

SAFETY DATA SHEET

Oxycodone Hydrochloride Tablets, USP

1. IDENTIFICATION

Manufacturer:

Ascent Pharmaceuticals Inc
550 S.Research Place
Central Islip, NY 11722
USP

Emergency Phone:

1-855-221-1622

Common Name: Oxycodone Hydrochloride Tablets, USP

Synonym(s): Not Applicable

Trade Name(s): Oxycodone Hydrochloride Tablets, USP 15 mg and 30 mg

2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Caution Statement: Narcotic. Toxic if swallowed. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. May cause drowsiness or dizziness

Classification:

Acute Toxicity (Oral) – Category 3

Respiratory Sensitization – Category 1

Skin Sensitization – Category 1

Label



Signal Word -

Danger



Environmental hazards OSHA defined hazards

Prevention -In case of inadequate ventilation wear respiratory protection. Avoid breathing dust. Use only outdoors or in a well-ventilated area. 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 inhaled: Remove person to fresh air and keep comfortable for breathing.

If experiencing respiratory symptoms: Call a poison center/doctor.

If skin irritation or rash occurs: Get medical advice/attention. Call a poison center/doctor if you feel unwell. Wash contaminated clothing before reuse.

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.

3.COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS</u>	<u>Concentration*</u>
Oxycodone HCl, USP	124-90-3	≈ 30 %
Excipients	NA	≈ 70 %

* All Concentrations are percent by weight.

4. FIRST AID MEASURES

Inhalation: If breathing is difficult, move to fresh air, if not breathing give artificial respiration. Get medical attention immediately.

Skin Contact: Wash with soap and water for at least 15 minutes. Get medical attention if symptoms occur.

Eye Contact: Any material that contacts the eye should be washed out immediately with water for at least 15 minutes. If easy to do, remove contact lenses if worn. Get medical attention if symptoms persist.



Ingestion: Call a physician or poison control center immediately. Never give anything by mouth to a victim who is unconscious or is having convulsions. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Use water spray, dry chemical, carbon dioxide or material appropriate for fire in surrounding area

Unusual Fire & Explosion Hazards: Not Applicable.

Special Fire Fighting Procedures: Wear full protective clothing and self-contained breathing apparatus.

Protective Measures: Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment. Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all firefighting procedures.

Environmental precautions: Do not release in to the environment.

Spill Cleanup methods: Sweep up or vacuum up spillage and collect in suitable container for disposal. Should not be released into the environment. Do not flush to sewer. All clean-up operations should be witnessed by more than one individual. The amount of material collected should be assessed and documented. See section 13 of the SDS.

7. HANDLING AND STORAGE

Handling: Special handling and storage requirements must be observed to assure compliance with Drug Enforcement Administration regulations. All employees who handle this material should be thoroughly trained to handle it safely. Empty containers may contain residual material; therefore, empty containers should be handled with care and disposed of properly. Do not breathe dust. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.

Storage: This material must be stored in a locked cabinet in a Controlled Substance Storage Room, per the requirements of regulations of the DEA and FDA at Controlled



Room Temperature: 15° to 30° C . Store the medicine in a tight, light resistant container at room temperature, away from heat, moisture, and direct light.

8.EXPOSURE CONTROLS / PERSONAL PROTECTION

Compressed tablets are not considered hazardous under normal handling procedures and protective equipment is not required. The following are recommended for manufacturing or other situations where exposure to the powder may occur.

Protective Measures: Not required when handling tablets or containers. Ventilation should be matched to conditions.

Respiratory Protection: Not required when handling tablets or containers. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to conditions.

Hand Protection: Chemical resistant gloves.

Eye Protection: Wear safety glasses with side shields (or goggles). If the work environment or activity involves dusty conditions, mist or aerosols, wear the appropriate goggles. Wear a face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and Body Protection: Not required when handling tablets. If containers are compromised or exposure is likely -wear: Goggles, Lab Coat and Gloves

Hygiene Measures: Wash skin thoroughly with soap and water.

9.PHYSICAL AND CHEMICAL PROPERTIES

Physical Properties:

Physical State: Solid

Form: Tablets

Appearance:

15 mg -Light Yellow, round, biconvex, beveled edge tablets debossed with 'T' and break line on one side and '188' on the other side.

30 mg -Light Yellow, round, flat faced with, beveled edge tablets debossed with 'T' and '189' with a break line on one side and plain on the other side.

10. STABILITY AND REACTIVITY

Possibility of hazardous reactions: Stable under ordinary conditions of use and storage.



Conditions to avoid: Excessive heat & Moisture.

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 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

12. ECOLOGICAL INFORMATION

General information: The information presented below pertains to the individual ingredients, and not to the mixture(s) or final formulations.

Revision:00

Effective Date: 14-August -2017



Eco toxicity: This product has no known eco-toxicological effects.

Acute toxicity (Aquatic invertebrates): No data available.

Bioaccumulation: No data available.

Mobility: No data available.

13.DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of waste must be in accordance with all applicable Federal, State and local laws. 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.

14.TRANSPORT INFORMATION

DOT: Not Regulated

IMDG: Not regulated

IATA: Not Regulated

15.REGULATORY INFORMATION

Stated regulatory information chosen primarily for possible usage of Ascent Pharmaceutical, Inc. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulatory Information

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 Sections Revised: New

GLOSSARY:

SDS	Safety Data Sheet
NA	Not Applicable
CAS Number	Chemical Abstract Service Registry Number
NTP	National Toxicology Program
NIOSH	National Institute for Occupational Safety and Health
DOT	Department of Transportation
IMDG	International Maritime Dangerous Goods Code
ICAO	International Civil Aviation Organization
IATA	International Air Transport Association
IMO	International Maritime Organization
TSCA	Toxic Substances Control Act
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
SARA	Superfund Amendments and Reauthorization Act
OSHA	Occupational Safety and Health Administration
DEA	Drug Enforcement Administration

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