SAFETY DATA SHEET

Issue Date 10-Jun-2010 **Revision Date** 23-Apr-2015 **Version** 2

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION

Product Name OxyContin® (oxycodone hydrochloride extended-release tablets) C-II

Synonyms OxyContin® 10, 15, 20, 30, 40, 60, 80 mg tablets

Other Information **This is a controlled substance under Schedule II of the Controlled Substances Act.**

Recommended Use Opioid analgesic

Uses advised against Do not use without a prescription.

Manufacturer Address Purdue Pharma L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, Connecticut 06901-3431
(888) 726-7535

24 Hour Emergency Phone Number Chemtrec (800) 424-9300
For all international transportation emergencies, call Chemtrec collect at (703) 527-3887.

2. HAZARDS IDENTIFICATION

Drugs when in solid final form (e.g. capsules, tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard, 29 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous.

Emergency Overview

Appearance Tablet **Physical state** Solid **Odor** No information available.

Hazards Not Otherwise Classified (HNOC)
Not Applicable.

Other Information
No information available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No	Weight %
Oxycodone hydrochloride	124-90-3	5-40
Magnesium stearate	557-04-0	1-5

4. FIRST AID MEASURES

First aid measures

Eye contact In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Skin contact In case of contact, remove contaminated clothing. Immediately flush skin with copious amounts of water for at least 15 minutes. Obtain medical attention if skin reaction occurs.

Inhalation In case of inhalation, remove to fresh air. If not breathing, provide artificial respiration. If breathing is difficult, administer oxygen. Seek medical attention immediately.

Ingestion In case of accidential ingestion, wash out mouth with copious amounts of water. Seek medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Self-protection of the first aider Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Most important symptoms and effects, both acute and delayed

Symptoms Oxycodone hydrochloride overexposure may cause dizziness, euphoria, flushing, itching, hypotension, pinpoint pupils, nausea/vomiting, constipation, reduced urination, respiratory depression, extreme somnolence, stupor or coma, skeletal muscle flaccidity, cold and clammy skin, bradycardia, apnea, circulatory collapse, cardiac arrest, and eventually death.

Indication of any immediate medical attention and special treatment needed

Note to physicians OxyContin® tablets contain oxycodone hydrochloride. Oxycodone hydrochloride is a pure opioid with an analgesic potency about twice that of morphine. Naloxone is a specific antidote against respiratory depression from opioid overexposure. Opioid antagonists should not be administered in the absence of clinically significant respiratory or circulatory depression secondary to oxycodone hydrochloride overexposure.

In cases of oxycodone hydrochloride overexposure, primary attention should be given to the re-establishment of a patent airway and institution of assisted or controlled ventilation. Supportive measures (including oxygen and vasopressors) should be employed in the management of circulatory shock and pulmonary edema accompanying overexposure as indicated. Cardiac arrest or arrhythmias may require cardiac massage or defibrillation

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable Extinguishing Media No information available.

Specific hazards arising from the chemical
In a manufacturing setting, avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Explosion Data
Sensitivity to Mechanical Impact None.
Sensitivity to Static Discharge None.

Protective equipment and precautions for firefighters
As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions Evacuate personnel to safe areas. Use personal protection recommended in Section 8.

Other Information Not Applicable.

Environmental precautions

Environmental precautions See section 12 for additional Ecological Information.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Wear suitable protective clothing and equipment. Sweep up intact tablets or vacuum up cut, broken or crushed tablets and place collected material into a suitable container for reclamation or disposal. Thoroughly wash area with detergent and water. Oxycodone hydrochloride is a Schedule II controlled substance. All clean-up operations should be witnessed by more than one individual. The amount of material collected should be assessed and documented. Notify appropriate company regulatory personnel. Dispose of all solid waste and wash and rinse water in accordance with federal, state, and local regulations.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling Do not cut, break or crush tablets. Avoid procedures that will generate dust. Local exhaust is recommended to avoid generation of significant airborne dust levels. Avoid contact with eyes, skin, or clothing. Wash thoroughly after handling. Wash contaminated clothing after use.

Conditions for safe storage, including any incompatibilities

Storage conditions Oxycodone hydrochloride is a Schedule II controlled substance and requires DEA-compliant storage. Keep container tightly closed. Protect from light.

Incompatible materials No information available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Magnesium stearate 557-04-0	TWA: 10 mg/m^3 except stearates of toxic metals, A4	-	-

Chemical Name	Performance-Based Exposure Band (PBEB)	Company OEG (ug/m^3)
Oxycodone hydrochloride	None	40 µg/m^3 (free base)

Engineering Controls Handle material under adequate ventilation (e.g., chemical fume hood, vented balance enclosure [VBE]). Keep container tightly closed. Minimize the amount of material handled at any one time.

Individual Protection Measures (Personal Protective Equipment)

Eye/face protection None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting or possibility of splashing. Contact a health and safety professional for specific information.

Skin and body protection None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. Contact a health and safety professional for specific information.

Respiratory protection Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where the exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. In the United States of America, if respirators are used, they are to be NIOSH-approved and part of a respiratory protection program instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Contact a health and safety professional or manufacturer for specific information.

General Hygiene Considerations Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical and Chemical Properties

Physical state Solid
Appearance Tablet

Odor	No information available.
Color	White 10 mg, Gray 15 mg, Pink 20 mg, Brown 30 mg, Yellow 40 mg, Red 60 mg, Green 80 mg
Odor threshold	No information available.

Property	**Values**	**Remarks • Method**
pH	No information available.	
Melting point / melting range	270-272°C	
Boiling point / boiling range	No information available.	
Flash point	No information available.	
Evaporation rate	No information available.	
Flammability (solid, gas)	No information available.	
Flammability limits in air		
Upper flammability limits		
Lower flammability limits		
Vapor pressure	No information available.	
Vapor density	No information available.	
Specific gravity	No information available.	
Water solubility	100 g/L	
Solubility in other solvents	No information available.	
Partition coefficient (n-octanol/water)	No information available.	
Autoignition temperature	No information available.	
Decomposition temperature	No information available.	
Kinematic viscosity	No information available.	
Dynamic viscosity	No information available.	
Explosive properties	No information available.	
Oxidizing properties	No information available.	

Other Information

Softening point	No information available.
Molecular weight	No information available.
VOC content; (%)	No information available.
Density	No information available.
Bulk density	No information available.

10. STABILITY AND REACTIVITY

Chemical stability Stable under recommended storage conditions.

Possibility of hazardous reactions No information available.

Hazardous polymerization Hazardous polymerization does not occur.

Conditions to avoid No information available.

Incompatible materials No information available.

Hazardous decomposition products None known based on available information.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information No data available.

Inhalation No data available.

Eye contact No data available.

Skin contact No data available.

Ingestion No data available.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Oxycodone hydrochloride	>100 mg/kg (Rat) >35 mg/kg (Mouse)	-	-

Information on toxicological effects

Symptoms Oxycodone hydrochloride overexposure may cause dizziness, euphoria, flushing, itching, hypotension, pinpoint pupils, nausea/vomiting, constipation, reduced urination, respiratory depression, extreme somnolence, stupor or coma, skeletal muscle flaccidity, cold and clammy skin, bradycardia, apnea, circulatory collapse, cardiac arrest, and eventually death

Sensitization Oxycodone hydrochloride tested negative for sensitization in an animal study. Repeated or prolonged contact may cause allergic reactions in very susceptible persons.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Germ cell mutagenicity Oxycodone hydrochloride was not genotoxic in the Ames test, the human lymphocyte chromosomal aberration test in the absence of metabolic activation by liver microsomes, or in the in vivo mouse micronucleus test, even at toxic / lethal doses and plasma levels of oxycodone and clinically relevant key metabolite levels that were many hundred-fold above the levels achieved in human clinical use

Carcinogenicity No information available.

Reproductive toxicity Oxycodone was not teratogenic at doses up to and including maternal maximum tolerated levels nor did it cause any toxic effects on fertility or reproductive performance up to the implantation stage up to 8 mg/kg/day. In the pre- and post-natal study, oxycodone did not affect reproductive performance in rats dosed during gestation and lactation; it did not affect long-term development (there was decreased body weight gain in high-dose pups during nursing and shortly after weaning, but it recovered) or reproductive performance in pups (F1 generation) born to rats treated with oxycodone during late pregnancy and lactation, and did not have developmental effects on rats born to the F1 generation females. Body weights were lower at 6 mg/kg/day, NOEL was 2 mg/kg/day.

No information on the potential effect of oxycodone on reproductive performance.

Oxycodone did not produce developmental toxicity in rats or rabbits at dosages as high as 8 and 125 mg/kg/day, respectively. Repetitive maternal exposure to opioids has been associated with respiratory depression and/or withdrawal symptoms in neonates.

Oxycodone has been detected in breast milk.

STOT-single exposure Respiratory tract and CNS.

Rat oral tox, NOAEL of 25 mg/kg, LD50 greater than or equal to 100 mg/kg.

STOT-repeated exposure

CNS, Respiratory System and Gastrointestinal Tract.

In a 3-month oral toxicity study in rats, 1.6 mg/kg/day (lowest dose tested) and 4.0 mg/kg/day produced stereotypic behavior and increased and/or decreased activity; these changes were observed after 2-6 weeks of treatment. Prior to that time, no effects were observed. Dosages of 10 and 25 mg/kg/day were associated with stereotypic behavior, increased activity, postural rigidity, and pale color of the extremities. One rat that received 25 mg/kg/day did not survive past 22 days of dosing.

In a 12-day oral study in rabbits, no effects were observed at 4.5 mg/kg/day; doses greater than or equal to 22 mg/kg/day were, not was associated with decreased activity, reduced fecal output, and convulsions. An animal that received 269 mg/kg/day did not survive six doses.

In a 28-day oral study in dogs, a dosage of 1 mg/kg/day was associated with minimal effects including excessive salivation and slow capillary refill in the oral mucosa; doses of 4, 8, or 20 mg/kg/day were associated with decreased activity, sedation, ataxia, pale color and slow capillary refill of the oral mucosa. One dog given 20 mg/kg/day did not survive past 3 days of dosing and one animal given 20 mg/kg/day had convulsions.

In a 3-month oral study in dogs, 0.3 mg/kg/day (lowest dose tested) produced no effects; doses of 1 mg/kg/day produced effects similar to those observed in the 28-day study.

Chronic Toxicity

No information available.

Subchronic toxicity

No information available.

Aspiration hazard

No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Oxycodone hydrochloride	NOEC 13 mg/L (Growth and Biomass)	NOEC 2.5 mg/L (Reproduction)	NOEC > 1000 mg/L (in 7 species)	NOEC 6 mg/L (Reproduction) 18 mg/L (Growth) (Daphnia magna)

Persistence and degradability

Oxycodone hydrochloride: Aerobic biodegradation: sewer sludge: estimated $t_{1/2}$ of 276 days.

Bioaccumulation

No information available.

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of wastes

Disposal should be in accordance with applicable regional, national, and local laws, and regulations.

Contaminated Packaging

Do not reuse container.

14. TRANSPORT INFORMATION

DOT Not regulated.

IATA Not regulated.

15. REGULATORY INFORMATION

OxyContin Tablets are on the DEA Scheduled II List of controlled substances.

International Inventories

TSCA	Not determined.
DSL	Not determined.

Legend:

TSCA - United States Toxic Substances Control Act Section 8 (b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

US Federal Regulations

SARA 313
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

CWA (Clean Water Act)
This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA
This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65
This product does not contain any Proposition 65 chemicals.

US State Right-to-Know Regulations
This product may contain substances regulated by state right-to-know regulations.

US EPA Label Information
EPA Pesticide Registration Number Not Applicable.

16. OTHER INFORMATION

NFPA	**Health Hazards** 2	**Flammability** 1	**Instability** 0	**Physical and Chemical Properties** -
HMIS	**Health Hazards** 2	**Flammability** 1	**Physical Hazards** 0	**Personal protection** X

General Information

In an industrial setting, refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for Safe Handling.

Prepared By

This SDS was prepared by the Occupational and Environmental Assessment Section of Purdue Pharma L.P.

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Disclaimer

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End of Safety Data Sheet