



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

PRODUCT NAME: Pitocin[®] (*oxytocin injection, USP*), synthetic **DATE OF ISSUE:** 3/7/08
FORMULA: Solution **SUPERCEDES:** 1/25/08 **REVISION:** 2.0
SYNONYMS: Oxytocin Injection, USP, Synthetic
NDC #: 42023-116-25 Pitocin[®] 10 units/mL, 1mL, SDV
42023-116-01 Pitocin[®] 10 units/mL, 10mL MDV
MANUFACTURING DIVISION: **ADDRESS:** **PHONE :**
JHP Pharmaceuticals, LLC. 870 Parkdale Road Emergency: 248-656-5400
Rochester, MI 48307 Medical Affairs: 866-923-2474

SECTION 2 INGREDIENT(S)

CAS #: 50-56-6 **INGREDIENT NAME:** Oxytocin

EXPOSURE LIMITS/ GUIDELINES
OSHA PEL: N/A
ACGIH TLV: N/A
OTHER: N/A
LISTED AS CARCINOGEN: No

SECTION 3 HAZARD IDENTIFICATION

EMERGENCY OVERVIEW

COLOR: Colorless
PHYSICAL FORM: Solution
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**

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

EYES: Flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops or persists

SKIN: Wash skin with soap and water for at least 15 minutes while removing contaminated clothing 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. Get immediate 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**

STORE AS STATED IN PRODUCT LABELING.

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

SOLUBILITY: N/A

WATER: N/A

SPECIFIC GRAVITY: 1.002

pH: 2.5 – 4.5 @ 25°C

OTHER:

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)

SECTION 12 ECOLOGICAL INFORMATION

NA

SECTION 13 DISPOSAL

Dispose of in accordance with all applicable regulations.

SECTION 14 TRANSPORTATION INFORMATION

Not regulated.

SECTION XI REGULATORY INFORMATION

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.