

MATERIAL SAFETY DATA SHEET

FUJISAWA PRIOR TO APRIL 2005

Date Prepared: 08/06/1996

Date Reviewed: 04/14/2004

ADENOCARD**1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION**

Product Identifier: Adenocard
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 INGREDIENTSComponent: **Adenosine**

CAS Registry #: 58-61-7

UN Number: NG

Chemical
Name:

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: 9 mg/mL

Component: **Water for Injection**

CAS Registry #: 7732-18-5

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: NG

Note: QS to volume

3. HAZARD IDENTIFICATION

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

CHEMICAL LISTING AS CARCINOGEN:

COMPONENT	CAS No.	NTP	IARC	OSHA	COMMENT
Adenosine	58-61-7	No Data	No Data	No Data	This component has target organ effects per OSHA 29CFR1910.1200(g).
Sodium Chloride	7647-14-5	No Data	No Data	No Data	NE
Water for Injection	7732-18-5	No Data	No Data	No Data	NA

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- 8202; 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 NO_x fumes. Sodium Chloride evolves vapor when heated to temperatures with eye irritating properties

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

Explosion Hazards in the Presense of Various Substances: NG

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

Firefighting Equipment: Wear self-contained breathing apparatus and protective clothing.

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:	Water
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

INGREDIENT NAME	TEST	RESULT	ROUTE	SPECIES
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

INGREDIENT NAME	SPECIES	PERIOD	RESULT
** Not Available **			

BOD and COD:	NG
Biodegradable/OECD:	NG
Mobility:	NG
Products of Degradation:	NG
Toxicity of the Products of Biodegradation:	NG
Special Remarks on the Products of Biodegradation:	NG

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	Class
United States (DOT)	Not Regulated		
PACKING GROUP:		LABEL:	
ADDITIONAL INFORMATION:			
Canada (TDG)	Not Regulated		
PACKING GROUP:		LABEL:	
ADDITIONAL INFORMATION:			
Mexico (NOM-004-SCT2-1994)	Not Regulated		
PACKING GROUP:		LABEL:	
ADDITIONAL INFORMATION:			

NAERG:

15. REGULATORY INFORMATION

HCS Classification: Not controlled under the HCS (US)

U.S. Federal Regulations: NG

SARA 313:

Form R - Reporting Requirements: NG

Supplier Notification: NG

State Regulations: NG

WHMIS (Canada): NG

Classification of the Degree of Risk (Mexico): NG

16. OTHER INFORMATION

National Fire
Protection
Association
(U.S.A)

Hazards

Fire: 0
Health: 0
Reactivity: 0
Special:

Label Requirements: NG

References:

Abbreviations:

ACGIH: American Conference Of Governmental Industrial Hygienists

HEPA: High-Efficiency Particulate Air

IARC: International Agency for Research on Cancer

NA: Not Applicable

NE: Not Established

NG: Not Given

NIOSH: National Institute for Occupational Safety and Health

NTP: National Toxicology Program

OSHA: Occupational Safety and Health Administration

PEL: Permissible Exposure Limit

PPM: Parts Per Million

QS: Quantity Sufficient

RCRA: Resource Conservation and Recovery Act

STEL: Short Term Exposure Limit

TLV: Threshold Limit Value
