

MATERIAL SAFETY DATA SHEET

Date Prepared: 8/6/1996 Date Reviewed: 10/18/2005



ADENOSCAN

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Identifier: Adenosine

General Use: Diagnostic Agent

MANUFACTURED FOR:

Astellas Pharma US, Inc.
3 Parkway North
Deerfield, IL 60015-2538
(847) 317-8800

EMERGENCY TELEPHONE NUMBER:

(800) 727-7003

2. COMPOSITION/INFORMATION ON INGREDIENTS

Component: **Adenosine**

Chemical Name: 6- amino -9-beta-D-ribofuranosyl-9-H-purine

CAS Registry #: 58-61-7

UN Number: NG

OSHA PEL: NE mg/m3 OSHA PEL: NE ppm

ACGIH TLV: NE mg/m3 ACGIH TLV: NE ppm

STEL: NE mg/m3 STEL: NE ppm

Percent of Product: <1% Note: 3 mg/mL

Component: **Sodium Chloride**

CAS Registry #: 7647-14-5

UN Number: NG

OSHA PEL: NG mg/m3 OSHA PEL: NG ppm

ACGIH TLV: NG mg/m3 ACGIH TLV: NG ppm

STEL: NG mg/m3 STEL: NG ppm

Percent of Product: <1% Note: NG

Component: **Water for Injection**

CAS Registry #: 7732-18-5

UN Number: NA

OSHA PEL: NA mg/m3 OSHA PEL: NA ppm

ACGIH TLV: NA mg/m3 ACGIH TLV: NA ppm

STEL: NA mg/m3 STEL: NA ppm

Percent of Product: NG Note: QS to volume

3. HAZARD IDENTIFICATION

PRIMARY ROUTES OF EXPOSURE - Inhalation, Eye/Skin Absorption and Ingestion.

CHEMICAL LISTING AS CARCINOGEN:

<u>COMPONENT</u>	<u>CAS No.</u>	<u>NTP</u>	<u>IARC</u>	<u>OSHA</u>
Adenosine	58-61-7	No Data	No Data	No Data
Sodium Chloride	7647-14-5	No Data	No Data	No Data
Water for Injection	7732-18-5	No Data	No Data	No Data

4. EMERGENCY AND FIRST AID PROCEDURES

INHALATION: Move person to fresh air immediately. Give artificial respiration and cardiopulmonary resuscitation (CPR) if required. Seek medical attention.

INGESTION: Flush mouth out with water immediately. Seek medical attention.

SKIN CONTACT: Remove contaminated clothing immediately. Flush area with water for at least 15 minutes. Seek medical attention.

EYE CONTACT: Immediately flush with water for at least 15 minutes. Seek medical attention.

For Adverse Drug Reaction Information: phone (847) 317- 1464; fax: (847)-317-1241; email:safety-us@us.astellas.com

5. FIRE FIGHTING MEASURES

Fire and Explosion Data:

Product Flammability:	Non-Flammable	Closed Cup Flash Pt.	NE
Autoignition:	NE	Open Cup Flash Pt.	NE
Flammability Limits:	NE		

Products of Combustion: Smoke, and NOx fumes. Sodium Chloride evolves vapor when heated to temperatures with eye irritating properties

Fire Hazards in Presence of Various Substances: When heated to decomposition it emits toxic fumes of NOx

Explosion Hazards in Presence of Various Substances: NG

Fire Fighting Media and Instructions: Water spray, dry chemical, carbon dioxide or foam as appropriate

Firefighting Equipment: NG

Protective Clothing (fire): Protective clothing

Special Remarks on Fire Hazards: NG

6. ACCIDENTAL RELEASE MEASURES

CLEAN-UP: Wear recommended personal protective equipment. Use absorbent towels or booms to clean-up spill. Wipe surfaces clean and wash with soap and water.

7. HANDLING AND STORAGE

When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product.

Store product between 15 - 30 °C (59 - 86°F); do not refrigerate; protect from freezing.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS:

Under indicated use, general room ventilation is usually satisfactory. Use local exhaust ventilation when necessary.

PERSONAL PROTECTION:

Respirators - With satisfactory ventilation, respiratory protection not usually required.

Eyes - Safety glasses or goggles recommended.

Gloves - Disposable latex gloves recommended.

Clothing - Disposable garments if direct skin contact is anticipated.

Also see Section 2 (Composition/Information on Ingredients) for exposure limits.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance, other characteristics: Sterile solution.

Boiling Point:	NE	Vapor Density:	NE
Melting Point:	234-235° C	Percent Volatiles:	NE
Freezing Point:	NE	pH:	5.5-7.5
Vapor Pressure:	NE	Molecular Weight:	267.34
Note:	NA	Solubility:	Miscible
Color:	Clear	Odor:	None noted
Specific Gravity:	NE	LogK:	NE

10. STABILITY AND REACTIVITY

Stability: Stable
Conditions/Materials to Avoid: Protect from refrigeration and freezing
Hazardous Polymerization: Will not occur

11. TOXICOLOGY INFORMATION

Toxicity Data

<u>Ingredient Name</u>	<u>Test</u>	<u>Result</u>	<u>Route</u>	<u>Species</u>
Adenosine	LD50	>20Gm/kg	oral	mouse

SIGNS & SYMPTOMS OF OVEREXPOSURE MAY INCLUDE:

This product is intended for therapeutic use only when prescribed by a physician. If this product is inhaled it may cause exacerbation of asthma. Potential adverse reactions from prescribed doses and overdoses are described in the package insert; and include: flushing, chest discomfort, dyspnea or urge to breathe deeply, headache, throat, neck or jaw discomfort, gastrointestinal discomfort, lightheadedness/dizziness, upper extremity discomfort, ST segment depression, first-degree atrio-ventricular(AV) block, second-degree AV block, paresthesia, hypotension, nervousness and arrhythmias. Occupational exposure has not been fully investigated.

MEDICAL CONDITIONS GENERALLY RECOGNIZED AS BEING AGGRAVATED BY EXPOSURE:

Pre-existing skin and respiratory conditions; may cause exacerbation of asthma; second or third degree heart block.

IMMEDIATE EFFECTS:

EYE- Irritation has been experienced with patient administration.

SKIN- Irritation has been experienced with patient administration.

INHALATION- Has been reported to induce bronchospasm in asthmatic patients, but not in normal individuals.

DELAYED EFFECTS: Studies in animals have not been performed to evaluate the carcinogenic potential of Adenocan (adenosine). Adenosine tested negative for mutagenic potential in the Ames test. adenosine is known to produce a variety of chromosomal alterations. Altered sperm counts and morphology have been shown in rats and mice with intraperitoneal injection. Human reproductive studies have not been performed. Modertely toxic by intraperitoneal route; human mutation data reported.

12. ECOLOGICAL INFORMATION

Ecotoxicity Data

<u>Ingredient Name</u>	<u>Species</u>	<u>Period</u>	<u>Result</u>
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** Not Available **

BOD and COD: NE
 Biodegradable/OECD: NE
 Mobility: NE
 Products of Degradation: NE
 Toxicity of the Products of Biodegradation: The product itself and its products of degradation are not toxic
 Special Remarks on the Products of Biodegradation: NE

13. WASTE DISPOSAL

Waste Disposal - Waste product should be incinerated in accordance with all federal, state and local regulations.

14. TRANSPORT INFORMATION

Regulatory Information	UN Number	Proper Shipping Name	Class
United States (DOT) Packing Group: NE Additional Information: None	Not Regulated	NE Label: NE	NE
Canada (TDG) Packing Group: NE Additional Information: None	Not regulated	NE Label: NE	NE
Mexico (NOM-004-SCT2-1994) Packing Group: NE Additional Information: None	Not Regulated	NE Label: NE	NE

NAERG: NA

15. REGULATORY INFORMATION

HCS Classification: Not controlled under the HCS (US)

U.S. Federal Regulations: TSCA 8(b) inventory: All components listed
 Clean Water Act (CWA) 307: No products were found
 Clean Water Act (CWA) 311: No products were found
 Clean Air Act (CAA) 112 accidental release prevention: No products were found
 Clean Air Act (CAA) 112 regulated flammable substances: No products were found
 Clean Air Act (CAA) 112 toxic substances: No products were found
 SARA 302/304/311/312 extremely hazardous substances- No products found
 SARA 302/304 emergency planning and notification: no products were found
 SARA 302/304/311/312 hazardous chemicals: No products were found
 SARA 311/312 MSDS distribution- chemical inventory-hazard identification: No products were found

SARA 313

Form R - Reporting Requirements: No products were found

Supplier Notification: No products were found

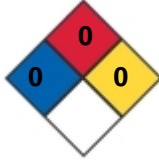
State Regulations: No products were found

WHMIS (Canada): Not controlled under WHMIS
 CEPA DSL: All components listed.

Classification of the Degree of Risk (Mexico): No hazardous ingredients

16. OTHER INFORMATION

National Fire
Protection
Association
(U.S.A.)



Hazards

Fire: 0
Health: 0
Reactivity: 0
Special:

Label Requirements:

References:

Abbreviations:

ACGIH: American Conference Of Governmental Industrial Hygienists
ANSI: American National Standards Institute
CAS: Chemical Abstract Service
HCS: Hazard Communication Standard
HEPA: High Efficiency Particulate Air
IARC: Internal Agency for Research on Cancer
LD50: Median Lethal Dose
MRHD: Maximum Recommended Human Dose
NA: Not Available
NE: Not Established
NG: Not Given
NIOSH: National Institute for Occupational Safety and Health
NTP: National Toxicology Program
OEL: Occupational Exposure Limit
OSHA: Occupational Safety and Health Administration
PEL: Permissible Exposure Limit
PPM: Parts Per Million
QS: Quantity Sufficient
RCRA: Resource Conservation and Recovery Act
SARA: Superfund Amendments and Reauthorization Act
STEL: Short Term Exposure Limit
TLV: Threshold Limit Value
TSCA: Toxic Substances Control Act
USP: United States Pharmacopoeia
