

Safety Data Sheet

1. IDENTIFICATION

Products: Oxycodone Hydrochloride Tablets 5mg
Oxycodone Hydrochloride Tablets 10mg


Recommended Use of the Chemical and Restrictions On Use: Pharmaceutical Product, Opioid Analgesic

Manufacturer: Nesher Pharmaceuticals (USA) LLC
13910 St Charles Rock Road
Earth City, MO. 63044
Phone: 314-209-4700

Emergency Phone Number: 314-209-4700

2. HAZARDS IDENTIFICATION

Classification:

Health	Environmental	Physical
Respiratory Sensitization – Category 1B Skin Sensitization – Category 1B	None	None
GHS Label		
		
<p>DANGER! May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.</p> <p>Prevention: Avoid breathing dust. In case of inadequate ventilation wear respiratory protection. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves.</p>	<p>Response: IF INHALED: remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor. IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical attention. Wash contaminated clothing before reuse.</p> <p>Disposal: P501 Dispose of contents/container to an approved waste disposal plant.</p>	

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No.	Amount
Oxycodone Hydrochloride	124-90-3	4-10%
Amorphous Silicon Dioxide	7631-86-9	1-5%

Note: The exact percentage is withheld as a trade secret

4. FIRST AID MEASURES

Eye: Immediately flush victim's eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Remove contact lenses if present and easy to do. Get medical attention if irritation persists.

Skin: Wash skin thoroughly with soap and water after handling. Get medical attention if irritation develops and persists. Remove and launder contaminated clothing before reuse.

Ingestion: Do not induce vomiting unless directed to do so by medical personnel. Get immediate medical attention for overdose.

Inhalation: Remove victim to fresh air. Get medical attention if irritation or other symptoms persist.

Most important symptoms/effects, acute and delayed: This product is a narcotic. Effects of exposure include dizziness, sleepiness, headache, nausea, difficulty in breathing, change in heart rate, respiratory depression and collapse.

Indication of immediate medical attention and special treatment needed, if necessary: Seek immediate medical treatment for ingestion overdose or significant inhalation of dust from crushed tablets. Physicians should treat for narcotic overdose as appropriate.

5. FIRE FIGHTING MEASURES

Suitable Extinguishing Media: Use water spray or fog, dry chemical, CO₂ or foam. Do not use straight water streams if large amounts of dust are present.

Specific Hazards Arising from the Chemical: High concentrations of dust that may be present if tablets are crushed or damages may present a dust explosion hazard. Combustion products may be toxic and include oxides of carbon and chlorine compounds.

Special Protective Equipment and Precautions for Fire-Fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment, and Emergency Procedures: Wear appropriate protective clothing as described in Section 8. Eliminate sources of ignition if dust from tablets is present.

Methods and Materials for Containment and Cleaning Up: Carefully sweep up or shovel, avoiding creating airborne dust. Place in an appropriate containers for disposal. Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

7. HANDLING AND STORAGE

Precautions for Safe Handling: Do not crush or break tablets. Avoid processes that generate dust. Avoid contact with the eyes, skin and clothing. Avoid breathing dust. Wear protective clothing and equipment as described in Section 8. Handle with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use. Follow good housekeeping procedures to minimize the accumulation of combustible dusts on surfaces, including overhead surfaces. High concentrations of dust may present a dust explosion hazard. Handle and store as a controlled substance.

Conditions for Safe Storage, including any incompatibilities: Store in a dry area. Store as a controlled substance. Store away from acids, bases and oxidizers.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines:

Oxycodone Hydrochloride	100 ug/m3 TWA (manufacturer recommended)
Amorphous Silicon Dioxide	80 mg/m3/%SiO2 TWA OSHA PEL

Appropriate Engineering Controls: No special controls are required for handling undamaged tablets. If tablets are damaged, use with general or adequate local exhaust ventilation to maintain exposure levels below the occupational exposure limits. If dust is generated in handling, explosion-proof equipment is required.

Respiratory Protection: No respiratory protection is required for handling undamaged tablets. If tablets are damaged and dust is present, a NIOSH approved respirator with particulate filters or supplied air respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with OSHA 1910.134 and good industrial hygiene practice.

Skin Protection: Wear impervious gloves such as rubber or neoprene to avoid skin contact when handling tablets. Wear protective clothing as needed to avoid skin contact and prevent contamination of personal clothing.

Eye Protection: Chemical safety goggles or safety glasses recommended.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Tablets, various colors.	Odor: None
Viscosity: Not applicable	Odor Threshold: Not applicable
Vapor Density: Not applicable	Boiling Point/Range: Not applicable
Solubilities: Soluble in water	Vapor Pressure: Not applicable
Relative Density: Not determined	Evaporation Rate: Not applicable
Melting Point/Freezing Point: Not determined	pH: Not applicable
Decomposition Temperature: Not determined	Partition Coefficient(n- Octanol/Water): Not determined
Flashpoint: None	Autoignition Temperature: Not applicable
Flammable Limits: LFL: Not applicable UFL: Not applicable	Flammability (solid, gas): No applicable data available

10. STABILITY AND REACTIVITY

Reactivity: Not considered reactive.

Chemical Stability: Stable under normal storage and handling conditions.

Possibility of Hazardous Reactions: May react with strong oxidizers generating heat.

Conditions to Avoid: Avoid damaging tablets and creating dust.

Incompatible Materials: Strong acids, bases and oxidizers.

Hazardous Decomposition Products: Thermal decomposition or combustion will generate oxides of carbon and chlorine compounds.

11. TOXICOLOGICAL INFORMATION

Ingestion: May be harmful if large amounts swallowed. This product is a narcotic drug. Overdosage may result in dizziness, sleepiness, headache, nausea, difficulty in breathing, change in heart rate, respiratory depression and collapse. Severe overdose may result in stopped breathing, circulatory collapse, low blood pressure and death.

Inhalation: Inhalation of dust may cause irritation of the nose, throat and upper respiratory tract and symptoms of overdose similar to ingestion.

Eye: May cause irritation of the eyes with redness and tearing.

Skin: May cause mild skin irritation. Oxycodone hydrochloride can be absorbed through the skin causing effects as described under ingestion.

Chronic Effects: No significant adverse effects have been observed in repeat dose studies in animals other than expected behavioral effects.

Carcinogenicity: None of the components is listed as a carcinogen or suspected carcinogen by ACGIH, IARC, NTP or OSHA. No carcinogenicity data is available for oxycodone hydrochloride.

Reproductive Toxicity: No adverse effects have been observed in studies with oxycodone hydrochloride in laboratory animals.

Germ Cell Mutagenicity: Oxycodone hydrochloride has produced mixed results in laboratory assays. It was negative in bacterial assays and the mouse micronucleus assays but positive in the mouse lymphoma and weakly positive in a human lymphocyte chromosome aberration assay.

Numerical Measures of Toxicity:

Oxycodone hydrochloride: No data available

Oxycodone: LD50 oral mouse 482 mg/kg

Amorphous Silica: No data available

12. ECOLOGICAL INFORMATION

No data is currently available. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with local, state and federal environmental regulations.

14. TRANSPORT INFORMATION

Transportation of Dangerous Goods Description:

Proper Shipping Name: Not regulated

UN Number: None

Hazard Class/Packing Group: None

Labels Required: None

15. REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS:

CERCLA 103 Reportable Quantity: This product is not subject to CERCLA reporting. Many states have more stringent spill reporting requirements. Report spill in compliance with all federal, state and local requirements.

SARA TITLE III:

Hazard Category for Section 311/312: Acute Health, Chronic Health

Section 313 Toxic Chemicals: This product contains the following chemicals subject to SARA Title III
Section 313 Reporting requirements: None

Section 302 Extremely Hazardous Substances (TPQ): None

EPA Toxic Substances Control Act (TSCA) Status: This product is a drug and not subject to TSCA.

STATE REGULATIONS:

California Proposition 65: These products contain the following substances known to the State of California to cause cancer and/or reproductive harm: None known

16. OTHER INFORMATION

SDS Date of Preparation/Revision: April 15, 2012