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

<table>
<thead>
<tr>
<th>Appearance</th>
<th>Physical state</th>
<th>Odor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tablet</td>
<td>Solid</td>
<td>No information available.</td>
</tr>
</tbody>
</table>

Hazards Not Otherwise Classified (HNOC)
Not Applicable.

Other Information
No information available.
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS No</th>
<th>Weight %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxycodone hydrochloride</td>
<td>124-90-3</td>
<td>5-40</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>1-5</td>
</tr>
</tbody>
</table>

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 accidental 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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH TLV</th>
<th>OSHA PEL</th>
<th>NIOSH IDLH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>TWA: 10 mg/m³ except stearates of toxic metals, A4</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Performance-Based Exposure Band (PBEB)</th>
<th>Company OEG (µg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxycodone hydrochloride</td>
<td>None</td>
<td>40 µg/m³ (free base)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Physical state</th>
<th>Solid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Tablet</td>
</tr>
</tbody>
</table>
### 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
<th>Remarks • Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Color</td>
<td>White 10 mg, Gray 15 mg, Pink 20 mg, Brown 30 mg, Yellow 40 mg, Red 60 mg, Green 80 mg</td>
<td></td>
</tr>
<tr>
<td>Odor threshold</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>pH</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Melting point / melting range</td>
<td>270-272°C</td>
<td></td>
</tr>
<tr>
<td>Boiling point / boiling range</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Flash point</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Flammability limits in air</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper flammability limits</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower flammability limits</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Vapor density</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Specific gravity</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>100 g/L</td>
<td></td>
</tr>
<tr>
<td>Solubility in other solvents</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Partition coefficient</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>(n-octanol/water)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Kinematic viscosity</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Dynamic viscosity</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Explosive properties</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Softening point</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>VOC content; (%)</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Density</td>
<td>No information available.</td>
<td></td>
</tr>
<tr>
<td>Bulk density</td>
<td>No information available.</td>
<td></td>
</tr>
</tbody>
</table>

#### 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.

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Inhalation
No data available.

Eye contact
No data available.

Skin contact
No data available.

Ingestion
No data available.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Oral LD50</th>
<th>Dermal LD50</th>
<th>Inhalation LC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxycodone hydrochloride</td>
<td>&gt;100 mg/kg (Rat)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>&gt;35 mg/kg (Mouse)</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Algae/aquatic plants</th>
<th>Fish</th>
<th>Toxicity to microorganisms</th>
<th>Crustacea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxycodone hydrochloride</td>
<td>NOEC 13 mg/L (Growth and Biomass)</td>
<td>NOEC 2.5 mg/L (Reproduction)</td>
<td>NOEC &gt; 1000 mg/L (in 7 species)</td>
<td>NOEC 6 mg/L (Reproduction) 18 mg/L (Growth) (Daphnia magna)</td>
</tr>
</tbody>
</table>

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
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.

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

The information contained in this Safety Data Sheet is believed to be accurate and represents the best information available at the time of preparation. However, no warranty, express or implied, with respect to such information, is made. The data in this Safety Data Sheet relate only to the specific material designated herein and do not relate to use in combination with any other material. The data in this Safety Data Sheet are subject to revision as additional knowledge and experience are gained.

End of Safety Data Sheet