Safety Data Sheet

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

Section 1: Identification

Product Name Oxycodone Hydrochloride USP
Commercial Name Not available.
Product Use Active pharmaceutical ingredient
Restrictions On Use Not available.

Product Code 20-1008

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 toxicity, oral Category 3 Acute toxicity, inhalation Category 3 Sensitization, respiratory Category 1 Sensitization, skin Category 1 Specific target organ toxicity, single exposure Category 3 narcotic effects

Signal Word DANGER

Hazard Statement(s) May form combustible dust concentrations in air. harmful if swallowed. Hathing difficulties if inhaled. May cause an allergic skin reaction. May cause drowsiness or dizziness.

Pictogram(s) or Symbol(s)

Precautionary Statement(s):

Prevention Avoid breathing dust. Use only outdoors or in a well-ventilated area. In case of inadequate ventilation wear respiratory protection. Do not eat, drink or smoke when using this product. Wear protective gloves. Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace.

Response If swallowed: Immediately call a poison center/doctor. Rinse mouth. If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor. If experiencing respiratory symptoms: Call a poison center/doctor. Wash contaminated clothing before reuse. Call a poison center/doctor if you feel unwell.

Storage Store in a well-ventilated place. Keep container tightly closed. 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 Oxycodone Hydrochloride
% By Weight 100
CAS# 124-90-3
Molecular Weight 351.83 g/mole
Chemical Formula C18H21NO4.HCl
Synonym(s) Dihydrohydroxycodeinone hydrochloride Oxycodone Hydrochloride Analytical Research Standard-(FOR R&D USE ONLY) Morphinan-6-one, 4,5-epoxy-14-hydroxy-3-methoxy-17-methyl- , hydrochloride, (5.alpha.)
-

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Oxycodone HCl	124-90-3	100	Not available.	Not available.

Section 4: First-Aid Measures

Inhalation If dust from the material is inhaled, remove the affected person immediately to fresh air. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

Skin Contact ctSkin contact IF ON SKIN: Gently wash with plenty of soap and water. For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing and shoes. If skin irritation or rash occurs: Get medical advice/attention. Wash clothing separately before reuse.

Eye Contact Immediately flush eyes with plenty of water for at least 15 minutes. If a contact lens is present, DO NOT delay irrigation or attempt to remove the lens. Get medical attention immediately.

Ingestion IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Never give anything by mouth to a victim who is unconscious or is having convulsions. Do not induce vomiting without advice from poison control center. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Rinse mouth. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.

Symptoms/Effects

Acute Exposure may cause sedation, pinpoint pupils, mood alterations, nausea, vomiting, constipation, respiratory depression; also tolerance, dependence and withdrawal. Large doses can lead to respiratory or cardiac arrest and death. May lead to habituation or addiction.

Delayed Exposure may cause sedation, pinpoint pupils, mood alterations, nausea, vomiting, constipation, respiratory depression; also tolerance, dependence and withdrawal. Large doses can lead to respiratory or cardiac arrest and death. May lead to habituation or addiction.

Immediate Medical Attention

In case of shortness of breath, give oxygen. Keep victim warm. Symptoms may be delayed.

Section 5: Fire-Fighting Measures

Suitable Extinguishing Media

Water. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable Extinguishing Media

Not available.

Products of Combustion

The product is not flammable. Dust may form explosive mixture with air. In case of fire and/or explosion do not breathe fumes. In the event of fire, cool tanks with water spray. Move containers from fire area if you can do so without risk. As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

Firefighters Special Equipment and Precautions

During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion. Dust may form explosive mixture with air. Wear full protective clothing, including helmet, self-contained positive pressure or pressure demand breathing apparatus, protective clothing and face mask. In the event of fire and/or explosion do not breathe fumes. Move container from fire area if it can be done without risk. Cool containers exposed to flames with water until well after the fire is out. Follow handling guidance appropriate for OEB-2 potent compounds, (see section 7).

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Ensure adequate ventilation. Keep unnecessary personnel away. Local authorities should be advised if significant spillages cannot be contained. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear appropriate protective equipment and clothing during clean-up. Avoid contact with spilled material. Avoid inhalation of dust from the spilled material. Ventilate closed spaces before entering them. Methods and materials for containment and cleaning up: Stop the flow of material, if this is without risk. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Collect spillage. If sweeping of a contaminated area is necessary use a dust suppressant agent which does not react with the product. Prevent entry into waterways, sewer, basements or confined areas. Do not flush to sewer. Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dust formation. Collect dust using a vacuum cleaner equipped with HEPA filter. Use only non-sparking tools. Clean surface thoroughly to remove residual contamination. All clean-up operations should be witnessed by more than one individual. The amount of material collected should be assessed and documented. For waste disposal, see section 13 of the SDS. Environmental precautions: Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

Section 7: Handling and Storage

Precautions for safe handling: Do not use in areas without adequate ventilation. DO NOT handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Avoid breathing dust. Keep formation of airborne dusts to a minimum. Provide appropriate exhaust ventilation at places where dust is formed. Use personal protective equipment as required. Avoid contact with skin and eyes. Do not ingest. Wash thoroughly after handling. When using, do not eat, drink or smoke. Avoid release to the environment. Handle and open container with care. Conditions for safe storage, Conditions for safe storage including any incompatibilities: Store locked up. Keep container tightly closed. Store in a cool, dry place. Store in a well-ventilated place. Guard against dust accumulation of this material. Keep away from heat and sources of ignition. Use care in handling/storage. Store in accordance with local/regional/national/international regulation. Further information: CONTROLLED SUBSTANCE: Location of storage area must comply with all Drug Enforcement Agency regulations. Oxycodone hydrochloride has potent pharmacological activity and is classified as an OEB-2* material. Handling practices for OEB-2 substances are described below. LABORATORY: *Wear appropriate gloves, lab coat, and safety glasses. Use good lab practices. *No local exhaust ventilation required for transfer/handling of quantities of powder less than 100 g (total weight transferred or handled). However, if the source container contains 2 kg or more, pilot plant practices apply. *No local exhaust ventilation required for solutions of these compounds. *Quantities of solid above 100 g require use of a powders weighing hood or other approved containment/ventilation system. *High-energy operations such as milling, particle-sizing, spraying or fluidizing should be done within an approved emission control or containment system. *Develop cleaning procedures and techniques that limit potential exposure. PILOT PLANT PRODUCTION: *Wear appropriate gloves; lab coat, nylon coveralls or disposable Tyvek suit; safety glasses and safety shoes. Use good manufacturing practices (i.e., cGMPs). *Use local exhaust and/or enclosure at dust-generating points. Emphasis is to be placed on closed material transfer systems and process containment, with limited open handling of powders. *Where open handling of powders occurs, use a powered, air-purifying respirator (PAPR) with HEPA cartridges or a supplied-air respirator (SAR), unless air-monitoring data has shown that a lower level of respiratory protection is adequate. *Protective garments (coveralls, Tyveks, lab coat) are not to be worn in common areas (e.g., cafeterias) or out-of-doors. *High-energy operations such as milling, particle-sizing, spraying or fluidizing should be done within an approved emission control or containment system. *Develop cleaning procedures and techniques that limit potential expo

Section 8: Exposure Controls/Personal Protection

Exposure Limits OEB 2 OEB OEG 25 µg/m3 8-hour time-weighted average STEG 75 µg/m3 15-minute average No biological exposure limits noted for the ingredient(s).

Engineering Controls Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Ventilation should be sufficient to effectively remove and prevent buildup of any dusts or fumes that may be generated during handling or thermal processing. If engineering measures are not sufficient to maintain concentrations of dust particulates below the Occupational Exposure Limit (OEL), suitable respiratory protection must be worn. If material is ground, cut, or used in any operation which may generate dusts, use appropriate local exhaust ventilation to keep exposures below the recommended exposure limits. Ensure adequate ventilation, especially in confined areas.

Personal Protection	Eye/face protection: Chemical goggles are recommended. Provide eyewash station and safety shower. Skin protection Hand protection: Wear protective gloves. Other: Wear appropriate gloves; lab coat, nylon coveralls or disposable Tyvek suit; safety glasses, safety shoes, and disposable booties. Respiratory protection: Where open handling of powders occurs, use a powered, air-purifying respirator (PAPR) with HEPA cartridges or a supplied-air respirator (SAR), unless air-monitoring data has shown that a lower level of respiratory protection is adequate. Thermal hazards: Wear appropriate thermal protective clothing, when necessary. General hygiene considerations: When using, do not eat, drink or smoke. Avoid breathing dust. Avoid contact with eyes. Avoid contact with skin. Wash hands after handling and before eating. Contaminated work clothing should not be allowed out of the workplace. Handle in accordance with good industrial hygiene and safety practice. See Section 7 for additional information on occupational control measures appropriate for OEB-2 potent compounds.

Section 9: Physical and Chemical Properties

Appearance	Solid. (Powdered solid.) Color: White
Odor	Odorless.
Odor Threshold	Not available.

Melting Point	Not available	**pH**	Not available.
Freezing Point	Not available.	**Vapor Pressure**	Not applicable.
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	Density 1.80 g/cm3 Molecular formula C18H21NO4.ClH Molecular weight 351.83

Section 10: Stability and Reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical Stability	Discoloration upon exposure to light.
Hazardous Polymerization	Hazardous polymerization does not occur
Conditions to Avoid	Heat, flames and sparks. Exposure to light.
Incompatible Materials	Oxidizing agents
Hazardous Decomposition Products	Nitrogen oxides (NOx). Toxic gas

Section 11: Toxicological Information

RTECS CD2470000

Acute Toxicity
Toxic if swallowed. Toxic by inhalation. Chronic exposure may lead to tolerance, dependence, and unpleasant withdrawal symptoms upon abrupt discontinuation of use (e.g., sweating, restlessness, irritability, hallucinations).

Skin Corrosion/Irritation
May be irritating to the skin

Serious Eye Damage/Irritation
Dust or powder may irritate eye tissue

Respiratory or Skin Sensitization
May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.

Germ Cell Mutagenicity
Not available.

Carcinogenicity
Not available.

Reproductive Toxicity
Not available.

Routes of Entry
Ingestion. Inhalation. Skin. Eye.

Symptoms Related to Exposure
Exposure may cause sedation, pinpoint pupils, mood alterations, nausea, vomiting, constipation, respiratory depression; also tolerance, dependence and withdrawal. Large doses can lead to respiratory or cardiac arrest and death. May lead to habituation or addiction. May cause allergic espiratory and skin reactions.

Potential Health Effects
Not available.

Target Organ(s) Narcotic effects.

Section 12: Ecological Information

Ecotoxicity
This product has no known eco-toxicological effects.

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
Notify site Drug Enforcement Agency compliance officer and local DEA office for appropriate disposal procedures. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Follow handling guidance appropriate for OEB-2 potent compounds, (see Section 7). Dispose of contents/container in accordance with local/regional/national/international regulations.

Disposal of Container
Not available.

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 transportation regulations (ADR/RID-IMDG-ICAO/IATA).

Section 15: Regulatory Information

Regulations

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. CERCLA/SARA Hazardous Substances - Not applicable. TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D) Not regulated. CERCLA Hazardous Substance List (40 CFR 302.4)CERCLA Hazardous Substance List (40 CFR 302.4)CERCLA Hazardous Substance List (40 CFR 302.4)CERCLA Hazardous Substance List (40 CFR 302.4) Not listed. SARA 304 Emergency release notificationSARA 304 Emergency release notificationSARA 304 Emergency release notificationSARA 304 Emergency release notification Not regulated. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050) Not listed CERCLA (Superfund) reportable quantityCERCLA (Superfund) reportable quantityCERCLA (Superfund) reportable quantityCERCLA (Superfund) reportable quantity None Superfund Amendments and Reauthorization Act of 1986 (SARA)Superfund Amendments and Reauthorization Act of 1986 (SARA)Superfund Amendments and Reauthorization Act of 1986 (SARA)Superfund Amendments and Reauthorization Act of 1986 (SARA) Hazard categoriesHazard categoriesHazard categoriesHazard categories Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No SARA 302 Extremely hazardous substanceSARA 302 Extremely hazardous substanceSARA 302 Extremely hazardous substanceSARA 302 Extremely hazardous substance Not listed. SARA 311/312 HazardousSARA 311/312 HazardousSARA 311/312 HazardousSARA 311/312 Hazardous chemicalchemicalchemicalchemical Yes Other federal regulationsOther federal regulationsOther federal regulationsOther federal regulations Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) ListClean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) ListClean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) ListClean 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)Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130) Not regulated. Safe Drinking Water ActSafe Drinking Water ActSafe Drinking Water ActSafe Drinking Water Act (SDWA)(SDWA)(SDWA)(SDWA) Not regulated. Drug EnforcementDrug EnforcementDrug EnforcementDrug Enforcement Administration (DEA) (21 CFRAdministration (DEA) (21 CFRAdministration (DEA) (21 CFRAdministration (DEA) (21 CF

Other

WHMIS Not controlled under WHMIS (Canada). (Canada);DSCL (EEC) R36- Irritating to eyes.;Gloves.;Lab coat.;Dust respirator. Be sure to use an approved/certified respirator or equivalent.;Splash goggles.

Section 16: Other Information

Not available.