MSDS: Adenosine Injection USP, 3 mg/mL

Manufacturer: Akorn Incorporated
150 S. Wyckles Road
Decatur, IL 62522

Contact Telephone: 1-800-932-5676
Email: customer.service@akorn.com

Section 1 - IDENTIFICATION

Common/Trade Name: Adenosine Injection USP, 3 mg/mL
Description: Adenosine Injection is a sterile, injectable, liquid, drug provided in a vial. The solution is for rapid bolus intravenous injection.

Chemical Name: Adenosine, 6-amino-9-beta-D-ribofuranosyl-9H-purine, C_{10}H_{13}N_{5}O_{4}

Category: Prescription Only; Antiarrhythmic

Section 2 – HAZARDOUS INGREDIENTS / COMPOSITION INFORMATION

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS #</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adenosine</td>
<td>58-61-7</td>
<td>0.3 %</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>7647-14-5</td>
<td>0.9 %</td>
</tr>
<tr>
<td>Water for Injection</td>
<td>7732-18-5</td>
<td>qs</td>
</tr>
</tbody>
</table>

Section 3 – HEALTH HAZARD DATA

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.

Carcinogenicity:
- NTP: No
- IARC: No
- OSHA Regulated: No

Note: Health Hazard (Acute & Chronic): 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.
Section 4 – FIRST AID MEASURES

Eyes: Immediately flush eyes with copious amounts of water for at least 15 minutes. Contact a physician.

Skin: Remove from source of exposure. Remove all contaminated clothing and wash skin with copious amounts of water for at least 15 minutes. Contact physician if skin becomes irritated.

Inhalation: Remove into fresh air. If victim is not breathing, clear airway and immediately begin artificial respiration. Seek medical attention immediately.

Ingestion: Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person. Seek medical attention immediately.

Note to physicians: Treat symptomatically and supportively

Section 5 – FIRE FIGHTING MEASURES

FIRE AND EXPLOSION DATA
Closed Cup Flash Point: Not Established
Open Cup Flash Point: Not Established
Fire Point: Not Established
Auto ignition: Not Established
Lower Explosion Limit: Not Established
Upper Explosion Limit: Not Established
General Hazard: Toxic fumes may be emitted at combustion.
Fire Fighting Instructions: Evacuate all personnel to a safe area. Wear protective clothing and self-contained breathing apparatus.

Fire Fighting Equipment: Carbon dioxide, dry chemical, halon, foam, water spray or fog as appropriate for surrounding fire and materials
Hazardous Combustion Products: Toxic fumes may be emitted.

Section 6 – ACCIDENTAL RELEASE MEASURES

Clean-Up: Wear respiratory protection and protective clothing. Absorb with inert material, and containerize prior to disposal in accordance with local, state, and federal regulations.

Handling: Avoid contact with skin, eyes, nostrils, and mouth
Avoid inhalation of dust, fumes, mist, and/or vapors
Wash thoroughly after handling
Section 7 – HANDLING AND STORAGE

General Handling: Avoid contact with skin, eyes, nostrils, and mouth
Avoid inhalation of dust, fumes, mist, and/or vapors
Wash thoroughly after handling

Storage Conditions: Store at 20° to 25°C

Section 8 – EXPOSURE CONTROLS / PERSONAL PROTECTIVE

Engineering Controls: No special containment is required.
Use local exhaust ventilation when necessary.

Personal Protective Equipment

Eye Protection: Safety glasses or chemical splash goggles recommended

Hand Protection: Latex, nitrile or rubber gloves recommended

Respiratory Protection: With satisfactory ventilation, respiratory protection is usually not required.

Skin Protection: Protective laboratory coat, apron, or disposable garment

Contaminated Equipment: Wash contaminated clothing separately.
Wash equipment with soap and water.
Release rinse water into an approved wastewater system or according to federal, state and local regulations.

Exposure Limits:

<table>
<thead>
<tr>
<th>Compound</th>
<th>TLV (mg/m³)</th>
<th>PEL (mg/m³)</th>
<th>OEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adenosine</td>
<td>Not Established</td>
<td>Not Established</td>
<td>Not Established</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>Not Established</td>
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<td>Water for Injection</td>
<td>Not Established</td>
<td>Not Established</td>
<td>Not Established</td>
</tr>
</tbody>
</table>

Section 9 – PHYSICAL/CHEMICAL CHARACTERISTICS

Physical Form/Appearance: Clear, colorless solution free from foreign matter
Boiling Point/Boiling Range: Not Established
Melting Point/Melting Range: Not Applicable
Freezing Point: Similar to water
Vapor Pressure: Not Established
Relative Vapor Density: Not Established
Percent Volatiles: Not Established
pH: 4.5 to 7.5
Osmolality: ~290mOsm/Kg
Molecular Weight: 267.25
Solvent Solubility: Soluble in water
Latex Free: Yes
MSDS: Adenosine Injection USP, 3 mg/mL

Section 10 – STABILITY AND REACTIVITY

| Stability: | Stable under recommended storage conditions |
| Conditions to Avoid: | None are known to exist |
| Hazardous Polymerization: | Generally compatible with common materials in a medical facility |

Section 11 – TOXICOLOGICAL INFORMATION

Signs & Symptoms of Exposure & Overexposure:
Exposure can cause dilation of the blood vessels and an increase in contraction of some smooth muscles.

Medical Conditions Aggravated by Accidental 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.

Acute Toxicity: active ingredient (RTECS Number AU7175000)

<table>
<thead>
<tr>
<th>Compound</th>
<th>Type</th>
<th>Route</th>
<th>Species</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adenosine</td>
<td>TD&lt;sub&gt;Lo&lt;/sub&gt;</td>
<td>intravenous</td>
<td>human</td>
<td>200 µm/kg</td>
</tr>
<tr>
<td>Adenosine</td>
<td>LD&lt;sub&gt;50&lt;/sub&gt;</td>
<td>intraperitoneal</td>
<td>mouse</td>
<td>500 mg/kg</td>
</tr>
<tr>
<td>Adenosine</td>
<td>LD&lt;sub&gt;50&lt;/sub&gt;</td>
<td>oral</td>
<td>mouse</td>
<td>20 g/kg</td>
</tr>
<tr>
<td>Adenosine</td>
<td>LD&lt;sub&gt;50&lt;/sub&gt;</td>
<td>subcutaneous</td>
<td>mouse</td>
<td>39.6 µg/kg</td>
</tr>
</tbody>
</table>

Other: PREGNANCY CATEGORY C

Animal reproduction studies have not been conducted with adenosine; nor have studies been performed in pregnant women. As adenosine is a naturally occurring material, widely dispersed throughout the body, no fetal effects would be anticipated. However, since it is not known whether adenosine injection can cause fetal harm when administered to pregnant women, adenosine injection should be used during pregnancy only if clearly needed.

Section 12 – TRANSPORTATION INFORMATION

| UN/NA Number: | |
| U.S. DOT Hazard Class: | Not classified as hazardous by DOT regulations |
| Proper Shipping Name: | Adenosine Injection USP, 3mg/mL |
| Shipping Label: | Not classified as hazardous by DOT regulations |
| Transportation Data: | Not a DOT marine pollutant |

Section 13 – DISPOSAL INFORMATION

Disposal Procedure: Dispose of in accordance with county, regional, federal, state, and local regulations. Handle in a manner to prevent spills or releases into the environment. Incineration is recommended.
Section 14 – ENVIRONMENTAL IMPACT INFORMATION

SARA 313 listed: No
CERCLA listed: No
RCRA listed: No
TSCA Inventory: Yes, TSCA Section 8(b) Chemical Inventory

Section 15 – OTHER

Date Prepared: March 2011