MATERIAL SAFETY DATA SHEET

Product Name: Oxytocin Injection, USP

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  
Oxytocin Injection, USP

Synonyms  
Cys-Tyr-Ile-Gln-Asn-Cys-Pro-Leu-Gly-NH2 cyclic (1®6) disulphide, monoacetate;  
[2-Leucine,7-isoleucine]vasopressin; 3-Isoleucine-8-leucine vasopressin, 
monoacetate.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name  
Oxytocin Monoacetate

Chemical Formula  
C_{43}H_{66}N_{12}O_{12}S_{2} \cdot C_{2}H_{4}O_{2}

Preparation  
Non-hazardous ingredients include Water for Injection. Hazardous ingredients 
present at <1% (w/w) include sodium chloride and sodium acetate. Acetic acid is 
added for pH adjustment). Chlorobutanol (0.5%) is added as a preservative.

<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>Oxytocin Monoacetate</td>
<td>0.002</td>
<td>6233-83-6</td>
<td>RS7534000 (Oxytocin)</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>Oxytocin Monoacetate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview  
Oxytocin Injection, USP contains oxytocin monoacetate, a cyclic nonapeptide having the 
structure of the hormone produced by the posterior lobe of the pituitary. Clinically, oxytocin is 
used to stimulate uterine contractions and milk ejection. In the workplace, this material should 
be considered a potent drug, a potential reproductive hazard, and potentially irritating to the 
skin, eyes, and respiratory tract. Based on clinical use, possible target organs include the 
cardiovascular system, central nervous system and uterus.

Occupational Exposure Potential  
Information on the absorption of this material via inhalation or skin contact is limited. Oxytocin 
is absorbed when administered as nasal spray/drops or via the buccal route. Avoid aerosol 
generation and skin contact.

Signs and Symptoms  
None known from workplace exposures. In men, administration of 16 international units (IU) 
(about 32 mcg) oxytocin by nasal spray produced minor side effects including flushing and a
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transient slight headache; administration of 300 IU (about 600 mcg) of oxytocin by the buccal route for 14 days did not produce any side effects. In men, administration of 600 IU (about 1200 mcg) per day by the buccal route for a minimum of seven weeks did not produce any effects on blood pressure, pulse rate, or clinical hematology parameters. In women, oxytocin acts on smooth muscle in the uterus to induce strong contractions. In clinical use in women, large parenteral doses of oxytocin have produced nausea and vomiting, and severe decreases in maternal blood pressure, accompanied by an increase in heart rate. Hypotension may be followed by weakness, dizziness, and hypertension with a severe headache. Strong uterine contractions and postpartum hemorrhage have also been reported from clinical use. In men, transient headache and flushing have been reported after intravenous bolus or intra-nasal bolus administration.

Medical Conditions
Aggravated by Exposure

Pre-existing central nervous system or cardiovascular ailments; 2nd or 3rd trimester pregnancy.

### 4. FIRST AID MEASURES

<table>
<thead>
<tr>
<th>Condition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye contact</td>
<td>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.</td>
</tr>
<tr>
<td>Skin contact</td>
<td>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.</td>
</tr>
<tr>
<td>Inhalation</td>
<td>Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.</td>
</tr>
</tbody>
</table>

### 5. FIRE FIGHTING MEASURES

<table>
<thead>
<tr>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability</td>
<td>None anticipated for this aqueous product.</td>
</tr>
<tr>
<td>Fire &amp; Explosion Hazard</td>
<td>None anticipated for this aqueous product.</td>
</tr>
<tr>
<td>Extinguishing media</td>
<td>As with any fire, use extinguishing media appropriate for primary cause of fire.</td>
</tr>
<tr>
<td>Special Fire Fighting Procedures</td>
<td>No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.</td>
</tr>
</tbody>
</table>

### 6. ACCIDENTAL RELEASE MEASURES

<table>
<thead>
<tr>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spill Cleanup and Disposal</td>
<td>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.</td>
</tr>
</tbody>
</table>

### 7. HANDLING AND STORAGE

<table>
<thead>
<tr>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handling</td>
<td>No special handling required under conditions of normal use.</td>
</tr>
</tbody>
</table>
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
Women working with oxytocin in open containers, and who are in the second or third trimester of pregnancy, should be informed of the potential of oxytocin to induce uterine contractions and labor, and should consult a health and/or safety professional prior to working with open containers of this product.

<table>
<thead>
<tr>
<th>8. EXPOSURE CONTROLS/PERSONAL PROTECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Exposure Guidelines</strong></td>
</tr>
<tr>
<td><strong>Exposure limits</strong></td>
</tr>
<tr>
<td><strong>Component</strong></td>
</tr>
<tr>
<td>Oxytocin monoacetate</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 (N99 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. Since protection provided by air purifying respirators is limited, a powered air purifying respirator or supplied air should be considered during an uncontrolled release event, if exposure levels are not known, or during events where air-purifying respirators may not provide adequate protection. 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 this material 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 material.

<table>
<thead>
<tr>
<th>9. PHYSICAL/CHEMICAL PROPERTIES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance/Physical State</strong></td>
</tr>
<tr>
<td><strong>Color</strong></td>
</tr>
<tr>
<td><strong>Odor</strong></td>
</tr>
<tr>
<td><strong>Odor Threshold:</strong></td>
</tr>
<tr>
<td><strong>pH:</strong></td>
</tr>
<tr>
<td><strong>Melting point/Freezing point:</strong></td>
</tr>
<tr>
<td><strong>Initial Boiling Point/Boiling Point Range:</strong></td>
</tr>
<tr>
<td><strong>Evaporation Rate:</strong></td>
</tr>
<tr>
<td><strong>Flammability (solid, gas):</strong></td>
</tr>
<tr>
<td><strong>Upper/Lower Flammability or Explosive Limits:</strong></td>
</tr>
<tr>
<td><strong>Vapor Pressure:</strong></td>
</tr>
<tr>
<td><strong>Vapor Density:</strong></td>
</tr>
</tbody>
</table>
Product Name: Oxytocin Injection, USP

Specific Gravity: NA
Solubility: Very soluble in water and dilute solutions of dehydrated alcohol and of acetic acid.
Partition coefficient: n-octanol/water: NA
Auto-ignition temperature: NA
Decomposition temperature: NA

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) and nitrogen oxides (NOx) and sulfur oxides (SOx).
Hazardous Polymerization Not anticipated to occur with this material.

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>Oxytocin</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>&gt;20.52 mg/kg</td>
<td>&gt;514 mg/kg</td>
<td>Rat Mouse</td>
</tr>
<tr>
<td>Oxytocin</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>2.28 mg/kg</td>
<td>5.8 mg/kg</td>
<td>Rat Mouse</td>
</tr>
</tbody>
</table>

Aspiration Hazard None anticipated from normal handling of this product.

Dermal Irritation/Corrosion None anticipated to occur during the normal use of this product.

Ocular Irritation/Corrosion None anticipated to occur during the normal use of this product. However, inadvertent contact of this product with eyes may produce irritation with redness and discomfort.

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

Reproductive Effects Animal fertility and/or developmental toxicity studies have not been conducted with oxytocin. In clinical use, strong uterine contractions and postpartum hemorrhage have been reported in patients.

Mutagenicity Studies to evaluate the mutagenic potential of oxytocin have not been conducted.
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Carcinogenicity  Studies to evaluate carcinogenic potential of oxytocin have not been conducted.

Target Organ Effects  Based on clinical use, possible target organs include the cardiovascular system, central nervous system and uterus.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity  Not determined

Persistence/Biodegradability  Not determined

Bioaccumulation  Not determined

Mobility in Soil  Not determined

13. DISPOSAL CONSIDERATIONS

Waste Disposal  All waste materials must be properly characterized by the waste generator. Further, disposal of all pharmaceuticals 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>Oxytocin Monoacetate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Exempt</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,
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intended for the final user:

Hazard Class Not Applicable
Hazard Category Not Applicable
Signal Word Not Applicable
Symbol Not Applicable

Prevention P260 - Do not breathe dust /fume /gas /mist /vapors /spray.
Hazard Statement Not Applicable
Response: Not Applicable

EU Classification* *Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Oxytocin Monoacetate.

Classification(s): Not Applicable
Symbol: Not Applicable

Indication of Danger: Not Applicable

Risk Phrases: Not Applicable

Safety Phrases: S23 - Do not breathe vapor.
S24 - Avoid contact with skin.
S25 - Avoid contact with 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: 10/31/2011
Product Name: Oxytocin Injection, USP

Obsolete Date: 07/07/2009

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