

Sagent Pharmaceuticals, Inc.				
Adenosine Inject	ion, USP		Material Safety Data	Sheet (MSDS)
Issue Date: Apr 26, 2010	MSDS No.: MSDS 001	Version No.: <b>5.0</b>	Form Number: R-SOP-009-F001	Page: <b>1 of 8</b>

### **Section 1 - Chemical Product and Company**

**Distributor:** 

Sagent Pharmaceuticals, Inc. 1901 N. Roselle Rd, Suite 700 Schaumburg, IL 60195 847-908-1600

**Emergency Telephone:** 866-625-1618

**Product Identifier:** Adenosine Injection, USP

**Product Code:** 25021-301

**Common/Trade Name:** Adenosine Injection

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

Chemical Family: Antiarrhythmic Product Use: Pharmaceutical

**Product Type:** Regulated Prescription Drug

**Container Information:** 2mL and 4 mL Pre-filled syringes, Single-dose Vial

### **Section 2 - Composition / Information on Ingredients**

Ingredient	Weight %	CAS No.
Adenosine	0.3	58-61-7
Sodium Chloride	0.9	7647-14-5
Water for Injection	98.8	7732-18-5

### **Section 3 - Hazards Identification**

Primary Physical and Health Hazards:

Adenosine Injection is an anti-arrhythmic 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.

**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.



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Signs & Symptoms of Exposure:

Exposure can cause dilation of the blood vessels and an increase in

contraction of some smooth muscles.

**Chemical Listed as** 

Carcinogen:

NTP: No IARC: No OSHA: No

**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.

### **Section 4 - First Aid Measures**

**Eye Exposure:** Flush eyes with large volumes of water for 15 minutes or more. Seek

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.

**Notes to Physician:** See patient package insert in shipping carton for complete information.

### **Section 5 - Fire Fighting Measures**

Flash Point Not determined

**Autoignition** Not determined

**Temperature:** 

Flammable Limits Lower %: Not determined

in Air Upper %: Not determined

Flammable Limits: Not determined



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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 6 - Accidental Release Measures**

**Spill:** Use the appropriate personal protective equipment, see Section 8.

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 7 - Handling and Storage**

**General Handling:** When handling pharmaceutical products, avoid all contact with skin,

eyes, nostrils and mouth. Avoid inhalation of dust, fumes, mist, and/or

vapors associated with the product.

Waste Disposal

**Method:** 

Incineration in an approved incinerator is recommended. Refer to local,

state, and federal rules.

**Storage** 

Store at controlled room temperature 20°-25°C (68°-77°F). Follow

**Conditions:** instructions provided in packaging.

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### **Section 8 - Exposure Controls / Personal Protection**

Under normal use and handling conditions, no protective equipment is required. The following is recommended for a production setting.

**Respiratory** Under normal use, respirators are not required. If aerosols are **Protection:** generated, a disposable dust/mist respirator (N95) may be used

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.

**Eye Protection:** Safety glasses

**Ventilation:** Good general ventilation should be sufficient to control airborne levels.

**Skin Protection:** Work uniform or laboratory coat.

Other Protective

**Equipment:** 

Protective Latex or Nitrile gloves

**Additional** Wash hands following use. No eating, drinking, or smoking while

**Exposure** handling this product.

**Precautions:** 

### **Exposure Limits**

Compound	<u>Issuer</u>	<b>Type</b>	<u>OEL</u>
Adenosine	OSHA ACGIH	TLV TLV STEL	NE NE NE
Sodium Chloride	OSHA ACGIH	PEL TLV STEL	NE NE NE

### **SI**

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### **Section 9 - Physical and Chemical Properties**

Physical State:LiquidSpecific Gravity:Approx to waterAppearance and Odor:Clear, no OdorEvaporation Rate:Approx to water

Boiling Point:Not availableSolubility in Water:SolubleVapor Pressure:Not availablepH:4.5 - 7.5

Vapor Density: Not available

### Section 10 - Stability and Reactivity

**Stability:** Stable at normal temperature and pressures.

Incompatibility (Materials to

avoid):

None identified

**Hazardous** Decomposition products of this compound may include potentially

**Decomposition:** hazardous byproducts such as oxides of carbon and nitrogen.

Hazardous

**Polymerization:** 

**Conditions to** 

Avoid:

None identified

Will not occur.

### **Section 11 - Toxicological Information**

Signs & Symptoms of Exposure & Overexposure:

This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Side effects from therapeutic doses include: gastrointestinal, allergic, hematologic, renal, and hepatic laboratory abnormalities. Occupational exposure has not

been fully investigated.

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### **Acute Toxicity**

Component	Туре	Route	Species	Dosage
Adenosine	LD <sub>50</sub>	Oral	Mouse	20g/Kg
Sodium Chloride	LD <sub>50</sub>	Inhalation	Rat	42 g/m <sup>3</sup> /1H
Water	LD <sub>50</sub>	Oral	Rat	50000 mg/Kg

### **Section 12 - Ecological Information**

No applicable ecological information found.

### **Section 13 - Disposal Considerations**

**Waste Disposal:** Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

### **Section 14 - Transport Information**

### **Regulatory Organizations:**

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

### **Section 15 - Regulatory Information**

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

### **U.S. Regulations**

TSCA - No

CERCLA - Not on this list

SARA 302 - Not on this list

SARA 313 - Not on this list

OSHA Substance Specific - No

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### **Section 16 - Other Information**

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact: Sagent Pharmaceuticals, Inc. 1901 N. Roselle Rd, Suite 700 Schaumburg, IL 60195 847-908-1600



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**Glossary:** This glossary contains definitions of general terms used in MSDSs. Not all of these Glossary Terms will necessarily apply to this MSDS.

Glossary Term	ns will necessarily apply to this MSDS.
ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
USF	1 United States I narmacopera