Not applicable

Packing Group: Not applicable

DOT Label(s) Required: Not applicable

North American Emergency Response Guidebook Number (1996): Not applicable.

MARINE POLLUTANT: No component of this product is listed as a Marine Pollutant (49 CFR 172.101, Appendix B)

Transport Canada Transportation of Dangerous Goods Regulations: Not applicable

### 15. REGULATORY INFORMATION

#### U.S. REGULATIONS:

U.S. SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304 and 313 of Title II of the Superfund Amendments and Reauthorization Act.

U.S. SARA Threshold Planning Quantity: Not applicable

U.S. CERCLA Reportable Quantities (RQ): Not applicable

U.S. TSCA Inventory Status: Adenosine is a "drug" as defined by the Federal Food, Drug and Cosmetic Act and is therefore not a chemical substance under TSCA.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): This product does NOT contain a chemical known to the State of California to cause developmental and reproductive effects.

Other U.S. Federal Regulations: Based on this product's use, the requirements of the OSHA Bloodborne pathogen Standard (29 CFR 1910.1030) are applicable.

ANSI Labeling (Based on 129.1, Provided to Summarize Occupational Exposure Hazards):

**CAUTION!** EYE AND SKIN IRRITANT. Adenosine should be administered under the supervision of a qualified physician. Avoid over-exposure. Avoid contact with eyes, skin and clothing. Do not eat, drink or smoke when handling Adenosine Injection. Do not taste or swallow. Wash thoroughly after handling. Clean up spills promptly.

#### CANADIAN REGULATIONS:

Canadian DSL/NDSL Status: Adenosine is regulated by the Food and Drug Administration of Health Canada and is therefore exempt from the requirements of CEPA.



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### 16. OTHER INFORMATION

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