TEVA PARENTERAL MEDICINES

Material Safety Data Sheet

Oxytocin Injection, USP

1. PRODUCT IDENTIFICATION

Product Name Oxytocin Injection, USP
Product Use Medical Treatment; Induction or stimulation of labor
Manufacturer Teva Parenteral Medicines, Inc.
Address 11 Hughes
Irvine, CA 92618-1902

Chemtrec Emergency No. 1-800-424-9300 (United States)
1-202-483-7617 (International Collect)
Business Phone 1-800-729-9991
Website Address http://www.newsicor.com

Common Names Pitocin® Injection

Chemical Formula $C_{43}H_{66}N_{12}O_{12}S_2$
Chemical Family Peptide hormone
How Supplied 10 units/ml in 2 ml and 10 ml vials

Date of Preparation: May 3, 2004

2. COMPOSITION AND INGREDIENTS

CHEMICAL NAME	CAS#		EXPOSURE LIMITS IN AIR				
		Wt%	ACGIH		OSHA		Other
			TLV	STEL	PEL	STEL	
Oxytocin, USP	50-56-6	NLT 0.0025	NE	NE	NE	NE	NE
Chlorobutanol	57-15-8	0.5	NE	NE	NE	NE	NE
Water (for injection)	7732-18-5	Balance	NE	NE	NE	NE	NE

NE - Not Established
NLT-No Less Than

NOTE: All WHMIS required information is included. It is located in appropriate sections based on the ANSI Z400.1 format
CHEMTREC NUMBER: Use only in the event of a chemical emergency involving a spill, leak, fire, exposure or accident involving this drug.

3. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW: Material is clear, colorless solution. Avoid contact with eyes, skin and clothing. Do not taste or swallow. Wash thoroughly after handling.

3. HAZARD IDENTIFICATION cont.

Symptoms of Overexposure by Route of Exposure: This material is intended for intravenous or intramuscular use under the supervision of physicians.

Inhalation: Inhalation of significant amounts of the product is not anticipated to occur because of the small size of individual containers.

Contact with Skin or Eyes: Contact may cause mild irritation. Effects may include stinging, watering, and redness of the eyes and redness and a burning sensation on the skin.

Ingestion: Ingestion is not an anticipated route of occupational exposure. However, the active ingredient, Oxytocin, is moderately toxic if ingested. Symptoms similar to those identified under injection may occur.

Injection: Local redness and pain are the primary symptoms of accidental injection in an occupational setting. Medical personnel are not anticipated to experience over-exposures to the therapeutic doses of this product. However, effects including nausea, vomiting and hypotension may occur. See package insert for other adverse reactions associated with therapeutic doses of this product.

Health Effects or Risks From Exposure **(An explanation in lay terms):**

Acute: The primary health effects anticipated in an occupational setting include irritation of eyes and skin as well as redness and local swelling after accidental injection. In case of over-exposure by injection, effects such as nausea, vomiting and hypotension may occur.

Cancer: No studies identified for Oxytocin.

Chronic: Based on animal data, Oxytocin is not considered a developmental or reproductive toxicant (see Section 11).

Target Organs: No studies identified for Oxytocin.

Other Comments: Rare cases of hypersensitivity reactions, sometimes severe have been reported. Some reactions were accompanied by loss of consciousness, collapse, convulsions, hypotension, shock, and breathing difficulties.

Pre-Existing Medical Conditions: None known.

4. FIRST-AID MEASURES

Skin Exposure: Remove contaminated shoes and clothing and cleanse affected area(s) thoroughly by washing with mild soap and water. If irritation or redness develops and persists, seek medical attention.

Eye Exposure: If irritation or redness develops, move victim away from exposure and into fresh air. Flush eyes with clean water and seek medical attention.

Inhalation: If respiratory symptoms develop, move victim away from source of exposure and into fresh air. If symptoms persist, seek medical attention. If victim is not breathing, clear airway and immediately begin artificial respiration. If breathing difficulties develop, oxygen should be administered by qualified personnel. Seek immediate medical attention.

Ingestion: If swallowed, seek emergency medical attention. If victim is drowsy or unconscious and vomiting, place on the left side with the head down and DO NOT give anything by mouth. If not vomiting and professional advice is not available, DO NOT induce vomiting. If possible, do not leave victim unattended and observe closely for adequacy of breathing.

Victims of chemical exposure must be taken for medical attention. Take a copy of the MSDS to the physician or health professional with victim. Physicians should refer to Section 11 (Toxicological Information) as well as the Physicians Desk Reference for additional treatment information.

5. FIRE-FIGHTING MEASURES

Flash Point: Non-flammable Autoignition Temperature: Not applicable

Flammable Limits (in air by volume, %): Lower: Not applicable Upper: Not applicable

Fire Extinguishing Equipment: Use extinguishing agent suitable for type of surrounding fire.

Water Spray: OK	Carbon Dioxide: OK	Halon: OK
Foam: OK	Dry Chemical: OK	Other: Any "ABC" Class

Unusual Fire and Explosion Hazards: No unusual fire or explosion hazards are expected.

Explosion Sensitivity to Mechanical Impact: Not sensitive.
Explosion Sensitivity to Static Discharge: Not sensitive.

Special Fire Fighting Procedures.: For fires beyond the incipient stage, emergency responders in the immediate hazard area should wear bunker gear. When the potential chemical hazard is unknown, in enclosed or confined spaces, or when explicitly required by DOT, a self-contained breathing apparatus should be worn. In addition, wear other appropriate protective equipment as conditions warrant (see Section 8). Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Move undamaged containers from immediate hazard area if it can be done with minimal risk. Cool equipment exposed to fire with water, if it can be done with minimal risk.

NFPA HAZARD CLASS:	Health:	2 (Moderate)
	Flammability:	0 (Least)
	Reactivity:	0 (Least)

6. ACCIDENTAL RELEASE MEASURES

Spill and Leak Response:

For small releases of this product, wear latex or nitrile gloves and safety glasses. Absorb spilled liquid and rinse area thoroughly with soap and water.

For large or uncontrolled releases, stay away from spill. Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Wear appropriate protective equipment including respiratory protection as conditions warrant (see Section 8). Prevent spilled material from entering sewers, storm drains, other unauthorized treatment drainage systems, and natural waterways. Dike far ahead of spill for later recovery or disposal. Spilled material may be absorbed into an appropriate absorbent material. Notify appropriate federal, state, and local agencies. Immediate cleanup of any spill is recommended.

7. HANDLING and STORAGE

Work and Hygiene Practices: As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling.

Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Precautions should be taken during the following activities:

- Withdrawal of needles from drug vials.
- Drug transfers using syringes and needles or filter straws.
- Expulsion of air from drug-filled syringes.

Storage and Handling Practices: Employees must be trained to properly use the product. Ensure vials are properly labeled. Keep away from sources of ignition and any incompatible materials or conditions (see Section 10).

Protective Practices During Maintenance of Contaminated Equipment: When cleaning non-disposable equipment, wear latex or nitrile gloves (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. All needles, syringes, vials and other disposable items contaminated with this product should be disposed of properly.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

Ventilation and Engineering Controls: Use with adequate ventilation. Follow standard medical product handling procedures.

Respiratory Protection: Not normally required for routine, medical administration of this product. A NIOSH certified air-purifying respirator with a type 95 filter may be used under conditions where airborne concentrations are expected to be excessive. Protection provided by air purifying respirators is limited (see manufacturer's respirator selection guide). Use a positive pressure air supplied respirator if there is potential for uncontrolled release, exposure levels are not known, or any other circumstances 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 warrant a respirator's use.

Eye Protection: Approved eye protection to safeguard against potential eye contact, irritation or injury is recommended. Depending on conditions of use, a face shield may be necessary.

Hand Protection: Use latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before and after using gloves.

Body Protection: No special body protection required for routine, medical administration of this product. Wear lab coat, gown, or smock, as appropriate for procedure.

Product Preparation Instructions for Medical Personnel: Follow standard procedure for handling pharmaceutical materials and recommendations presented on the Package Insert.

9. PHYSICAL and CHEMICAL PROPERTIES

Relative Vapor Density (air = 1):	ND	Evaporation Rate (n-BuAc=1):	ND
Specific Gravity (water = 1):	1.002	Melting/Freezing Point:	0°C
Solubility in Water:	Soluble	Boiling Point:	100°C
Vapor Pressure, mm Hg @ 25°C.	ND	pH:	3.0 to 5.0
Odor Threshold: ND			
Appearance and Color: Clear, colorless solution			

ND = No Data

10. STABILITY and REACTIVITY

Stability: Stable under normal conditions of storage and handling.

Materials With Which Substance is Incompatible: This product is generally compatible with other common materials in a medical facility.

Hazardous Polymerization: Will not occur.

Hazardous Combustion Products: Oxides of carbon.

11. TOXICOLOGICAL INFORMATION

Toxicity Data: The following information is for Oxytocin, the active ingredient

Oral LD50(rat) >20 mg/kg	IV LD50(rat) = 2275 ug/kg	SubQ LD50(rat) >20 mg/kg
Oral LD50(mouse) >514 mg/kg	IV LD50(mouse) = 5800 ug/kg	SubQ LD50(mouse) >514 mg/kg
		SubQ LD50 (rat) = 1mg/kg

Chronic Toxicity: No studies identified for Oxytocin.

Carcinogenicity: No studies identified for Oxytocin. It is not listed as carcinogenic by NTP, IARC or OSHA.

Irritancy of Product: This product is not expected to be irritating to contaminated skin, eyes and other tissues.

Sensitization to the Product: Not considered a sensitizer, though incidence of specific hypersensitivity reactions has been reported in hypersensitive individuals.

Reproductive Toxicity Information: Listed below is information concerning the effects of Oxytocin on human and animal reproductive systems.

Mutagenicity: No studies identified for Oxytocin.

Embryotoxicity/Teratogenicity: Negative for teratogenic effects in limited studies conducted with rats. Administration of Oxytocin to pregnant female rats late in pregnancy at doses over 100 times those used therapeutically in humans resulted in reduced birth weights in offspring (this effect has not been observed in humans at therapeutic doses). Behavioral alterations were observed in the adult offspring of rats treated with doses ranging from 580-1160 times the recommended therapeutic dose in humans.

Reproductive Toxicity: No fertility impairment studies identified. In rats, treatment with Oxytocin has been associated with an increase in ovarian and uterine weight, and with increases of plasma estradiol. In animals, Oxytocin appears to regulate ovarian cyclicity, most likely through stimulation of uterine prostaglandins and associated luteolysis; it is presently not known if it exerts a similar function in humans.

ACGIH Biological Exposure Indices: Currently there are no Biological Exposure Indices (BEIs) associated with the components of this product.

12. ECOLOGICAL INFORMATION

All work practices must be aimed at eliminating environmental contamination.

Environmental Stability: This product will be relatively stable under ambient environmental conditions.

Effect of Materials on Plants or Animals: No specific information is available on the effect of Oxytocin on plants or animals in the environment. Due to the small product size and dilute concentration of the components, this product is not anticipated to cause adverse effects.

Effect of Chemicals on Aquatic Life: No specific information is available on the effect of Oxytocin on plants or animals in the aquatic environment. Due to the small product size and dilute concentration of the components, this product is not anticipated to cause adverse effects.

13. DISPOSAL CONSIDERATIONS

Preparing Wastes for Disposal: This material, if discarded as produced, is not a RCRA "listed" or "characteristic" hazardous waste. Use resulting in chemical or physical change or contamination may subject it to regulation as a hazardous waste. Along with properly characterizing all waste materials consult state and local regulations regarding the proper disposal of this material.

U.S. EPA Waste Number: None

14. TRANSPORTATION INFORMATION

This Materials is not Hazardous as Defined by 49 CFR 172.101 by the U. S. Department of Transportation

Proper Shipping Name: Not applicable
Hazard Class Number and Description: Not applicable
UN Identification Number: Not applicable
Packing Group: Not applicable
DOT Label(s) Required: Not applicable
North American Emergency Response Guidebook Number (1996): Not applicable.
MARINE POLLUTANT: No component of this product is listed as a Marine Pollutant (49 CFR 172.101, Appendix B)

Transport Canada Transportation of Dangerous Goods Regulations: Not applicable

15. REGULATORY INFORMATION

U.S. REGULATIONS:

U.S. SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304 and 313 of Title II of the Superfund Amendments and Reauthorization Act.

U.S. SARA Threshold Planning Quantity: Not applicable

U.S. TSCA Inventory Status: Oxytocin is a "drug" as defined by the Federal Food, Drug and Cosmetic Act and is therefore not a chemical substance under TSCA.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): This product does not contain a chemical which is known to the State of California to cause cancer, developmental or other reproductive effects.

Other U.S. Federal Regulations: Based on this product's use, the requirements of the OSHA Bloodborne pathogen Standard (29 CFR 1910.1030) are applicable.

CANADIAN REGULATIONS:

Canadian DSL/NDSL Status: Oxytocin is regulated by the Food and Drug Administration of Health Canada and is therefore exempt from the requirements of CEPA.

ANSI Labeling (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): Oxytocin should be administered under the supervision of a qualified physician. Avoid over-exposure. Avoid contact with eyes, skin and clothing. Do not eat, drink or smoke when handling Oxytocin. Do not taste or swallow. Wash thoroughly after handling. Clean up spills promptly.

16. OTHER INFORMATION

Issue Date: 05/03/04
Previous Issue Date: None

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