# MATERIAL SAFETY DATA SHEET

**Product Name:** Desmopressin Acetate Injection

## 1. CHEMICAL PRODUCT AND COMPANY INFORMATION

| Manufacturer Name And Address | Hospira Inc.  
275 North Field Drive  
Lake Forest, Illinois USA  
60045 |
|-------------------------------|----------------------------------|
| Emergency Telephone           | CHEMTREC: North America: 800-424-9300;  
International 1-703-527-3887; Australia (02) 8014 4880 |
| Hospira, Inc., Non-Emergency  | 224-212-2000 |
| Product Name                  | Desmopressin Acetate Injection |
| Synonyms                      | 1-(3-mercaptopropionic acid)-8-D-arginine vasopressin monoacetate (salt) trihydrate. |

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

**Active Ingredient Name**  Desmopressin Acetate Trihydrate  

**Chemical Formula**  

\[ C_{46}H_{64}N_{14}O_{12}S_2 \cdot C_2H_4O_2 \cdot 3H_2O \]

**Preparation**  

Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% include sodium chloride. Hydrochloric acid may be added to adjust the pH.

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Desmopressin Acetate Trihydrate</td>
<td>0.001</td>
<td>62357-86-2</td>
<td>YW9000000</td>
</tr>
</tbody>
</table>

## 3. HAZARD INFORMATION

**Carcinogen List**

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Desmopressin Acetate Trihydrate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

**Emergency Overview**  Desmopressin Acetate Injection is a solution containing desmopressin acetate, an antidiuretic hormone used to control polydipsia, polyurea and dehydration in patients with diabetes insipidus. It is also used to treat primary nocturnal enuresis and spontaneous or trauma-induced bleeding episodes. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract and a potent drug. Based on clinical use, potential target organs include the cardiovascular system, skin, eyes, and kidneys.

**Occupational Exposure Potential**  Information on the absorption of this product via skin contact is not available. The active ingredient is bioavailable via the nasal route. Avoid liquid aerosol generation and skin contact.

**Signs and Symptoms**  None anticipated from normal handling of this product. In clinical use, adverse effects may include headache, nausea, and mild abdominal cramps; pain and swelling at the site of injection have been reported. Following large intravenous doses, hypotension, with tachycardia and facial flushing, may occur; some patients may experience an increase in blood pressure.
Product Name: Desmopressin Acetate Injection

Infrequently, there may be cerebral or coronary thrombosis. Hypersensitivity reactions have also occurred. The antidiuretic action of desmopressin can produce water intoxication and hyponatraemia, occasionally leading to convulsions. Nasal doses may cause local irritation, congestion, and epistaxis. Nosebleeds have also been reported.

Medical Conditions Aggravated by Exposure: Pre-existing hypersensitivity to desmopressin acetate or to any of the components of Desmopressin Acetate Injection; pre-existing moderate to severe renal impairment.

4. FIRST AID MEASURES

Eye contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability: None anticipated for this aqueous product.

Fire & Explosion Hazard: None anticipated for this aqueous product.

Extinguishing media: As with any fire, use extinguishing media appropriate for primary cause of fire.

Special Fire Fighting Procedures: No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal: Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling: No special handling required under conditions of normal product use.

Storage: No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions: No special precautions required for hazard control.
Product Name: Desmopressin Acetate Injection

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Desmopressin Acetate Trihydrate</td>
<td>Hospira EEL</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>8hr TWA</td>
</tr>
</tbody>
</table>

**Respiratory protection**

Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA’s 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

**Skin protection**

If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

**Eye protection**

Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

**Engineering Controls**

Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance/Physical State</td>
<td>Liquid</td>
</tr>
<tr>
<td>Color</td>
<td>Clear</td>
</tr>
<tr>
<td>Odor</td>
<td>NA</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>NA</td>
</tr>
<tr>
<td>pH:</td>
<td>3.5 to 6.0</td>
</tr>
<tr>
<td>Melting point/Freezing point:</td>
<td>NA</td>
</tr>
<tr>
<td>Initial Boiling Point/Boiling Point Range:</td>
<td>NA</td>
</tr>
<tr>
<td>Evaporation Rate:</td>
<td>NA</td>
</tr>
<tr>
<td>Flammability (solid, gas):</td>
<td>NA</td>
</tr>
<tr>
<td>Upper/Lower Flammability or Explosive Limits:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Pressure:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Density:</td>
<td>NA</td>
</tr>
<tr>
<td>Specific Gravity:</td>
<td>NA</td>
</tr>
<tr>
<td>Solubility:</td>
<td>NA</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water:</td>
<td>NA</td>
</tr>
<tr>
<td>Auto-ignition temperature:</td>
<td>NA</td>
</tr>
<tr>
<td>Decomposition temperature:</td>
<td>NA</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity
Not determined.

Chemical Stability
Stable under standard use and storage conditions.

Hazardous Reactions
Not determined.

Conditions to avoid
Not determined.

Incompatibilities
Not determined.

Hazardous decomposition products
Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and sulfur oxides (SOx).

Hazardous Polymerization
Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity
Not determined for the product formulation. Information for the ingredients is as follows:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Desmopressin Acetate Trihydrate</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>&gt;2</td>
<td>mg/kg</td>
<td>Rat, Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Intravenous</td>
<td>&gt;50</td>
<td>mcg/kg</td>
<td>Rabbit</td>
</tr>
</tbody>
</table>

Aspiration Hazard
None anticipated from normal handling of this product.

Dermal Irritation/Corrosion
None anticipated from normal handling of this product.

Ocular Irritation/Corrosion
None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product.

Reproductive Effects
Fertility studies have not been conducted. However, teratology studies in rats and rabbits at dosages from 0.05 to 10 mcg/kg/day (approximately 0.1 times the maximum systemic human exposure in rats and up to 38 times the maximum systemic human exposure in rabbits based on surface area, mg/m2) revealed no harm to the fetus due to desmopressin acetate.

Mutagenicity
Studies with desmopressin acetate have not been performed to evaluate the mutagenic potential.

Carcinogenicity
Studies with desmopressin acetate have not been performed to evaluate the carcinogenic potential.

Target Organ Effects
Based on clinical use, potential target organs include the cardiovascular system, skin, eyes, and kidneys.
12. ECOLOGICAL INFORMATION

Aquatic Toxicity  
Not determined for product.

Persistence/Biodegradability  
Not determined for product.

Bioaccumulation  
Not determined for product.

Mobility in Soil  
Not determined for product.

13. DISPOSAL CONSIDERATIONS

Waste Disposal  
All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal  
Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS:  
Not regulated

IMDG STATUS:  
Not regulated

ICAO/IATA STATUS:  
Not regulated

Transport Comments:  
None

15. REGULATORY INFORMATION

USA Regulations

<table>
<thead>
<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Desmopressin Acetate Trihydrate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

RCRA Status  
Not Listed

U.S. OSHA Classification  
Target Organ Toxin

Possible Irritant

GHS Classification  
*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

Hazard Class  
Not Applicable

Hazard Category  
Not Applicable

Signal Word  
Not Applicable
Product Name: Desmopressin Acetate Injection

Symbol: Not Applicable


Hazard Statement: Not Applicable

Response: 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. Wash hands after handling.

Get medical attention if you feel unwell.

**EU Classification**
*Medical products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Desmopressin Acetate Trihydrate.*

Classification(s): Not Applicable

Symbol: Not Applicable

Indication of Danger: Not Applicable

Risk Phrases: R00 - Not Applicable

Safety Phrases: S23 - Do not breathe vapour,
S24/25 - Avoid contact with skin and eyes,
S37/39 - Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION:

Notes:
ACGIH TLV American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS Chemical Abstracts Service Number
CERCLA US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT US Department of Transportation Regulations
EEL Employee Exposure Limit
IATA International Air Transport Association
LD50 Dosage producing 50% mortality
NA Not applicable/Not available
NE Not established
NIOSH National Institute for Occupational Safety and Health
OSHA PEL US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65 California Proposition 65
RCRA US EPA, Resource Conservation and Recovery Act
RTECS Registry of Toxic Effects of Chemical Substances
SARA Superfund Amendments and Reauthorization Act
STEL 15-minute Short Term Exposure Limit
TSCA Toxic Substance Control Act
TWA 8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
Date Prepared: 09/13/2011
Obsolete Date: 11/17/2010
Product Name: Desmopressin Acetate Injection

Disclaimer:
The information and recommendations contained herein are based upon tests believed to be reliable. However, Hospira does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage may be required. Hospira assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.