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Section 1 - Identification

- (a) **Product Identifier:** Adenosine Injection, USP
- (b) **Product Code:** 25021-301
25021-307
- Common/Trade Name:** Adenosine Injection
- Chemical Name:** 6-amino-9-beta-D-ribofuranosyl-9H-purine
- Chemical Family:** Antiarrhythmic
- (c) **Product Use:** Pharmaceutical
- Product Type:** Regulated Prescription Drug
- Container Information:** Pre-filled syringe and single-dose vial
- (d) **Distributor:** Sagent Pharmaceuticals, Inc., 1901 N. Roselle Rd, Suite 700, Schaumburg, IL 60195, 847-908-1600
- (e) **Emergency Telephone:** 866-625-1618

Section 2 - Hazards Identification

- (a) **Classification:** Not a hazardous substance or mixture.


HMIS Rating

Health Hazard	0
Flammability	0
Physical Hazard	0

NFPA Rating

Health Hazard	0
Fire Hazard	0
Reactivity Hazard	0

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
- Not a hazardous substance or mixture	

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(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
<u>Precautionary Statements:</u> P264 P305 + P351 + P338 P337 + P313 P314	<ul style="list-style-type: none"> - Wash hands thoroughly after handling - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. - If eye irritation persists, get medical attention - Get medical attention if you feel unwell


(d) Unknown Acute Toxicity: N/A

Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
6-amino-9-beta-D-ribofuranosyl-9H-purine	Adenosine	0.3% (w/v)	58-61-7	N/A
Sodium Chloride	Sodium Chloride	0.9% (w/v)	7647-14-5	N/A
Water for Injection	Water for Injection	98.8% (w/v)	7732-18-5	N/A

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.

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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

- (a) **Extinguishing Media** Use water or an ABC multi-purpose extinguisher.
- (b) **Hazardous Combustion Products:** Not determined
- (c) **Special Protective Equipment / Precautions:** 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.


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.
- 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

(a) Exposure Limits


Compound	Issuer	Type	Exposure Limit
Adenosine	OSHA	TLV	NE
	ACGIH	TLV	NE
	-----	STEL	NE
Sodium Chloride	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE

(b) Engineering Controls

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

(c) Individual Protection Measures

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
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.


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Section 9 - Physical and Chemical Properties

(a)	Appearance	Clear Liquid
(b)	Odor	No Odor
(c)	Odor Threshold	None
(d)	pH	4.5 – 7.5
(e)	Melting Point:	Not applicable
(f)	Initial Boiling Point:	Not available
(g)	Flash Point	Not determined
(h)	Evaporation Rate:	Approx to water
(i)	Flammability	Not determined
(j)	Upper Lower Flammability or Explosion Limits	Not determined
(k)	Vapor Pressure:	Not available
(l)	Vapor Density:	Not available
(m)	Relative Density	Approx to water
(n)	Solubility(ies)	Soluble in Water
(o)	Partition Coefficient: n-octanol/water	Not available
(p)	Auto-ignition Temperature	Not available
(q)	Decomposition Temperature	Not available
(r)	Viscosity	Not available

Section 10 - Stability and Reactivity

(a)	Reactivity	Not Reactive
(b)	Chemical Stability	Stable under normal conditions
(c)	Possibility of Hazardous Reactions	None
(d)	Conditions to Avoid	None identified
(e)	Incompatible Materials	None identified
(f)	Hazardous Decomposition Products	Decomposition products of this compound may include potentially hazardous byproducts such as oxides of carbon and nitrogen.

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Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Via contact with skin or eyes, or accidentally ingested.
(b)	Symptoms related to the physical, chemical and toxicological characteristics	Exposure can cause dilation of the blood vessels and an increase in contraction of some smooth muscles. 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.
(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	Adenosine has low chronic toxicity.

(d) 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

(e) Hazardous Chemical Listings

NTP: No

IARC: No

OSHA: No

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Section 12 - Ecological Information


(a)	Ecotoxicity	<u>Sodium Chloride</u> Water Flea – 340.7 – 469.2 mg/L, EC50, 48 h 1000 mg/L, EC50, 48 h <u>Fish</u> Oncorhynchus mykiss: 4747 – 7824 mg/L, LC50, 96 hrs Lepomis macrochirus: 5560 – 6080 mg/L, LC50, 96 hrs Pimephales promelas: 6020 – 7070 mg/L, LC50, 96 hrs Lepomis macrochirus: 12946 mg/L, LC50, 96 hrs Pimephales promelas: 7050 mg/L, LC50, 96 hrs
		(b) Persistence and degradability No applicable ecological information found.
		(c) Bioaccumulative potential No applicable ecological information found.
		(d) Mobility in soil No applicable ecological information found.
		(e) Other Adverse Effects 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

(a)	UN Number	Not available
(b)	UN Proper Shipping Name	Not available
(c)	Transport Hazard Class(es)	Not available
(d)	Packing Group	Not available
(e)	Environmental Hazards	Not available

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(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not available
(g)	Special Precautions	Not available

DOT: Not dangerous goods

ICAO/IATA: Not dangerous goods

IMO: Not dangerous goods

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 – Exempt from this list; it is FDA regulated.

CERCLA – Not listed

SARA 302 - Not listed

SARA 313 - Not listed

OSHA Substance Specific – Not available

California Prop. 65 – Not listed

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 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 SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
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
DSL	Domestic Substances List
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
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
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
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
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity

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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)