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	$C_{43}H_{66}N_{12}O_{12}S_2 \bullet C_2H_4O_2$
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.

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Oxytocin Monoacetate	0.002	6233-83-6	RS7534000 (Oxytocin)

3. HAZARD INFORMATION

Carcinogen List

Substance	IARC	NTP	OSHA
Oxytocin Monoacetate	Not Listed	Not Listed	Not Listed

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

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, oxytoxcn 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

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 firefighting 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 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	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.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

	Exposure limits			
Component	**OSHA-PEL**	**ACGIH-TLV**	**Hospira EEL**	**Other Limits**
Oxytocin monoacetate	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: Not Established	Not Established

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.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	Liquid
Color	Clear colorless liquid
Odor	NA
Odor Threshold:	NA
pH:	~3.9
Melting point/Freezing point:	NA
Initial Boiling Point/Boiling Point Range:	NA
Evaporation Rate:	NA
Flammability (solid, gas):	NA
Upper/Lower Flammability or Explosive Limits:	NA
Vapor Pressure:	NA
Vapor Density:	NA

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:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Oxytocin	100	LD50	Oral	>20.52 >514	mg/kg mg/kg	Rat Mouse
Oxytocin	100	LD50	Intravenous	2.28 5.8	mg/kg mg/kg	Rat Mouse

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.

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

Substance	TSCA Status	CERCLA Status	SARA 302 Status	SARA 313 Status	PROP 65 Status
Oxytocin Monoacetate	Not Listed	Not Listed	Not Listed	Not Listed	Exempt

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
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

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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
LD_{50}	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
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