



MATERIAL SAFETY DATA SHEET

While we believe the information provided herein is accurate and current, JHP Pharmaceuticals makes no representation or warranties, either explained or implied, and assume no responsibility for any damage or injuries of any kind, which may result from use or reliance upon this information

SECTION 1	MATERIAL IDENTIFICATION
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PRODUCT NAME: Pitocin® (oxytocin injection, USP), synthetic **DATE OF ISSUE:** 11/13/2012

FORMULA: C₄₃H₆₆N₁₂O₁₂S₂ **SUPERCEDES:** 9/10/2012 **REVISION:** 8.0

SYNONYMS: Oxytocin Injection, USP, Synthetic

NDC #: Pitocin 10 units/mL, 1 mL, SDV (pack of 25) 42023-116-25
 Pitocin 10 units/mL, 10 mL, MDV 42023-116-01
 Pitocin 10 units/mL, 10 mL, MDV (pack of 25) 42023-116-25
 Pitocin 10 units/mL, 50 mL, Pharmacy Bulk Pack (pack of 6) 42023-130-06

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SECTION 2	INGREDIENT(S)
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CAS #	INGREDIENT NAME	OSHA PEL	ACGIH TLV	OTHER	LISTED AS CARCINOGEN
50-56-6	Oxytocin	NA	NA	NA	NO

SECTION 3	HAZARD IDENTIFICATION
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EMERGENCY OVERVIEW

MAJOR HEALTH HAZARDS: No significant target effects reported.

POTENTIAL HEALTH EFFECTS:

INHALATION

SHORT TERM EXPOSURE: Possible irritation of mucous membranes; convulsions

LONG TERM EXPOSURE: Same as reported for short term exposures

SKIN CONTACT

SHORT TERM: ND

LONG TERM: ND

INGESTION

SHORT TERM: ND

LONG TERM: ND

SECTION 4**FIRST AID INFORMATION**

EYES: Flush eyes with plenty of water for at least 15 minutes. Get immediate medical attention.

SKIN: Wash exposed skin with soap and water for at least 15 minutes while removing contaminated clothes and shoes. Get medical attention if needed. Thoroughly clean and dry contaminated clothing and shoes before reuse.

INHALATION: If adverse effects occur, remove to uncontaminated area. Give artificial respiration if not breathing. If breathing is difficult, oxygen should be administered by qualified personnel. Get immediate medical attention.

INGESTION: If large amount is swallowed, get medical attention.

SECTION 5**FIRE AND EXPLOSION DATA**

FLASH POINT AND METHOD: >200°F (>93.3°C)

EXTINGUISHING MEDIUM: Carbon Dioxide, Regular Dry Chemical, Regular Foam, Water

SPECIAL FIRE PROCEDURES: Move container from fire area if it can be done without risk. Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low areas. Use approved self contained breathing apparatus.

HAZARDOUS DECOMPOSITION OR COMBUSTION PRODUCTS: Oxides of Carbon

FIRE HAZARDS: Slight

EXPLOSION HAZARDS: Slight

SECTION 6**ACCIDENTAL RELEASE MEASURES**

ACTION TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED: Contain spill without personal risk. Wipe or mop up spill and place in appropriate container for disposal.

SECTION 7**HANDLING AND STORAGE**

STORAGE: Store and handle in accordance with all current regulations and standards. See original container for storage recommendations. Keep separated from incompatible substances.

SECTION 8**SPECIAL PROTECTION INFORMATION**

VENTILATION: No special requirements under normal conditions.

EYE PROTECTION: Wear splash resistant safety goggles. Provide an emergency eye wash fountain and quick drench shower in the immediate work area.

CLOTHING: Wear appropriate chemical resistant clothing.

GLOVES: Wear appropriate chemical resistant gloves.

RESPIRATOR: No respirator is required under normal conditions of use. Ensure compliance with applicable exposure limits.

SECTION 9**PHYSICAL AND CHEMICAL DATA**

APPEARANCE: Clear

CHARACTERISTIC ODOR: N/A

SPECIFIC GRAVITY: 1.002

SOLUBILITY: N/A

pH: 2.5 – 4.5 @ 25°C

WATER: N/A

OTHER: NA

SECTION 10**STABILITY AND REACTIVITY**

REACTIVITY: Stable and normal temperatures and pressures.

CONDITIONS TO AVOID: Avoid heat, flames, sparks and other sources of ignition. Avoid contact with incompatible materials.

SECTION 11**TOXICOLOGY****TOXICITY INFORMATION:**

The following information pertains to the ingredient(s) individually and not to the product as marked. Included will be any data which emphasize the potential effects that may occur with the occupational handling (by inhalation or by dermal or by ocular contact) of this product.

Oxytocin: >20520 ug/kg oral-rat LD50. May be excreted in breast milk. Interactions with drugs may occur.

(Refer to package insert for further information)

CHRONIC TOXICITY: No studies identified for Oxytocin.

CARCINOGENICITY: No studies identified for Oxytocin. It is not listed as a carcinogen by NTP, IARC or OSHA.

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 no known if it exerts a similar function in humans.

MUTAGENICITY: No studies identified for Oxytocin.

TERATOGENICITY: Negative for teratogenic effects in limited studies conducted with rats.

SECTION 12**ECOLOGICAL INFORMATION**

NA

SECTION 13**DISPOSAL**

Dispose of in accordance with all applicable regulations.

SECTION 14	TRANSPORTATION INFORMATION
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PROPER SHIPPING NAME: NA	ID/UN NUMBER: NA	CONTAINER SPECIFICATION: NA
HAZARD CLASS: NA	LABEL: NA	PACKAGING GROUP: NA
SHIPPING LIMITATIONS: NA	MARKING: NA	OTHER COMMENTS: NA

SECTION XI	REGULATORY INFORMATION
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CERCLA SECTIONS 102A/103: Not regulated
SARA TITLE III 302, 304, 311/312, 313: Not regulated
CALIFORNIA PROPOSITION 65: Not regulated
TSCA: Exempt
TSCA 12(b): Exempt

N/A – NOT APPLICABLE

ND – NO DATA FOUND

The information provided in this Material Safety Data Sheet has been compiled from our experience and the data presented in various technical publications. It is the user’s responsibility to determine the suitability of this information for the adoption of safety precautions as may be necessary. We reserve the right to revise the Material Safety Data Sheets from time to time as new information becomes available. The user has the responsibility to contact the company to make sure the sheet is the latest one issued.