

Section 1 - Identification

(a) Product Identifier: Adenosine Injection, USP
(b) NDC: 25021-301-67, 25021-301-68

Common/Trade Name: Adenosine, Adenocard®

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

Chemical Family: Endogenous nucleoside

(c) Product Use: A pharmacological stress agent, used as an adjunct to thallium-

201 myocardial perfusion scintigraphy in patients unable to

exercise adequately.

Product Type: Regulated Prescription Drug

Container Information: Single use Pre-filled plastic syringe

(d) Distributor: Sagent Pharmaceuticals, Inc., 1901 N. Roselle Rd, Suite 450,

Schaumburg, IL 60195, 847-908-1600

(e) Emergency Telephone: 866-625-1618

Section 2 - Hazards Identification

(a) Classification:

GHS classification: Not classified

Label elements:

Signal words: Not classified

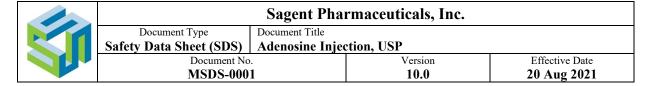
Hazard statement: Not classified in accordance with

international standards for workplace safety.

Other hazards: No data available

(b) Signal Word, Hazard	(c) Description of Hazards:
statement(s), Symbol(s),	
and/or Precautionary	
statement(s):	
-	

Previous Document No	Confidential - For Use Only By Affiliates	Page
SDS001	of Sagent Pharmaceuticals, Inc.	Page 1 of 10



(b) Signal Word, Hazard statement(s), Symbol(s),	(c) Description of Hazards:	
and/or Precautionary		
statement(s):		
Precautionary Statements:		
P264	- Wash hands thoroughly after handling	
P305 + P351 + P338	- IF IN EYES: Rinse cautiously with water for several	
	minutes. Remove contact lenses, if present and easy to	
	do. Continue rinsing.	
P337 + P313	- If eye irritation persists, get medical attention	
P314	- Get medical attention if you feel unwell	

(d) Unknown Acute Toxicity: No data available

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 plenty of water. Get

medical attention if irritation or signs of exposure are noted.

Ingestion: Do not induce vomiting, rinse 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.

Previous Document No	Confidential - For Use Only By Affiliates	Page
SDS001	of Sagent Pharmaceuticals, Inc.	Page 2 of 10

Inhalation: If difficulty with breathing, remove from exposure to fresh air. Seek

attention of a physician immediately.

Section 5 – Fire-fighting Measures

(a) Extinguishing Media Use appropriate extinguishing media for the surrounding fire.

(b) Hazardous Not determined

Combustion Products:

(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: Contain any spills using absorbents to prevent migration into sewers

and streams. Use the appropriate personal protective equipment, see Section 8. 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, use good industrial hygiene

and safety procedures. Avoid all contact with skin, eyes, nostrils and

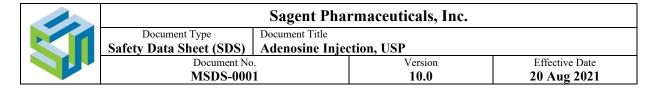
mouth. Avoid inhalation of dust, fumes, mist, and/or vapors

associated with the product.

Storage Conditions: Store at 20° to 25°C (68° to 77°F); [See USP Controlled Room

Temperature.] Do not Freeze. Do not refrigerate

Previous Document No	Confidential - For Use Only By Affiliates	Page
SDS001	of Sagent Pharmaceuticals, Inc.	Page 3 of 10



Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Adenosine	OSHA ACGIH	TLV	NE NE
		STEL	NE 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. Ensure all national/local regulations are observed.

(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 Colorless Liquid
(b)	Odor	No Odor
(c)	Odor Threshold	None
(d)	рН	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
(0)	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	Freezing and refrigeration
(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.

Previous Document No	Confidential - For Use Only By Affiliates	Page
SDS001	of Sagent Pharmaceuticals, Inc.	Page 5 of 10

Section 11 - Toxicological Information

Effective Date

20 Aug 2021

(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.

Skin irritation: Not classified

Eve contact/irritation: Not classified

Respiratory or skin sensitization: not classified

Germ cell mutagenicity: Not classified (Adenosine was negative for genotoxic potential in the

Salmonella (Ames test) and Mammalian Microsomal Assay)

Carcinogenicity: studies in animals have not been performed

Reproductive toxicity: studies in animals have not been performed

Teratogenicity: No data available

Specific target organ toxicity (single exposure): No data available Specific target organ toxicity (repeated exposure): No data available

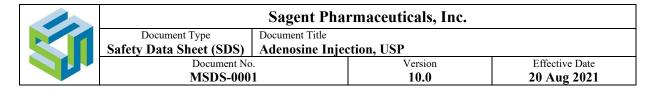
(d) Acute Toxicity

Component	Type	Route	Species	Dosage
Adenosine	LD_{50}	Oral	Mouse	20g/Kg
Sodium Chloride	LD_{50}	Inhalation	Rat	$42 \text{ g/m}^3/1\text{H}$
Water	LD ₅₀	Oral	Rat	50000 mg/Kg

(e) Hazardous Chemical Listings

NTP: Not listed IARC: Not listed OSHA: Not listed NIOSH 2016 list: Not listed

Previous Document No	Confidential - For Use Only By Affiliates	Page
SDS001	of Sagent Pharmaceuticals, Inc.	Page 6 of 10



Section 12 - Ecological Information

(a)	Ecotoxicity	Sodium Chloride Water Flea – 340.7 – 469.2 mg/L, EC50, 48 h 1000 mg/L, EC50, 48 h Fish Lepomis macrochirus: 5560 – 6080 mg/L, LC50, 96 hr Lepomis macrochirus: 12946 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 local, regional and national laws and regulations.

Section 14 - Transport Information

(a)	UN Number	N/A
(b)	UN Proper Shipping Name	N/A
(c)	Transport Hazard Class(es)	N/A
(d)	Packing Group	N/A
(e)	Environmental Hazards	N/A
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	N/A
(g)	Special Precautions	N/A

DOT: Not regulated for transport

Previous Document No	Confidential - For Use Only By Affiliates	Page
SDS001	of Sagent Pharmaceuticals, Inc.	Page 7 of 10

ICAO/IATA: Not regulated for transport

IMO: Not regulated for transport

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 -

Adenosine: Listed on United States TSCA Inventory Sodium chloride: Listed on United States TSCA Inventory Water for Injection: Listed on United States TSCA Inventory

CERCLA – Not listed SARA 302 - Not listed SARA 313 - Not listed OSHA Substance Specific – Not listed 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 450 Schaumburg, IL 60195 847-908-1600

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

Previous Document No	Confidential - For Use Only By Affiliates	Page
SDS001	of Sagent Pharmaceuticals, Inc.	Page 8 of 10



Sagent Pharmaceuticals, Inc. Document Title Adenosine Injection, USP

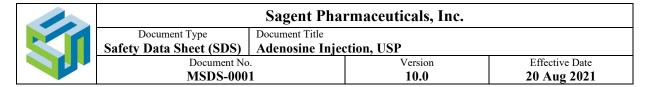
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CHAN	(of 1980)		
CHAN	Chemical Hazard Alert Notice		
CHEMTREC	Chemical Transportation Emergency Center		
DOT	Department of Transportation		
DSL	Domestic Substances List		
EPA	Environmental Protection Agency		
GHS	Globally Harmonized System of Classification 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		
TSCA	Toxic Substances Control Act		
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted		
UEL	Upper Explosive Limit		
UN	United Nations		
011	Omea radons		

Previous Document No	Confidential - For Use Only By Affiliates	Page
SDS001	of Sagent Pharmaceuticals, Inc.	Page 9 of 10



USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)