	Sagent Pharmaceuticals, Inc.			
	Adenosine Injection, USP		Material Safety Data Sheet (MSDS)	
	Issue Date: Apr 26, 2010	MSDS No.: MSDS 001	Version No.: 5.0	Form Number: R-SOP-009-F001

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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	Issue Date: Apr 26, 2010	MSDS No.: MSDS 001	Version No.: 5.0	Form Number: R-SOP-009-F001	Page: 2 of 8

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 Temperature:** Not determined
- Flammable Limits in Air** Lower %: Not determined
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 Conditions:

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

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 Exposure Precautions: Wash hands following use. No eating, drinking, or smoking while handling this product.

Exposure Limits

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

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Section 9 - Physical and Chemical Properties


Physical State:	Liquid	Specific Gravity:	Approx to water
Appearance and Odor:	Clear, no Odor	Evaporation Rate:	Approx to water
Boiling Point:	Not available	Solubility in Water:	Soluble
Vapor Pressure:	Not available	pH:	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:	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 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	Type	Route	Species	Dosage
Adenosine	LD ₅₀	Oral	Mouse	20g/Kg
Sodium Chloride	LD ₅₀	Inhalation	Rat	42 g/m ³ /1H
Water	LD ₅₀	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.

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
WEEL	Workplace Environmental Exposure Level (AIHA)