SAFETY DATA SHEET

1. Identification

Product identifier: Oxytocin

Other means of identification:
- Catalog number: 1491300
- CAS number: 50-56-6
- Synonyms: Posterior pituitary extract
- Chemical name: Oxytocin

Recommended use: Specified quality tests and assay use only.

Recommended restrictions: Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer:
- Company name: U. S. Pharmacopeia
- Address: 12601 Twinbrook Parkway
  Rockville
  MD
  20852-1790
  United States
- Telephone: RS Technical Services 301-816-8129
- Website: www.usp.org
- E-mail: RSTECH@usp.org
- Emergency phone number:
  CHEMTREC within US & Canada 1-800-424-9300
  CHEMTREC outside US & Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards: Not classified.

Health hazards:
- Acute toxicity, oral Category 2
- Reproductive toxicity Category 2

Environmental hazards: Not classified.

OSHA defined hazards: Not classified.

Label elements:

Signal word: Danger

Hazard statement: Fatal if swallowed. Suspected of damaging fertility or the unborn child.

Precautionary statement:
- Prevention: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.
- Response: If swallowed: Immediately call a poison center/doctor. Rinse mouth. If exposed or concerned: Get medical advice/attention.
- Storage: Store locked up.
- Disposal: Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC): None known.

Supplemental information: Pharmacologically active material.
3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance</th>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxytocin</td>
<td>Posterior pituitary extract</td>
<td>50-56-6</td>
<td>100</td>
<td></td>
</tr>
</tbody>
</table>

4. First-aid measures

**Inhalation**
Move to fresh air. Get medical attention if symptoms occur.

**Skin contact**
Rinse skin with water/shower. Get medical attention if irritation develops and persists.

**Eye contact**
Rinse with water. Get medical attention if irritation develops and persists.

**Ingestion**
Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

**Most important symptoms/effects, acute and delayed**
Uterine cramps. Pharmacologically active material. Occupational exposure may cause physiological effects.

**Indication of immediate medical attention and special treatment needed**
Treat symptomatically. Overdose treatment may include the following: Beta adrenergic agonists inhibit oxytocin-induced labor. Tocolytic agents such as ritodrine may be effective for relaxing the uterus. For water intoxication, restrict fluid intake, promote diuresis, administer IV normal saline or hypertonic saline solutions if clinically indicated, and correct electrolyte imbalances. For seizures, administer benzodiazepine; if seizures recur, consider phenobarbital. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia.

**General information**
Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

**Suitable extinguishing media**
Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.

**Unsuitable extinguishing media**
None known.

**Specific hazards arising from the chemical**
No unusual fire or explosion hazards noted.

**Special protective equipment and precautions for firefighters**
Wear suitable protective equipment.

**Fire fighting equipment/instructions**
Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

**Specific methods**
Use standard firefighting procedures and consider the hazards of other involved materials.

**General fire hazards**
No unusual fire or explosion hazards noted.

6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures**
Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

**Methods and materials for containment and cleaning up**
For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

**Environmental precautions**
Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

**Precautions for safe handling**
As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

**Conditions for safe storage, including any incompatibilities**
Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.
8. Exposure controls/personal protection

Occupational exposure limits  No exposure limits noted for ingredient(s).

Biological limit values  No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls  For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

   Eye/face protection  Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

   Skin protection
   Hand protection  Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

   Other  Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

   Respiratory protection  Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

   Thermal hazards  Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations  Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

   Appearance  Appearance descriptions are general information and not specific to any USP lot.

   Physical state  Solid.

   Form  Powder.

   Color  White. Off-white.

   Odor  Odorless. Slight.

   Odor threshold  Not available.

   pH  Not available.

   Melting point/freezing point  Not available.

   Initial boiling point and boiling range  Not available.

   Flash point  Not available.

   Evaporation rate  Not available.

   Flammability (solid, gas)  Not available.

   Upper/lower flammability or explosive limits

      Flammability limit - lower (%)  Not available.

      Flammability limit - upper (%)  Not available.

      Explosive limit - lower (%)  Not available.

      Explosive limit - upper (%)  Not available.

   Vapor pressure  < 0.0000001 kPa at 25 °C

   Vapor density  Not available.

   Relative density  Not available.

   Solubility(ies)

      Solubility (water)  Soluble.

      Solubility (other)  2-Butanol: Soluble.

      1-Butanol: Soluble.

      Dilute solutions of ethanol: Very soluble.
Dilute solutions of acetic acid: Very soluble.

Auto-ignition temperature: Not available.
Decomposition temperature: Not available.
Viscosity: Not available.

Other information:
- Chemical family: Cyclic nonapeptide.
- Molecular formula: C43-H66-N12-O12-S2
- Molecular weight: 1007.23 g/mol
- pH in aqueous solution: 3 - 6 (2% solution)

10. Stability and reactivity

Reactivity: The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability: Material is stable under normal conditions.
Possibility of hazardous reactions: No dangerous reaction known under conditions of normal use.
Conditions to avoid: Contact with incompatible materials.
Incompatible materials: Strong oxidizing agents.
Hazardous decomposition products: Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. SOx. NOx.

11. Toxicological information

Information on likely routes of exposure:
- Inhalation: Based on information from therapeutic use, this material may cause: Reproductive effects.
- Skin contact: Knowledge about health hazard is incomplete.
- Eye contact: Knowledge about health hazard is incomplete.
- Ingestion: Fatal if swallowed.

Information on toxicological effects:

<table>
<thead>
<tr>
<th>Acute toxicity</th>
<th>Fatal if swallowed.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxytocin (CAS 50-56-6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Mouse</td>
<td>&gt; 514 mg/kg</td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>&gt; 20520 µg/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; 20.52 mg/kg</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation: Knowledge about health hazard is incomplete.
Serious eye damage/eye irritation: Knowledge about health hazard is incomplete.

Respiratory or skin sensitization:
- Respiratory sensitization: Knowledge about health hazard is incomplete.
- Skin sensitization: Knowledge about health hazard is incomplete.
- Germ cell mutagenicity: Knowledge about mutagenicity is incomplete.
- Carcinogenicity: Knowledge about carcinogenicity is incomplete.

IARC Monographs. Overall Evaluation of Carcinogenicity: Not listed.
US. National Toxicology Program (NTP) Report on Carcinogens: Not listed.
Suspected of damaging fertility or the unborn child.
Use of oxytocin to induce or augment labor has sometimes resulted in fetal death or problems, including slow heartbeat, retinal hemorrhage, and jaundice in the newborn. Oxytocin stimulates uterine contractions and may induce miscarriage or labor.

Specific target organ toxicity - single exposure
Knowledge about health hazard is incomplete.

Specific target organ toxicity - repeated exposure
Knowledge about health hazard is incomplete.

Aspiration hazard
Based on available data, the classification criteria are not met.

Further information
Pharmacologically active material. Occupational exposure may cause physiological effects.

12. Ecological information
Ecotoxicity
The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability
No data is available on the degradability of this product.

Bioaccumulative potential
No data available.

Mobility in soil
No data available.

Other adverse effects
No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations
Disposal instructions
Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations
Dispose in accordance with all applicable regulations.

Hazardous waste code
The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products
Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging
Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information
DOT
UN number
UN2811
UN proper shipping name
Toxic solid, organic, n.o.s. (Oxytocin)
Transport hazard class(es)
Class 6.1
Subsidiary risk -
Packing group II

IATA
UN number
UN2811
UN proper shipping name
Toxic solid, organic, n.o.s. (Oxytocin)
Transport hazard class(es)
Class 6.1
Subsidiary risk -
Packing group II
Other information
Passenger and cargo aircraft
Allowed with restrictions.
Cargo aircraft only
Allowed with restrictions.
Not applicable.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
General information

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations

CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

This product is a “Hazardous Chemical” as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)
Not listed.

SARA 304 Emergency release notification
Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)
Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance
Not listed.

SARA 311/312 Hazardous chemical
Yes

Classified hazard categories
Acute toxicity (any route of exposure)
Reproductive toxicity

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)
Not regulated.

Safe Drinking Water Act (SDWA)
Not regulated.

US state regulations

California Proposition 65
California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
</tbody>
</table>
Country(s) or region | Inventory name | On inventory (yes/no)*
--- | --- | ---
Japan | Inventory of Existing and New Chemical Substances (ENCS) | Yes
Korea | Existing Chemicals List (ECL) | No
New Zealand | New Zealand Inventory | Yes
Philippines | Philippine Inventory of Chemicals and Chemical Substances (PICCS) | No
Taiwan | Taiwan Chemical Substance Inventory (TCSI) | Yes
United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | No

*A “Yes” indicates that all components of this product comply with the inventory requirements administered by the governing country(s).
A “No” indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date: 12-04-2006
Revision date: 07-26-2019
Version #: 04

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