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|  | Sagent Pharmaceuticals, Inc. | | |
| | Document Type Safety Data Sheet (SDS) | Document Title Adenosine Injection, USP | |
| | Document No. MSDS-0001 | Version 10.0 | Effective Date 20 Aug 2021 |


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 statement(s), Symbol(s), and/or Precautionary statement(s): | (c) Description of Hazards: |
| - | |

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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: 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

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| 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. |

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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 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:** 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

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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. 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) | 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 | 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. |

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Section 11 - Toxicological Information

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

Skin irritation: Not classified

Eye 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 g/m ³ /1H |
| 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

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Section 12 - Ecological Information

| | | |
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| (a) | Ecotoxicity | <p><u>Sodium Chloride</u></p> <p>Water Flea – 340.7 – 469.2 mg/L, EC50, 48 h 1000 mg/L, EC50, 48 h</p> <p><u>Fish</u></p> <p>Lepomis macrochirus: 5560 – 6080 mg/L, LC50, 96 hr Lepomis macrochirus: 12946 mg/L, LC50, 96 hrs</p> |
| (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

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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 |

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| | (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 |

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