Safety Data Sheet

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Section 1: Identification

Product Name Oxytocin USP Powder
Commercial Name Not available.
Product Use Therapeutical use — uterotonic (stimulates milk let -down, uterine contraction)
Restrictions On Use Not available.

Product Code 55-2843

Company
PCCA
9901 South Wilcrest
Houston, TX 77099
Phone: 1-800-331-2498
Fax: 1-800-874-5760

In case of emergency contact:
CHEMTREC (24hr) 1-800-424-9300

Section 2: Hazard(s) Identification

OSHA Haz Com: CFR 1910.1200 Acute toxcity, oral Category 2 Reproductive toxicity Category 2

Signal Word WARNING

Hazard Statement(s) Causes skin irritation. Causes serious eye irritation. May cause respiratory tract irritation. Suspected of damaging fertility or the unborn child

Pictogram(s) or Symbol(s)



Precautionary Statement(s):

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

Section 3: Composition/Information on Ingredients

Substance/Mixture Substance
Components Oxytocin USP Powder
% By Weight 100
CAS# 50-56-6
Molecular Weight 1007.19 g/mol
Chemical Formula C43H66N12O12S2
Synonym(s) Posterior pituitary extract

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Oxytocin USP Powder	50-56-6	100	N/A	N/A

Section 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
Symptoms/Effects	
Acute	Uterine cramps. Pharmacologically active material. Occupational exposure may cause physiological effects
Delayed	Uterine cramps. Pharmacologically active material. Occupational exposure may cause physiological effects

Immediate Medical Attention

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.

Section 5: Fire-Fighting Measures

Suitable Extinguishing Media

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

Unsuitable Extinguishing Media

Not available.

Products of Combustion

No unusual fire or explosion hazards noted

Firefighters Special Equipment and Precautions

Wear suitable protective equipment. 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. Use standard firefighting procedures and consider the hazards of other involved materials

Section 6: Accidental Release Measures

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.

Section 7: Handling and Storage

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. Storage: Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

Section 8: Exposure Controls/Personal Protection

Exposure Limits	Not available.
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.

Personal Protection	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.

Section 9: Physical and Chemical Properties

Appearance	Solid, hygroscopic powder. White or offwhite.
Odor	Odourless. Slight
Odor Threshold	Not available.

Melting Point	Not available.	**pH**	in aqueous solution 3 - 6 (2% soluti
Freezing Point	Not available.	**Vapor Pressure**	< 0.0000001 kPa at 25 °C
Boiling Point/Range	Not available.	**Vapor Density**	Not available.
Decomposition temperature	Not available.	**Viscosity**	Not available.
Partition Coefficient: n-octanol/water	Not available	**Evaporation Rate**	Not available.
Flash Point	Not available.	**Autoignition temperature**	Not available.
Flammability	Not available.	**Flammability or Explosive Limits:**	
		Lower	Not available.
		Upper	Not available.

Solubility(ies)	Soluble in water.
Other	2-Butanol: Soluble. 1-Butanol: Soluble. Dilute solutions of ethanol: Very soluble Dilute solutions of acetic acid: Very soluble Chemical family Cyclic nonapeptide. Molecular formula C43-H66-N12-O12-S2 Molecular weight 1007.23 g/mol

Section 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
Hazardous Polymerization	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

Section 11: Toxicological Information

RTECS RS7534000

Acute Toxicity
Oral: LD50 Mouse > 514 mg/kg, Rat > 20520 µg/kg, > 20.52 mg/kg

Skin Corrosion/Irritation
Not available.

Serious Eye Damage/Irritation
Not available.

Respiratory or Skin Sensitization
Not available.

Germ Cell Mutagenicity
Not available.

Carcinogenicity
Not available.

Reproductive Toxicity
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.

Routes of Entry
Ingestion.

Symptoms Related to Exposure
Headache. Irregular heartbeat. Nausea. Vomiting. Uterine contractions. Vaginal bleeding.

Potential Health Effects
Pharmacologically active material. Occupational exposure may cause physiological effects

Target Organ(s) Not available.

Section 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

Persistance and Degradability
Not available.

Bioaccumulative Potential
Not available.

Mobility in Soil
Not available

Other Adverse Effects
Not available.

Section 13: Disposal Considerations

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

Disposal of Container
Since emptied containers may retain product residue, follow label warnings even after container is emptied.

Other Considerations
Not available.

Section 14: Transport Information

DOT Classification
Not a DOT controlled material (United States). This material is not classified dangerous good according to international transportatDOT UN number: UN2811 UN proper shipping name: Toxic solid, organic, n.o.s. (Oxytocin) Transport hazard class(es) Class 6.1 Subsidiary risk - Packing groupion regulations III

Section 15: Regulatory Information

Regulations

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. SARA 302 Extremely hazardous substance Superfund Amendments and Reauthorization Act of 1986 (SARA) Not listed. YesSARA 311/312 Hazardous chemical Acute toxicity (any route of exposure) Reproductive toxicity Classified hazard categories 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. Not regulated.Safe Drinking Water Act (SDWA) 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 Country(s) or region Inventory name On inventory (yes/no)* YesAustralia Australian Inventory of Chemical Substances (AICS) YesCanada Domestic Substances List (DSL) NoCanada Non-Domestic Substances List (NDSL) NoChina Inventory of Existing Chemical Substances in China (IECSC) YesEurope European Inventory of Existing Commercial Chemical Substances (EINECS) NoEurope European List of Notified Chemical Substances (ELINCS) 6 / 7 Material name: Oxytocin 1491300 Version #: 04 Revision date: 07-26-2019 Issue date: 12-04-2006 USP SDS US

Other

Not available.

Section 16: Other Information

Explanation of the changes Material Safety Data Sheet has been revised pursuant to Commission Regulation (EC) 453/2010 and supplemented with information Literature references and sources for data Information from the Internet resources and JSC "Grindeks" reviewed data.