

Purdue Pharma L.P.

Material Safety Data Sheet

OxyContin[®] 10mg
(oxycodone hydrochloride
controlled release) Tablets

Version: 3-Jan-08

1. CHEMICAL PRODUCT/COMPANY IDENTIFICATION

Material Identification: OxyContin[®] 10mg Tablets

Chemical Name: mixture, not applicable

Active Ingredient:

4, 5-epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-one hydrochloride

Synonyms

Active Ingredient:

14-hydroxydihydrocodeinone hydrochloride

Molecular Formula: mixture

Molecular Weight: mixture

Active Ingredient: C₁₈H₂₁NO₄·HCl

Active Ingredient: 351.83

CAS Number: mixture, N/A

Active Ingredient: 124-90-3

Product Use: opioid analgesic

Company Identification:

Responsible Party

Purdue Pharma, L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901-3431
Telephone: (888) 726-7535

EMERGENCY CONTACT

Chemtrec (800) 424- 9300. For all international transportation emergencies call
Chemtrec collect at (703) 527-3887.

2. HAZARDOUS COMPONENTS

<u>Material</u>	<u>CAS Number</u>	<u>%</u>
Oxycodone Hydrochloride	124-90-3	7.7
Talc	14807-96-6	1.9

3. Hazards Identification

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Emergency Overview

White unscored, film-coated, controlled-release tablet
Slight, varnish-like odor

OxyContin[®] tablets do not pose a significant workplace hazard unless tablets are broken or crushed. The following information is provided for those circumstances where uncontrolled exposure to oxycodone may occur due to breakage or crushing of the OxyContin[®] tablet.

Target organs: central nervous system, gastrointestinal tract, cardiovascular system, respiratory tract

Serious overdosage of oxycodone produces respiratory depression, extreme somnolence, stupor or coma, skeletal muscle flaccidity, cold and clammy skin, bradycardia and hypotension.

Severe overdosage produces apnea, circulatory collapse, cardiac arrest, and death.

Broken or crushed tablets may be fatal if ingested.

Broken or crushed tablets may be harmful by inhalation or skin contact.

Contact with broken or crushed tablets, may cause eye and skin irritation.

Repetitive contact with broken or crushed tablets may cause allergic skin reactions.

Exposure to broken or crushed tablets may cause pinpoint pupils.

Potential Health Effects

OxyContin[®] is a film-coated, controlled-release tablet product. It does not pose a hazard under normal workplace handling conditions.

The active ingredient of OxyContin[®] is oxycodone, an orally active opioid analgesic approximately twice the potency of morphine. OxyContin[®] is designed to provide controlled release of oxycodone in the body. If OxyContin[®] tablets are broken or crushed, workplace exposure to oxycodone may occur. The following information is provided for those circumstances where uncontrolled exposure to the hazardous components in OxyContin[®] may occur due to breakage or crushing of the tablet.

Oxycodone

Oxycodone hydrochloride may cause eye irritation and mild skin irritation.

Repetitive exposure to oxycodone hydrochloride may cause skin and/or respiratory allergies. Systemic absorption may occur through skin.

Overdosage may cause dizziness, euphoria, flushing, itching, hypotension, pinpoint pupils, nausea/vomiting, constipation, and reduced urination.

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Serious overdose produces respiratory depression, extreme somnolence, stupor or coma, skeletal muscle flaccidity, cold and clammy skin, bradycardia and hypotension.

Severe overdosage produces apnea, circulatory collapse, cardiac arrest, and death.

Maternal exposure to OxyContin[®] may cause respiratory depression in the neonate. Repeated maternal exposure to oxycodone hydrochloride may produce respiratory depression and/or withdrawal in the neonate.

Talc

If crushed, exposure to talc can cause eye, skin, nose, throat and lung irritation resulting in coughing, wheezing and shortness of breath. Long term overexposure to talc is associated with talc pneumoconiosis. Symptoms include shortness of breath, clubbing of fingers, coughing with sputum, changes in lung x-ray, chronic lung disease with impaired lung function and can cause right-sided heart failure.

Conditions that may be aggravated by exposure to broken or crushed OxyContin[®] tablets include significant chronic obstructive lung disease, asthma, and hypotension.

Carcinogenicity Information

OxyContin[®] and its components are not listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

4. First Aid Measures

First Aid

INHALATION

If dusts are inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician (see notes to physician below). If allergic reactions occur (e.g., stuffy, runny or itchy nose, itchy throat, sneezing, watery/itchy eyes, etc.) see a physician.

SKIN CONTACT

Remove contaminated clothing. Flush skin with plenty of water and wash thoroughly with soap and water. If irritation (redness, itching, swelling) develops, seek medical attention. Wash contaminated clothing before reuse.

EYE CONTACT

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. See a physician.

INGESTION

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If swallowed, immediately give 2 glasses of water and induce vomiting under the direction of medical personnel. Never give anything by mouth to an unconscious person. Call a physician.

Notes to Physicians

OxyContin[®] (oxycodone hydrochloride controlled-release) Tablet is a pure opioid agonist with an analgesic potency about twice that of morphine. The extended release of oxycodone from OxyContin tablets should be taken into account when treating an overdose due to ingestion of intact tablets. Naloxone is a specific antidote against respiratory depression from opioid overdose. Opioid antagonists should not be administered in the absence of clinically significant respiratory or circulatory depression secondary to oxycodone overdose.

In cases of overdosage, 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 overdose as indicated. Cardiac arrest or arrhythmias may require cardiac massage or defibrillation.

If ingested and the patient is conscious, induction of emesis may be indicated. Gastric lavage may be indicated if the patient is unconscious.

5. Fire Fighting Measures

Flammable Properties

OxyContin[®] tablets are not considered flammable. However, concentrated dust from broken or crushed tablets may pose a dust explosion hazard. Eliminate sources of ignition. Bond and ground as necessary. Use non-sparking tools.

For Oxycodone

Minimum ignition energy: 10-25 mJ

Minimum ignition temperature – dust cloud: 420-440°C

Maximum explosion pressure (20 L sphere): 9.4 bar

Maximum rate of pressure rise: 779 bar/sec

K_{st}: 212 bar·m/sec

Extinguishing Media

Water spray, carbon dioxide, dry chemical powder, or foam as appropriate for the surrounding material.

Fire Fighting Instructions

Evacuate personnel to a safe area. Keep personnel removed and upwind of fire. Wear self-contained breathing apparatus. Wear full protective equipment.

6. Accidental Release Measures

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Safeguards (Personnel)

NOTE: Review FIRE FIGHTING MEASURES and HANDLING (PERSONNEL) sections before proceeding with clean-up. Use appropriate PERSONAL PROTECTIVE EQUIPMENT during clean-up to minimize exposure to this material. Evacuate personnel from the area.

Initial Containment

Prevent material from entering sewers, waterways, or low areas. Dike area for later disposal.

Spill Clean-up

Wear suitable protective clothing and equipment. Sweep up intact tablets or vacuum up broken or crushed tablets and place collected material into a suitable container for reclamation or disposal. Thoroughly wash area with detergent and water. Oxycodone 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

Handling (Personnel)

Do not 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.

Handling (Physical Aspects)

Close container after each use. Do not generate dust.

Storage

Oxycodone is a Schedule II controlled substance. Keep containers of OxyContin[®] tightly closed. Protect from light. To maintain potency, store at 25°C (77°F) and control temperature excursions to between 15-30°C (59-86°F).

8. Exposure Controls/Personal Protection

Engineering Controls

Handle material under adequate ventilation. Keep container tightly closed.

Personal Protective Equipment

Wear safety glasses with side shields if exposure to dust is possible. Wear full-face protection when judged that the possibility exists for eye and face contact.

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Wear an appropriate NIOSH-approved air purifying respirator or positive pressure air-supplied respirator in situations where a respirator is judged appropriate to prevent inhalation of dust.

Wear impervious clothing such as gloves, lab coat, shoe covers, apron, or jumpsuit, as appropriate, to prevent skin contact if exposure to broken or crushed tablets is possible. Consult the site safety professional for additional guidance, as needed.

Exposure Guidelines

Exposure Limits

None for OxyContin[®]

Oxycodone hydrochloride

PEL (OSHA): None established

TLV (ACGIH): None established

Purdue (Occupational Exposure Guideline): 40 µg/m³ (free base)

Talc (containing no asbestos fibers, respirable particulates):

TLV (ACGIH): 2 mg/m³ 8 hr shift

PEL (OSHA): 2 mg/m³ 8 hr shift

Talc (containing no asbestos and less than 1% quartz):

NIOSH (REL): 2 mg/m³ 10 hr shift

NIOSH (IDLH): 1,000 mg/m³

California (talc as a nuisance and particulate dust or respirable fraction)

(OEL): 5 mg/m³

Exposure Guideline Comments

For Oxycodone

May be absorbed through skin (crushed tablets); may cause skin or respiratory sensitization

9. Physical and Chemical Properties

Physical Data

For Oxycodone Hydrochloride:

Odor: odorless

Form: powder (solid)

Color: white to off-white

Vapor Pressure: no information available

Melting Point: 270-272°C

K_{ow}: <1 (pH 7); <10 (pH 9)

Solubility: 10gm in 100g of water

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10. Stability and Reactivity

Chemical Stability

Low stability hazard expected at normal operating temperatures.

Incompatibility with Other Materials

Strong oxidizers, acids, bases

Oxidizing materials will increase the risk of fire and explosion (e.g., potassium perchlorate, potassium nitrate)

Conditions to Avoid

Static charge, sparks, generation of dust, and temperatures above 200°C

Decomposition

Will not decompose under conditions of usual handling. Heating to decomposition may release acrid smoke and fumes.

Polymerization

Material will not polymerize.

11. Toxicological Information

Relevant Data

The following data for oxycodone hydrochloride are reflected as oxycodone free base. The information for talc is for non-asbestos containing material.

Skin/Eyes

Oxycodone

Oxycodone has not been evaluated in skin and eye irritation studies in animals. It is expected that oxycodone may produce mild skin irritation and may cause eye irritation.

Talc

Draize (human): 300 µg/3D mild reaction

Talc is not a primary skin irritant and it does not cause sensitization. Talc particles are physical irritants which cause inflammatory changes such as skin rash and can cause serious eye damage.

Acute

Oxycodone

LD₅₀: oral: 482 mg/kg (mouse)

LD₅₀: IP: 250 mg/kg (mouse)

LDL: IV: 20 mg/kg (rat)

Talc

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LD₅₀: oral: 920 mg/kg (rat)

Subchronic

Oxycodone

In a 10-day oral study in rats, 4.5 mg/kg/day (lowest dose tested) produced stereotypic behavior and increased activity only after 5 days of treatment. At 45 mg/kg/day, stereotypic behavior, body rigidity, labored breathing was observed on the first day of dosing. Animals that received ≥ 90 mg/kg/day did not survive past two days of dosing.

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; ≥ 22 mg/kg/day 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, and 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 ≥ 1 mg/kg/day produced effects similar to those observed in the 28-day study.

Chronic Toxicity

Oxycodone

No information available

Talc

No information available

Carcinogenicity

Oxycodone

No information available

Talc

Inhalation Studies

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Rats were exposed to non-asbestiform talc aerosols (0, 6, or 18 mg/m³) for 6 hours a day for 5 days a week for as long as 113 weeks for males and 122 weeks for females. Rats exhibited a concentration-time related increase in lung talc burden and impairment of lung function (total and vital lung capacities, compliance, gas exchange efficiency). Lung weights for rats in the 18mg/m³ group were greater than control values during and at the end of the study. Inhalation exposure produced inflammatory, reparative, and proliferative processes in the lungs. Female, but not male, rats in the 18 mg/m³ group exhibited clear evidence of carcinogenic activity in the lungs. Male, but not female, rats in the 18 mg/m³ group exhibited some evidence of carcinogenic activity in the adrenal gland (increased incidence of pheochromocytomas).

Mice were exposed to non-asbestiform talc aerosols (0, 6, 18 mg/m³) for 6 hours a day for 5 days a week for up to 104 weeks. The mice in the study exhibited a concentration-time increase in lung talc burden; lung function was not measured in this study. Talc inhalation was associated with chronic active inflammation in the lung but the proliferative changes observed in rats were not observed in the mice. There was no evidence of carcinogenic activity in the male or female mice.

Mutagenicity/Genotoxicity

Oxycodone

Bacterial mutagenicity: negative

Mouse micronucleus: negative

Human lymphocyte chromosome aberration: weakly positive

Mouse lymphoma: positive

Talc

Bacterial mutagenicity: negative

Developmental/Reproductive Toxicity

Oxycodone

Oxycodone administration to rats at dosages as high as 8 mg/kg/day had no effect on fertility or general reproductive performance.

Oxycodone did not produce developmental toxicity in rats or rabbits at dosages as high as 8 and 125 mg/kg/day, respectively.

Pups born to rats treated with oxycodone at a dosage of 6 mg/kg/day during late gestation through weaning had low body weight through lactation and the early growth phase. There was no effect on survival of the offspring. The no adverse effect level for the finding was 2 mg/kg/day.

Repetitive maternal exposure to opioids has been associated with respiratory depression and/or withdrawal symptoms in neonates.

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Oxycodone has been detected in breast milk.

Talc

Mice and rats were fed up to 1,600 mg/kg/day during pregnancy. Hamsters received 1,200 mg/kg/day during pregnancy and rabbits received 90-900 mg/kg/day orally during pregnancy. There was no evidence of teratogenicity or embryotoxicity in these species at these dosages.

12. Ecological Information

Ecotoxicological Information

Oxycodone HCl

24 hr LC₅₀: Daphnia magna: 300 mg/mL

Microbial Growth Inhibition EC₁₀: 7 species: > 1,000 mg/mL

Chemical Fate Information

Oxycodone HCl

Aerobic biodegradation: sewer sludge: est. t_{1/2}: 276 days

13. Disposal Considerations

Disposal

This material is not listed under US RCRA. It is a Schedule II drug. Disposal of this material must be in accordance with federal, state/provincial, and local regulations.

14. Transportation Information

Shipping Information

This material is non-hazardous under US DOT.

15. Regulatory/Statutory Information

US Federal: OxyContin[®] (Oxycodone preparations) are subject to control under the US Federal Controlled Substances Act of 1970 as schedule II (C-II) drugs.

California Hazardous Substance List: Talc (exempt if no inhalable dust is present or can be generated through use), polyvinylpyrrolidone

Illinois Toxic Substance Disclosure to Employees Act: Talc as a nuisance dust

Indiana OSHA Approved Implementation Plan: Talc, nuisance dust

Kentucky OSHA Approved Implementation Plan: Talc, nuisance dust

Massachusetts Right-to-Know Substance List: Talc (exempt if encapsulated or if particulates are not present or cannot be generated through use of this product)

Minnesota Hazardous Substance List: Talc as a nuisance dust

New Jersey Right-to-Know Substance List: Talc

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North Carolina: Talc as a nuisance dust

Pennsylvania Right-to-Know Hazardous Substance List: Talc @ 1% or greater

Rhode Island Hazardous Substances Right-to-Know Act: Talc

16. Other Information

The information contained in this Material 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 Material Safety Data Sheet relate only to the specific material designated herein and does not relate to use in combination with any other material. The data in this Material Safety Data Sheet are subject to revision as additional knowledge and experience are gained.

This MSDS was prepared for Purdue Pharma L.P. by the Occupational and Environmental Assessment Section of Purdue Pharma L.P. and Ariel Research Corporation.

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Material Safety Data Sheet

OxyContin[®] 15mg
(oxycodone hydrochloride
controlled release) Tablets

Version: 29-Jan-08

1. CHEMICAL PRODUCT/COMPANY IDENTIFICATION

Material Identification: OxyContin[®] 15mg Tablets

Chemical Name: mixture, not applicable

Active Ingredient:

4, 5-epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-one hydrochloride

Synonyms

Active Ingredient:

14-hydroxydihydrocodeinone hydrochloride

Molecular Formula: mixture

Molecular Weight: mixture

Active Ingredient: C₁₈H₂₁NO₄·HCl

Active Ingredient: 351.83

CAS Number: mixture, N/A

Active Ingredient: 124-90-3

Product Use: opioid analgesic

Company Identification:

Responsible Party

Purdue Pharma, L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901-3431
Telephone: (888) 726-7535

EMERGENCY CONTACT

Chemtrec (800) 424- 9300. For all international transportation emergencies call
Chemtrec collect at (703) 527-3887.

2. HAZARDOUS COMPONENTS

<u>Material</u>	<u>CAS Number</u>	<u>%</u>
Oxycodone Hydrochloride	124-90-3	7.7
Talc	14807-96-6	1.9

3. Hazards Identification

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Emergency Overview

White unscored, film-coated, controlled-release tablet
Slight, varnish-like odor

OxyContin[®] tablets do not pose a significant workplace hazard unless tablets are broken or crushed. The following information is provided for those circumstances where uncontrolled exposure to oxycodone may occur due to breakage or crushing of the OxyContin[®] tablet.

Target organs: central nervous system, gastrointestinal tract, cardiovascular system, respiratory tract

Serious overdosage of oxycodone produces respiratory depression, extreme somnolence, stupor or coma, skeletal muscle flaccidity, cold and clammy skin, bradycardia and hypotension.

Severe overdosage produces apnea, circulatory collapse, cardiac arrest, and death.

Broken or crushed tablets may be fatal if ingested.

Broken or crushed tablets may be harmful by inhalation or skin contact.

Contact with broken or crushed tablets, may cause eye and skin irritation.

Repetitive contact with broken or crushed tablets may cause allergic skin reactions.

Exposure to broken or crushed tablets may cause pinpoint pupils.

Potential Health Effects

OxyContin[®] is a film-coated, controlled-release tablet product. It does not pose a hazard under normal workplace handling conditions.

The active ingredient of OxyContin[®] is oxycodone, an orally active opioid analgesic approximately twice the potency of morphine. OxyContin[®] is designed to provide controlled release of oxycodone in the body. If OxyContin[®] tablets are broken or crushed, workplace exposure to oxycodone may occur. The following information is provided for those circumstances where uncontrolled exposure to the hazardous components in OxyContin[®] may occur due to breakage or crushing of the tablet.

Oxycodone

Oxycodone hydrochloride may cause eye irritation and mild skin irritation.

Repetitive exposure to oxycodone hydrochloride may cause skin and/or respiratory allergies. Systemic absorption may occur through skin.

Overdosage may cause dizziness, euphoria, flushing, itching, hypotension, pinpoint pupils, nausea/vomiting, constipation, and reduced urination.

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Serious overdose produces respiratory depression, extreme somnolence, stupor or coma, skeletal muscle flaccidity, cold and clammy skin, bradycardia and hypotension.

Severe overdosage produces apnea, circulatory collapse, cardiac arrest, and death.

Maternal exposure to OxyContin[®] may cause respiratory depression in the neonate. Repeated maternal exposure to oxycodone hydrochloride may produce respiratory depression and/or withdrawal in the neonate.

Talc

If crushed, exposure to talc can cause eye, skin, nose, throat and lung irritation resulting in coughing, wheezing and shortness of breath. Long term overexposure to talc is associated with talc pneumoconiosis. Symptoms include shortness of breath, clubbing of fingers, coughing with sputum, changes in lung x-ray, chronic lung disease with impaired lung function and can cause right-sided heart failure.

Conditions that may be aggravated by exposure to broken or crushed OxyContin[®] tablets include significant chronic obstructive lung disease, asthma, and hypotension.

Carcinogenicity Information

OxyContin[®] and its components are not listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

4. First Aid Measures

First Aid

INHALATION

If dusts are inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician (see notes to physician below). If allergic reactions occur (e.g., stuffy, runny or itchy nose, itchy throat, sneezing, watery/itchy eyes, etc.) see a physician.

SKIN CONTACT

Remove contaminated clothing. Flush skin with plenty of water and wash thoroughly with soap and water. If irritation (redness, itching, swelling) develops, seek medical attention. Wash contaminated clothing before reuse.

EYE CONTACT

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. See a physician.

INGESTION

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If swallowed, immediately give 2 glasses of water and induce vomiting under the direction of medical personnel. Never give anything by mouth to an unconscious person. Call a physician.

Notes to Physicians

OxyContin[®] (oxycodone hydrochloride controlled-release) Tablet is a pure opioid agonist with an analgesic potency about twice that of morphine. The extended release of oxycodone from OxyContin tablets should be taken into account when treating an overdose due to ingestion of intact tablets. Naloxone is a specific antidote against respiratory depression from opioid overdose. Opioid antagonists should not be administered in the absence of clinically significant respiratory or circulatory depression secondary to oxycodone overdose.

In cases of overdosage, 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 overdose as indicated. Cardiac arrest or arrhythmias may require cardiac massage or defibrillation.

If ingested and the patient is conscious, induction of emesis may be indicated. Gastric lavage may be indicated if the patient is unconscious.

5. Fire Fighting Measures

Flammable Properties

OxyContin[®] tablets are not considered flammable. However, concentrated dust from broken or crushed tablets may pose a dust explosion hazard. Eliminate sources of ignition. Bond and ground as necessary. Use non-sparking tools.

For Oxycodone

Minimum ignition energy: 10-25 mJ

Minimum ignition temperature – dust cloud: 420-440°C

Maximum explosion pressure (20 L sphere): 9.4 bar

Maximum rate of pressure rise: 779 bar/sec

K_{st}: 212 bar·m/sec

Extinguishing Media

Water spray, carbon dioxide, dry chemical powder, or foam as appropriate for the surrounding material.

Fire Fighting Instructions

Evacuate personnel to a safe area. Keep personnel removed and upwind of fire. Wear self-contained breathing apparatus. Wear full protective equipment.

6. Accidental Release Measures

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Safeguards (Personnel)

NOTE: Review FIRE FIGHTING MEASURES and HANDLING (PERSONNEL) sections before proceeding with clean-up. Use appropriate PERSONAL PROTECTIVE EQUIPMENT during clean-up to minimize exposure to this material. Evacuate personnel from the area.

Initial Containment

Prevent material from entering sewers, waterways, or low areas. Dike area for later disposal.

Spill Clean-up

Wear suitable protective clothing and equipment. Sweep up intact tablets or vacuum up broken or crushed tablets and place collected material into a suitable container for reclamation or disposal. Thoroughly wash area with detergent and water. Oxycodone 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

Handling (Personnel)

Do not 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.

Handling (Physical Aspects)

Close container after each use. Do not generate dust.

Storage

Oxycodone is a Schedule II controlled substance. Keep containers of OxyContin[®] tightly closed. Protect from light. To maintain potency, store at 25°C (77°F) and control temperature excursions to between 15-30°C (59-86°F).

8. Exposure Controls/Personal Protection

Engineering Controls

Handle material under adequate ventilation. Keep container tightly closed.

Personal Protective Equipment

Wear safety glasses with side shields if exposure to dust is possible. Wear full-face protection when judged that the possibility exists for eye and face contact.

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Wear an appropriate NIOSH-approved air purifying respirator or positive pressure air-supplied respirator in situations where a respirator is judged appropriate to prevent inhalation of dust.

Wear impervious clothing such as gloves, lab coat, shoe covers, apron, or jumpsuit, as appropriate, to prevent skin contact if exposure to broken or crushed tablets is possible. Consult the site safety professional for additional guidance, as needed.

Exposure Guidelines

Exposure Limits

None for OxyContin[®]

Oxycodone hydrochloride

PEL (OSHA): None established

TLV (ACGIH): None established

Purdue (Occupational Exposure Guideline): 40 µg/m³ (free base)

Talc (containing no asbestos fibers, respirable particulates):

TLV (ACGIH): 2 mg/m³ 8 hr shift

PEL (OSHA): 2 mg/m³ 8 hr shift

Talc (containing no asbestos and less than 1% quartz):

NIOSH (REL): 2 mg/m³ 10 hr shift

NIOSH (IDLH): 1,000 mg/m³

California (talc as a nuisance and particulate dust or respirable fraction)

(OEL): 5 mg/m³

Exposure Guideline Comments

For Oxycodone

May be absorbed through skin (crushed tablets); may cause skin or respiratory sensitization

9. Physical and Chemical Properties

Physical Data

For Oxycodone Hydrochloride:

Odor: odorless

Form: powder (solid)

Color: white to off-white

Vapor Pressure: no information available

Melting Point: 270-272°C

K_{ow}: <1 (pH 7); <10 (pH 9)

Solubility: 10gm in 100g of water

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10. Stability and Reactivity

Chemical Stability

Low stability hazard expected at normal operating temperatures.

Incompatibility with Other Materials

Strong oxidizers, acids, bases

Oxidizing materials will increase the risk of fire and explosion (e.g., potassium perchlorate, potassium nitrate)

Conditions to Avoid

Static charge, sparks, generation of dust, and temperatures above 200°C

Decomposition

Will not decompose under conditions of usual handling. Heating to decomposition may release acrid smoke and fumes.

Polymerization

Material will not polymerize.

11. Toxicological Information

Relevant Data

The following data for oxycodone hydrochloride are reflected as oxycodone free base. The information for talc is for non-asbestos containing material.

Skin/Eyes

Oxycodone

Oxycodone has not been evaluated in skin and eye irritation studies in animals. It is expected that oxycodone may produce mild skin irritation and may cause eye irritation.

Talc

Draize (human): 300 µg/3D mild reaction

Talc is not a primary skin irritant and it does not cause sensitization. Talc particles are physical irritants which cause inflammatory changes such as skin rash and can cause serious eye damage.

Acute

Oxycodone

LD₅₀: oral: 482 mg/kg (mouse)

LD₅₀: IP: 250 mg/kg (mouse)

LDL: IV: 20 mg/kg (rat)

Talc

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LD₅₀: oral: 920 mg/kg (rat)

Subchronic

Oxycodone

In a 10-day oral study in rats, 4.5 mg/kg/day (lowest dose tested) produced stereotypic behavior and increased activity only after 5 days of treatment. At 45 mg/kg/day, stereotypic behavior, body rigidity, labored breathing was observed on the first day of dosing. Animals that received ≥ 90 mg/kg/day did not survive past two days of dosing.

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; ≥ 22 mg/kg/day 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, and 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 ≥ 1 mg/kg/day produced effects similar to those observed in the 28-day study.

Chronic Toxicity

Oxycodone

No information available

Talc

No information available

Carcinogenicity

Oxycodone

No information available

Talc

Inhalation Studies

Purdue Pharma L.P.

Rats were exposed to non-asbestiform talc aerosols (0, 6, or 18 mg/m³) for 6 hours a day for 5 days a week for as long as 113 weeks for males and 122 weeks for females. Rats exhibited a concentration-time related increase in lung talc burden and impairment of lung function (total and vital lung capacities, compliance, gas exchange efficiency). Lung weights for rats in the 18mg/m³ group were greater than control values during and at the end of the study. Inhalation exposure produced inflammatory, reparative, and proliferative processes in the lungs. Female, but not male, rats in the 18 mg/m³ group exhibited clear evidence of carcinogenic activity in the lungs. Male, but not female, rats in the 18 mg/m³ group exhibited some evidence of carcinogenic activity in the adrenal gland (increased incidence of pheochromocytomas).

Mice were exposed to non-asbestiform talc aerosols (0, 6, 18 mg/m³) for 6 hours a day for 5 days a week for up to 104 weeks. The mice in the study exhibited a concentration-time increase in lung talc burden; lung function was not measured in this study. Talc inhalation was associated with chronic active inflammation in the lung but the proliferative changes observed in rats were not observed in the mice. There was no evidence of carcinogenic activity in the male or female mice.

Mutagenicity/Genotoxicity

Oxycodone

Bacterial mutagenicity: negative

Mouse micronucleus: negative

Human lymphocyte chromosome aberration: weakly positive

Mouse lymphoma: positive

Talc

Bacterial mutagenicity: negative

Developmental/Reproductive Toxicity

Oxycodone

Oxycodone administration to rats at dosages as high as 8 mg/kg/day had no effect on fertility or general reproductive performance.

Oxycodone did not produce developmental toxicity in rats or rabbits at dosages as high as 8 and 125 mg/kg/day, respectively.

Pups born to rats treated with oxycodone at a dosage of 6 mg/kg/day during late gestation through weaning had low body weight through lactation and the early growth phase. There was no effect on survival of the offspring. The no adverse effect level for the finding was 2 mg/kg/day.

Repetitive maternal exposure to opioids has been associated with respiratory depression and/or withdrawal symptoms in neonates.

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Oxycodone has been detected in breast milk.

Talc

Mice and rats were fed up to 1,600 mg/kg/day during pregnancy. Hamsters received 1,200 mg/kg/day during pregnancy and rabbits received 90-900 mg/kg/day orally during pregnancy. There was no evidence of teratogenicity or embryotoxicity in these species at these dosages.

12. Ecological Information

Ecotoxicological Information

Oxycodone HCl

24 hr LC₅₀: Daphnia magna: 300 mg/mL

Microbial Growth Inhibition EC₁₀: 7 species: > 1,000 mg/mL

Chemical Fate Information

Oxycodone HCl

Aerobic biodegradation: sewer sludge: est. t_{1/2}: 276 days

13. Disposal Considerations

Disposal

This material is not listed under US RCRA. It is a Schedule II drug. Disposal of this material must be in accordance with federal, state/provincial, and local regulations.

14. Transportation Information

Shipping Information

This material is non-hazardous under US DOT.

15. Regulatory/Statutory Information

US Federal: OxyContin[®] (Oxycodone preparations) are subject to control under the US Federal Controlled Substances Act of 1970 as schedule II (C-II) drugs.

California Hazardous Substance List: Talc (exempt if no inhalable dust is present or can be generated through use), polyvinylpyrrolidone

Illinois Toxic Substance Disclosure to Employees Act: Talc as a nuisance dust

Indiana OSHA Approved Implementation Plan: Talc, nuisance dust

Kentucky OSHA Approved Implementation Plan: Talc, nuisance dust

Massachusetts Right-to-Know Substance List: Talc (exempt if encapsulated or if particulates are not present or cannot be generated through use of this product)

Minnesota Hazardous Substance List: Talc as a nuisance dust

New Jersey Right-to-Know Substance List: Talc

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North Carolina: Talc as a nuisance dust

Pennsylvania Right-to-Know Hazardous Substance List: Talc @ 1% or greater

Rhode Island Hazardous Substances Right-to-Know Act: Talc

16. Other Information

The information contained in this Material 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 Material Safety Data Sheet relate only to the specific material designated herein and does not relate to use in combination with any other material. The data in this Material Safety Data Sheet are subject to revision as additional knowledge and experience are gained.

This MSDS was prepared for Purdue Pharma L.P. by the Occupational and Environmental Assessment Section of Purdue Pharma L.P. and Ariel Research Corporation.

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Material Safety Data Sheet

OxyContin[®] 20mg
(oxycodone hydrochloride
controlled release) Tablets

Version: 3-Jan-08

1. CHEMICAL PRODUCT/COMPANY IDENTIFICATION

Material Identification: OxyContin[®] 20mg Tablets

Chemical Name: mixture, not applicable

Active Ingredient:

4, 5-epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-one hydrochloride

Synonyms

Active Ingredient:

14-hydroxydihydrocodeinone hydrochloride

Molecular Formula: mixture

Molecular Weight: mixture

Active Ingredient: C₁₈H₂₁NO₄·HCl

Active Ingredient: 351.83

CAS Number: mixture, N/A

Active Ingredient: 124-90-3

Product Use: opioid analgesic

Company Identification:

Responsible Party

Purdue Pharma, L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901-3431
Telephone: (888) 726-7535

EMERGENCY CONTACT

Chemtrec (800) 424- 9300. For all international transportation emergencies call
Chemtrec collect at (703) 527-3887.

2. HAZARDOUS COMPONENTS

<u>Material</u>	<u>CAS Number</u>	<u>%</u>
Oxycodone Hydrochloride	124-90-3	12.37
Talc	14807-96-6	1.74

3. Hazards Identification

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Emergency Overview

Pink unscored, film-coated, controlled-release tablet
Slight, varnish-like odor

Target organs: central nervous system, gastrointestinal tract, cardiovascular system, respiratory tract

Serious overdosage of oxycodone produces respiratory depression, extreme somnolence, stupor or coma, skeletal muscle flaccidity, cold and clammy skin, bradycardia and hypotension.

Severe overdosage produces apnea, circulatory collapse, cardiac arrest, and death.

OxyContin[®] tablets do not pose a significant workplace hazard unless tablets are broken or crushed. The following information is provided for those circumstances where uncontrolled exposure to oxycodone may occur due to breakage or crushing of the OxyContin[®] tablet.

Broken or crushed tablets may be fatal if ingested.

Broken or crushed tablets may be harmful by inhalation or skin contact.

Contact with broken or crushed tablets, may cause eye and skin irritation.

Repetitive contact with broken or crushed tablets may cause allergic skin reactions.

Exposure to broken or crushed tablets may cause pinpoint pupils.

Potential Health Effects

OxyContin[®] is a film-coated, controlled-release tablet product. It does not pose a hazard under normal workplace handling conditions.

The active ingredient of OxyContin[®] is oxycodone, an orally active opioid analgesic approximately twice the potency of morphine. OxyContin[®] is designed to provide controlled release of oxycodone in the body. If OxyContin[®] tablets are broken or crushed, workplace exposure to oxycodone may occur. The following information is provided for those circumstances where uncontrolled exposure to the hazardous components in OxyContin[®] may occur due to breakage or crushing of the tablet.

Oxycodone

Oxycodone hydrochloride may cause eye irritation and mild skin irritation.

Repetitive exposure to oxycodone hydrochloride may cause skin and/or respiratory allergies. Systemic absorption may occur through skin.

Overdosage may cause dizziness, euphoria, flushing, itching, hypotension, pinpoint pupils, nausea/vomiting, constipation, and reduced urination.

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Serious overdose produces respiratory depression, extreme somnolence, stupor or coma, skeletal muscle flaccidity, cold and clammy skin, bradycardia and hypotension.

Severe overdosage produces apnea, circulatory collapse, cardiac arrest, and death.

Maternal exposure to OxyContin[®] may cause respiratory depression in the neonate. Repeated maternal exposure to oxycodone hydrochloride may produce respiratory depression and/or withdrawal in the neonate.

Talc

If crushed, exposure to talc can cause eye, skin, nose, throat and lung irritation resulting in coughing, wheezing and shortness of breath. Long term overexposure to talc is associated with talc pneumoconiosis. Symptoms include shortness of breath, clubbing of fingers, coughing with sputum, changes in lung x-ray, chronic lung disease with impaired lung function and can cause right-sided heart failure.

Conditions that may be aggravated by exposure to broken or crushed OxyContin[®] tablets include significant chronic obstructive lung disease, asthma, and hypotension.

Carcinogenicity Information

OxyContin[®] and its components are not listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

4. First Aid Measures

First Aid

INHALATION

If dusts are inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician (see notes to physician below). If allergic reactions occur (e.g., stuffy, runny or itchy nose, itchy throat, sneezing, watery/itchy eyes, etc.) see a physician.

SKIN CONTACT

Remove contaminated clothing. Flush skin with plenty of water and wash thoroughly with soap and water. If irritation (redness, itching, swelling) develops, seek medical attention. Wash contaminated clothing before reuse.

EYE CONTACT

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. See a physician.

INGESTION

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If swallowed, immediately give 2 glasses of water and induce vomiting under the direction of medical personnel. Never give anything by mouth to an unconscious person. Call a physician.

Notes to Physicians

OxyContin[®] (oxycodone hydrochloride controlled-release) Tablet is a pure opioid agonist with an analgesic potency about twice that of morphine. The extended release of oxycodone from OxyContin tablets should be taken into account when treating an overdose due to ingestion of intact tablets. Naloxone is a specific antidote against respiratory depression from opioid overdose. Opioid antagonists should not be administered in the absence of clinically significant respiratory or circulatory depression secondary to oxycodone overdose.

In cases of overdosage, 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 overdose as indicated. Cardiac arrest or arrhythmias may require cardiac massage or defibrillation.

If ingested and the patient is conscious, induction of emesis may be indicated. Gastric lavage may be indicated if the patient is unconscious.

5. Fire Fighting Measures

Flammable Properties

OxyContin[®] tablets are not considered flammable. However, concentrated dust from broken or crushed tablets may pose a dust explosion hazard. Eliminate sources of ignition. Bond and ground as necessary. Use non-sparking tools.

For Oxycodone

Minimum ignition energy: 10-25 mJ

Minimum ignition temperature – dust cloud: 420-440°C

Maximum explosion pressure (20 L sphere): 9.4 bar

Maximum rate of pressure rise: 779 bar/sec

K_{st}: 212 bar·m/sec

Extinguishing Media

Water spray, carbon dioxide, dry chemical powder, or foam as appropriate for the surrounding material.

Fire Fighting Instructions

Evacuate personnel to a safe area. Keep personnel removed and upwind of fire. Wear self-contained breathing apparatus. Wear full protective equipment.

6. Accidental Release Measures

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Safeguards (Personnel)

NOTE: Review FIRE FIGHTING MEASURES and HANDLING (PERSONNEL) sections before proceeding with clean-up. Use appropriate PERSONAL PROTECTIVE EQUIPMENT during clean-up to minimize exposure to this material. Evacuate personnel from the area.

Initial Containment

Prevent material from entering sewers, waterways, or low areas. Dike area for later disposal.

Spill Clean-up

Wear suitable protective clothing and equipment. Sweep up intact tablets or HEPA vacuum up broken or crushed tablets and place collected material into a suitable container for reclamation or disposal. Thoroughly wash area with detergent and water. Oxycodone 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

Handling (Personnel)

Do not 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.

Handling (Physical Aspects)

Close container after each use. Do not generate dust.

Storage

Oxycodone is a Schedule II controlled substance. Keep containers of OxyContin[®] tightly closed. Protect from light. To maintain potency, store at 25°C (77°F) and control temperature excursions to between 15-30°C (59-86°F).

8. Exposure Controls/Personal Protection

Engineering Controls

Handle material under adequate ventilation. Keep container tightly closed.

Personal Protective Equipment

Wear safety glasses with side shields if exposure to dust is possible. Wear full-face protection when judged that the possibility exists for eye and face contact.

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Wear an appropriate NIOSH-approved air purifying respirator or positive pressure air-supplied respirator in situations where a respirator is judged appropriate to prevent inhalation of dust.

Wear impervious clothing such as gloves, lab coat, shoe covers, apron, or jumpsuit, as appropriate, to prevent skin contact if exposure to broken or crushed tablets is possible. Consult the site safety professional for additional guidance, as needed.

Exposure Guidelines

Exposure Limits

None for OxyContin[®]

Oxycodone hydrochloride

PEL (OSHA): None established

TLV (ACGIH): None established

Purdue (Occupational Exposure Guideline): 40 µg/m³ (free base)

Talc (containing no asbestos fibers, respirable particulates):

TLV (ACGIH): 2 mg/m³ 8 hr shift

PEL (OSHA): 2 mg/m³ 8 hr shift

Talc (containing no asbestos and less than 1% quartz):

NIOSH (REL): 2 mg/m³ 10 hr shift

NIOSH (IDLH): 1,000 mg/m³

California (talc as a nuisance and particulate dust or respirable fraction)

(OEL): 5 mg/m³

Exposure Guideline Comments

For Oxycodone

May be absorbed through skin (crushed tablets); may cause skin or respiratory sensitization

9. Physical and Chemical Properties

Physical Data

For Oxycodone Hydrochloride:

Odor: odorless

Form: powder (solid)

Color: white to off-white

Vapor Pressure: no information available

Melting Point: 270-272°C

K_{ow}: <1 (pH 7); <10 (pH 9)

Solubility: 10gm in 100g of water

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10. Stability and Reactivity

Chemical Stability

Low stability hazard expected at normal operating temperatures.

Incompatibility with Other Materials

Strong oxidizers, acids, bases

Oxidizing materials will increase the risk of fire and explosion (e.g., potassium perchlorate, potassium nitrate)

Conditions to Avoid

Static charge, sparks, generation of dust, and temperatures above 200°C

Decomposition

Will not decompose under conditions of usual handling. Heating to decomposition may release acrid smoke and fumes.

Polymerization

Material will not polymerize.

11. Toxicological Information

Relevant Data

The following data for oxycodone hydrochloride are reflected as oxycodone free base. The information for talc is for non-asbestos containing material.

Skin/Eyes

Oxycodone

Oxycodone has not been evaluated in skin and eye irritation studies in animals. It is expected that oxycodone may produce mild skin irritation and may cause eye irritation.

Talc

Draize (human): 300 µg/3D mild reaction

Talc is not a primary skin irritant and it does not cause sensitization. Talc particles are physical irritants which cause inflammatory changes such as skin rash and can cause serious eye damage.

Acute

Oxycodone

LD₅₀: oral: 482 mg/kg (mouse)

LD₅₀: IP: 250 mg/kg (mouse)

LDL: IV: 20 mg/kg (rat)

Talc

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LD₅₀: oral: 920 mg/kg (rat)

Subchronic

Oxycodone

In a 10-day oral study in rats, 4.5 mg/kg/day (lowest dose tested) produced stereotypic behavior and increased activity only after 5 days of treatment. At 45 mg/kg/day, stereotypic behavior, body rigidity, labored breathing was observed on the first day of dosing. Animals that received ≥ 90 mg/kg/day did not survive past two days of dosing.

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; ≥ 22 mg/kg/day 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, and 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 ≥ 1 mg/kg/day produced effects similar to those observed in the 28-day study.

Chronic Toxicity

Oxycodone

No information available

Talc

No information available

Carcinogenicity

Oxycodone

No information available

Talc

Inhalation Studies

Purdue Pharma L.P.

Rats were exposed to non-asbestiform talc aerosols (0, 6, or 18 mg/m³) for 6 hours a day for 5 days a week for as long as 113 weeks for males and 122 weeks for females. Rats exhibited a concentration-time related increase in lung talc burden and impairment of lung function (total and vital lung capacities, compliance, gas exchange efficiency). Lung weights for rats in the 18mg/m³ group were greater than control values during and at the end of the study. Inhalation exposure produced inflammatory, reparative, and proliferative processes in the lungs. Female, but not male, rats in the 18 mg/m³ group exhibited clear evidence of carcinogenic activity in the lungs. Male, but not female, rats in the 18 mg/m³ group exhibited some evidence of carcinogenic activity in the adrenal gland (increased incidence of pheochromocytomas).

Mice were exposed to non-asbestiform talc aerosols (0, 6, 18 mg/m³) for 6 hours a day for 5 days a week for up to 104 weeks. The mice in the study exhibited a concentration-time increase in lung talc burden; lung function was not measured in this study. Talc inhalation was associated with chronic active inflammation in the lung but the proliferative changes observed in rats were not observed in the mice. There was no evidence of carcinogenic activity in the male or female mice.

Mutagenicity/Genotoxicity

Oxycodone

Bacterial mutagenicity: negative

Mouse micronucleus: negative

Human lymphocyte chromosome aberration: weakly positive

Mouse lymphoma: positive

Talc

Bacterial mutagenicity: negative

Developmental/Reproductive Toxicity

Oxycodone

Oxycodone administration to rats at dosages as high as 8 mg/kg/day had no effect on fertility or general reproductive performance.

Oxycodone did not produce developmental toxicity in rats or rabbits at dosages as high as 8 and 125 mg/kg/day, respectively.

Pups born to rats treated with oxycodone at a dosage of 6 mg/kg/day during late gestation through weaning had low body weight through lactation and the early growth phase. There was no effect on survival of the offspring. The no adverse effect level for the finding was 2 mg/kg/day.

Repetitive maternal exposure to opioids has been associated with respiratory depression and/or withdrawal symptoms in neonates.

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Oxycodone has been detected in breast milk.

Talc

Mice and rats were fed up to 1,600 mg/kg/day during pregnancy. Hamsters received 1,200 mg/kg/day during pregnancy and rabbits received 90-900 mg/kg/day orally during pregnancy. There was no evidence of teratogenicity or embryotoxicity in these species at these dosages.

12. Ecological Information

Ecotoxicological Information

Oxycodone HCl

24 hr LC₅₀: Daphnia magna: 300 mg/mL

Microbial Growth Inhibition EC₁₀: 7 species: > 1,000 mg/mL

Chemical Fate Information

Oxycodone HCl

Aerobic biodegradation: sewer sludge: est. t_{1/2}: 276 days

13. Disposal Considerations

Disposal

This material is not listed under US RCRA. It is a Schedule II drug. Disposal of this material must be in accordance with federal, state/provincial, and local regulations.

14. Transportation Information

Shipping Information

This material is non-hazardous under US DOT.

15. Regulatory/Statutory Information

US Federal: OxyContin[®] (Oxycodone preparations) are subject to control under the US Federal Controlled Substances Act of 1970 as schedule II (C-II) drugs.

California Hazardous Substance List: Talc (exempt if no inhalable dust is present or can be generated through use), polyvinylpyrrolidone

Illinois Toxic Substance Disclosure to Employees Act: Talc as a nuisance dust

Indiana OSHA Approved Implementation Plan: Talc, nuisance dust

Kentucky OSHA Approved Implementation Plan: Talc, nuisance dust

Massachusetts Right-to-Know Substance List: Talc (exempt if encapsulated or if particulates are not present or cannot be generated through use of this product)

Minnesota Hazardous Substance List: Talc as a nuisance dust

New Jersey Right-to-Know Substance List: Talc

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North Carolina: Talc as a nuisance dust

Pennsylvania Right-to-Know Hazardous Substance List: Talc @ 1% or greater

Rhode Island Hazardous Substances Right-to-Know Act: Talc

16. Other Information

The information contained in this Material 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 Material Safety Data Sheet relate only to the specific material designated herein and does not relate to use in combination with any other material. The data in this Material Safety Data Sheet are subject to revision as additional knowledge and experience are gained.

This MSDS was prepared for Purdue Pharma L.P. by the Occupational and Environmental Assessment Section of Purdue Pharma L.P. and Ariel Research Corporation.

Purdue Pharma L.P.

Material Safety Data Sheet

OxyContin[®] 30mg
(oxycodone hydrochloride
controlled release) Tablets

Version: 29-Jan-08

1. CHEMICAL PRODUCT/COMPANY IDENTIFICATION

Material Identification: OxyContin[®] 30mg Tablets

Chemical Name: mixture, not applicable

Active Ingredient:

4, 5-epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-one hydrochloride

Synonyms

Active Ingredient:

14-hydroxydihydrocodeinone hydrochloride

Molecular Formula: mixture

Molecular Weight: mixture

Active Ingredient: C₁₈H₂₁NO₄·HCl

Active Ingredient: 351.83

CAS Number: mixture, N/A

Active Ingredient: 124-90-3

Product Use: opioid analgesic

Company Identification:

Responsible Party

Purdue Pharma, L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901-3431
Telephone: (888) 726-7535

EMERGENCY CONTACT

Chemtrec (800) 424- 9300. For all international transportation emergencies call
Chemtrec collect at (703) 527-3887.

2. HAZARDOUS COMPONENTS

<u>Material</u>	<u>CAS Number</u>	<u>%</u>
Oxycodone Hydrochloride	124-90-3	15.4
Talc	14807-96-6	1.9

3. Hazards Identification

Purdue Pharma L.P.

Emergency Overview

Pink unscored, film-coated, controlled-release tablet
Slight, varnish-like odor

Target organs: central nervous system, gastrointestinal tract, cardiovascular system, respiratory tract

Serious overdosage of oxycodone produces respiratory depression, extreme somnolence, stupor or coma, skeletal muscle flaccidity, cold and clammy skin, bradycardia and hypotension.

Severe overdosage produces apnea, circulatory collapse, cardiac arrest, and death.

OxyContin[®] tablets do not pose a significant workplace hazard unless tablets are broken or crushed. The following information is provided for those circumstances where uncontrolled exposure to oxycodone may occur due to breakage or crushing of the OxyContin[®] tablet.

Broken or crushed tablets may be fatal if ingested.

Broken or crushed tablets may be harmful by inhalation or skin contact.

Contact with broken or crushed tablets, may cause eye and skin irritation.

Repetitive contact with broken or crushed tablets may cause allergic skin reactions.

Exposure to broken or crushed tablets may cause pinpoint pupils.

Potential Health Effects

OxyContin[®] is a film-coated, controlled-release tablet product. It does not pose a hazard under normal workplace handling conditions.

The active ingredient of OxyContin[®] is oxycodone, an orally active opioid analgesic approximately twice the potency of morphine. OxyContin[®] is designed to provide controlled release of oxycodone in the body. If OxyContin[®] tablets are broken or crushed, workplace exposure to oxycodone may occur. The following information is provided for those circumstances where uncontrolled exposure to the hazardous components in OxyContin[®] may occur due to breakage or crushing of the tablet.

Oxycodone

Oxycodone hydrochloride may cause eye irritation and mild skin irritation.

Repetitive exposure to oxycodone hydrochloride may cause skin and/or respiratory allergies. Systemic absorption may occur through skin.

Overdosage may cause dizziness, euphoria, flushing, itching, hypotension, pinpoint pupils, nausea/vomiting, constipation, and reduced urination.

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Serious overdose produces respiratory depression, extreme somnolence, stupor or coma, skeletal muscle flaccidity, cold and clammy skin, bradycardia and hypotension.

Severe overdosage produces apnea, circulatory collapse, cardiac arrest, and death.

Maternal exposure to OxyContin[®] may cause respiratory depression in the neonate. Repeated maternal exposure to oxycodone hydrochloride may produce respiratory depression and/or withdrawal in the neonate.

Talc

If crushed, exposure to talc can cause eye, skin, nose, throat and lung irritation resulting in coughing, wheezing and shortness of breath. Long term overexposure to talc is associated with talc pneumoconiosis. Symptoms include shortness of breath, clubbing of fingers, coughing with sputum, changes in lung x-ray, chronic lung disease with impaired lung function and can cause right-sided heart failure.

Conditions that may be aggravated by exposure to broken or crushed OxyContin[®] tablets include significant chronic obstructive lung disease, asthma, and hypotension.

Carcinogenicity Information

OxyContin[®] and its components are not listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

4. First Aid Measures

First Aid

INHALATION

If dusts are inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician (see notes to physician below). If allergic reactions occur (e.g., stuffy, runny or itchy nose, itchy throat, sneezing, watery/itchy eyes, etc.) see a physician.

SKIN CONTACT

Remove contaminated clothing. Flush skin with plenty of water and wash thoroughly with soap and water. If irritation (redness, itching, swelling) develops, seek medical attention. Wash contaminated clothing before reuse.

EYE CONTACT

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. See a physician.

INGESTION

Purdue Pharma L.P.

If swallowed, immediately give 2 glasses of water and induce vomiting under the direction of medical personnel. Never give anything by mouth to an unconscious person. Call a physician.

Notes to Physicians

OxyContin[®] (oxycodone hydrochloride controlled-release) Tablet is a pure opioid agonist with an analgesic potency about twice that of morphine. The extended release of oxycodone from OxyContin tablets should be taken into account when treating an overdose due to ingestion of intact tablets. Naloxone is a specific antidote against respiratory depression from opioid overdose. Opioid antagonists should not be administered in the absence of clinically significant respiratory or circulatory depression secondary to oxycodone overdose.

In cases of overdosage, 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 overdose as indicated. Cardiac arrest or arrhythmias may require cardiac massage or defibrillation.

If ingested and the patient is conscious, induction of emesis may be indicated. Gastric lavage may be indicated if the patient is unconscious.

5. Fire Fighting Measures

Flammable Properties

OxyContin[®] tablets are not considered flammable. However, concentrated dust from broken or crushed tablets may pose a dust explosion hazard. Eliminate sources of ignition. Bond and ground as necessary. Use non-sparking tools.

For Oxycodone

Minimum ignition energy: 10-25 mJ

Minimum ignition temperature – dust cloud: 420-440°C

Maximum explosion pressure (20 L sphere): 9.4 bar

Maximum rate of pressure rise: 779 bar/sec

K_{st}: 212 bar·m/sec

Extinguishing Media

Water spray, carbon dioxide, dry chemical powder, or foam as appropriate for the surrounding material.

Fire Fighting Instructions

Evacuate personnel to a safe area. Keep personnel removed and upwind of fire. Wear self-contained breathing apparatus. Wear full protective equipment.

6. Accidental Release Measures

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Safeguards (Personnel)

NOTE: Review FIRE FIGHTING MEASURES and HANDLING (PERSONNEL) sections before proceeding with clean-up. Use appropriate PERSONAL PROTECTIVE EQUIPMENT during clean-up to minimize exposure to this material. Evacuate personnel from the area.

Initial Containment

Prevent material from entering sewers, waterways, or low areas. Dike area for later disposal.

Spill Clean-up

Wear suitable protective clothing and equipment. Sweep up intact tablets or HEPA vacuum up broken or crushed tablets and place collected material into a suitable container for reclamation or disposal. Thoroughly wash area with detergent and water. Oxycodone 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

Handling (Personnel)

Do not 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.

Handling (Physical Aspects)

Close container after each use. Do not generate dust.

Storage

Oxycodone is a Schedule II controlled substance. Keep containers of OxyContin[®] tightly closed. Protect from light. To maintain potency, store at 25°C (77°F) and control temperature excursions to between 15-30°C (59-86°F).

8. Exposure Controls/Personal Protection

Engineering Controls

Handle material under adequate ventilation. Keep container tightly closed.

Personal Protective Equipment

Wear safety glasses with side shields if exposure to dust is possible. Wear full-face protection when judged that the possibility exists for eye and face contact.

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Wear an appropriate NIOSH-approved air purifying respirator or positive pressure air-supplied respirator in situations where a respirator is judged appropriate to prevent inhalation of dust.

Wear impervious clothing such as gloves, lab coat, shoe covers, apron, or jumpsuit, as appropriate, to prevent skin contact if exposure to broken or crushed tablets is possible. Consult the site safety professional for additional guidance, as needed.

Exposure Guidelines

Exposure Limits

None for OxyContin[®]

Oxycodone hydrochloride

PEL (OSHA): None established

TLV (ACGIH): None established

Purdue (Occupational Exposure Guideline): 40 $\mu\text{g}/\text{m}^3$ (free base)

Talc (containing no asbestos fibers, respirable particulates):

TLV (ACGIH): 2 mg/m^3 8 hr shift

PEL (OSHA): 2 mg/m^3 8 hr shift

Talc (containing no asbestos and less than 1% quartz):

NIOSH (REL): 2 mg/m^3 10 hr shift

NIOSH (IDLH): 1,000 mg/m^3

California (talc as a nuisance and particulate dust or respirable fraction)

(OEL): 5 mg/m^3

Exposure Guideline Comments

For Oxycodone

May be absorbed through skin (crushed tablets); may cause skin or respiratory sensitization

9. Physical and Chemical Properties

Physical Data

For Oxycodone Hydrochloride:

Odor: odorless

Form: powder (solid)

Color: white to off-white

Vapor Pressure: no information available

Melting Point: 270-272°C

K_{ow} : <1 (pH 7); <10 (pH 9)

Solubility: 10gm in 100g of water

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10. Stability and Reactivity

Chemical Stability

Low stability hazard expected at normal operating temperatures.

Incompatibility with Other Materials

Strong oxidizers, acids, bases

Oxidizing materials will increase the risk of fire and explosion (e.g., potassium perchlorate, potassium nitrate)

Conditions to Avoid

Static charge, sparks, generation of dust, and temperatures above 200°C

Decomposition

Will not decompose under conditions of usual handling. Heating to decomposition may release acrid smoke and fumes.

Polymerization

Material will not polymerize.

11. Toxicological Information

Relevant Data

The following data for oxycodone hydrochloride are reflected as oxycodone free base. The information for talc is for non-asbestos containing material.

Skin/Eyes

Oxycodone

Oxycodone has not been evaluated in skin and eye irritation studies in animals. It is expected that oxycodone may produce mild skin irritation and may cause eye irritation.

Talc

Draize (human): 300 µg/3D mild reaction

Talc is not a primary skin irritant and it does not cause sensitization. Talc particles are physical irritants which cause inflammatory changes such as skin rash and can cause serious eye damage.

Acute

Oxycodone

LD₅₀: oral: 482 mg/kg (mouse)

LD₅₀: IP: 250 mg/kg (mouse)

LDL: IV: 20 mg/kg (rat)

Talc

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LD₅₀: oral: 920 mg/kg (rat)

Subchronic

Oxycodone

In a 10-day oral study in rats, 4.5 mg/kg/day (lowest dose tested) produced stereotypic behavior and increased activity only after 5 days of treatment. At 45 mg/kg/day, stereotypic behavior, body rigidity, labored breathing was observed on the first day of dosing. Animals that received ≥ 90 mg/kg/day did not survive past two days of dosing.

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; ≥ 22 mg/kg/day 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, and 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 ≥ 1 mg/kg/day produced effects similar to those observed in the 28-day study.

Chronic Toxicity

Oxycodone

No information available

Talc

No information available

Carcinogenicity

Oxycodone

No information available

Talc

Inhalation Studies

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Rats were exposed to non-asbestiform talc aerosols (0, 6, or 18 mg/m³) for 6 hours a day for 5 days a week for as long as 113 weeks for males and 122 weeks for females. Rats exhibited a concentration-time related increase in lung talc burden and impairment of lung function (total and vital lung capacities, compliance, gas exchange efficiency). Lung weights for rats in the 18mg/m³ group were greater than control values during and at the end of the study. Inhalation exposure produced inflammatory, reparative, and proliferative processes in the lungs. Female, but not male, rats in the 18 mg/m³ group exhibited clear evidence of carcinogenic activity in the lungs. Male, but not female, rats in the 18 mg/m³ group exhibited some evidence of carcinogenic activity in the adrenal gland (increased incidence of pheochromocytomas).

Mice were exposed to non-asbestiform talc aerosols (0, 6, 18 mg/m³) for 6 hours a day for 5 days a week for up to 104 weeks. The mice in the study exhibited a concentration-time increase in lung talc burden; lung function was not measured in this study. Talc inhalation was associated with chronic active inflammation in the lung but the proliferative changes observed in rats were not observed in the mice. There was no evidence of carcinogenic activity in the male or female mice.

Mutagenicity/Genotoxicity

Oxycodone

Bacterial mutagenicity: negative

Mouse micronucleus: negative

Human lymphocyte chromosome aberration: weakly positive

Mouse lymphoma: positive

Talc

Bacterial mutagenicity: negative

Developmental/Reproductive Toxicity

Oxycodone

Oxycodone administration to rats at dosages as high as 8 mg/kg/day had no effect on fertility or general reproductive performance.

Oxycodone did not produce developmental toxicity in rats or rabbits at dosages as high as 8 and 125 mg/kg/day, respectively.

Pups born to rats treated with oxycodone at a dosage of 6 mg/kg/day during late gestation through weaning had low body weight through lactation and the early growth phase. There was no effect on survival of the offspring. The no adverse effect level for the finding was 2 mg/kg/day.

Repetitive maternal exposure to opioids has been associated with respiratory depression and/or withdrawal symptoms in neonates.

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Oxycodone has been detected in breast milk.

Talc

Mice and rats were fed up to 1,600 mg/kg/day during pregnancy. Hamsters received 1,200 mg/kg/day during pregnancy and rabbits received 90-900 mg/kg/day orally during pregnancy. There was no evidence of teratogenicity or embryotoxicity in these species at these dosages.

12. Ecological Information

Ecotoxicological Information

Oxycodone HCl

24 hr LC₅₀: Daphnia magna: 300 mg/mL

Microbial Growth Inhibition EC₁₀: 7 species: > 1,000 mg/mL

Chemical Fate Information

Oxycodone HCl

Aerobic biodegradation: sewer sludge: est. t_{1/2}: 276 days

13. Disposal Considerations

Disposal

This material is not listed under US RCRA. It is a Schedule II drug. Disposal of this material must be in accordance with federal, state/provincial, and local regulations.

14. Transportation Information

Shipping Information

This material is non-hazardous under US DOT.

15. Regulatory/Statutory Information

US Federal: OxyContin[®] (Oxycodone preparations) are subject to control under the US Federal Controlled Substances Act of 1970 as schedule II (C-II) drugs.

California Hazardous Substance List: Talc (exempt if no inhalable dust is present or can be generated through use), polyvinylpyrrolidone

Illinois Toxic Substance Disclosure to Employees Act: Talc as a nuisance dust

Indiana OSHA Approved Implementation Plan: Talc, nuisance dust

Kentucky OSHA Approved Implementation Plan: Talc, nuisance dust

Massachusetts Right-to-Know Substance List: Talc (exempt if encapsulated or if particulates are not present or cannot be generated through use of this product)

Minnesota Hazardous Substance List: Talc as a nuisance dust

New Jersey Right-to-Know Substance List: Talc

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North Carolina: Talc as a nuisance dust

Pennsylvania Right-to-Know Hazardous Substance List: Talc @ 1% or greater

Rhode Island Hazardous Substances Right-to-Know Act: Talc

16. Other Information

The information contained in this Material 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 Material Safety Data Sheet relate only to the specific material designated herein and does not relate to use in combination with any other material. The data in this Material Safety Data Sheet are subject to revision as additional knowledge and experience are gained.

This MSDS was prepared for Purdue Pharma L.P. by the Occupational and Environmental Assessment Section of Purdue Pharma L.P. and Ariel Research Corporation.

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Material Safety Data Sheet

OxyContin[®] 40mg
(oxycodone hydrochloride
controlled release) Tablets

Version: 3-Jan-08

1. CHEMICAL PRODUCT/COMPANY IDENTIFICATION

Material Identification: OxyContin[®] 40mg Tablets

Chemical Name: mixture, not applicable

Active Ingredient:

4, 5-epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-one hydrochloride

Synonyms

Active Ingredient:

14-hydroxydihydrocodeinone hydrochloride

Molecular Formula: mixture

Molecular Weight: mixture

Active Ingredient: C₁₈H₂₁NO₄·HCl

Active Ingredient: 351.83

CAS Number: mixture, N/A

Active Ingredient: 124-90-3

Product Use: opioid analgesic

Company Identification:

Responsible Party

Purdue Pharma, L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901-3431
Telephone: (888) 726-7535

EMERGENCY CONTACT

Chemtrec (800) 424- 9300. For all international transportation emergencies call
Chemtrec collect at (703) 527-3887.

2. HAZARDOUS COMPONENTS

<u>Material</u>	<u>CAS Number</u>	<u>%</u>
Oxycodone Hydrochloride	124-90-3	30.8
Talc	14807-96-6	1.9

3. Hazards Identification

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Emergency Overview

Yellow unscored, film-coated, controlled-release tablet
Slight, varnish-like odor

Target organs: central nervous system, gastrointestinal tract, cardiovascular system, respiratory tract

Serious overdosage of oxycodone produces respiratory depression, extreme somnolence, stupor or coma, skeletal muscle flaccidity, cold and clammy skin, bradycardia and hypotension.

Severe overdosage produces apnea, circulatory collapse, cardiac arrest, and death.

OxyContin[®] tablets do not pose a significant workplace hazard unless tablets are broken or crushed. The following information is provided for those circumstances where uncontrolled exposure to oxycodone may occur due to breakage or crushing of the OxyContin[®] tablet.

Broken or crushed tablets may be fatal if ingested

Broken or crushed tablets may be harmful by inhalation or skin contact

Contact with broken or crushed tablets, may cause eye and skin irritation

Repetitive contact with broken or crushed tablets may cause allergic skin reactions

Exposure to broken or crushed tablets may cause pinpoint pupils

Potential Health Effects

OxyContin[®] is a film-coated, controlled-release tablet product. It does not pose a hazard under normal workplace handling conditions.

The active ingredient of OxyContin[®] is oxycodone, an orally active opioid analgesic approximately twice the potency of morphine. OxyContin[®] is designed to provide controlled release of oxycodone in the body. If OxyContin[®] tablets are broken or crushed, workplace exposure to oxycodone may occur. The following information is provided for those circumstances where uncontrolled exposure to the hazardous components in OxyContin[®] may occur due to breakage or crushing of the tablet.

Oxycodone

Oxycodone hydrochloride may cause eye irritation and mild skin irritation.

Repetitive exposure to oxycodone hydrochloride may cause skin and/or respiratory allergies. Systemic absorption may occur through skin.

Overdosage may cause dizziness, euphoria, flushing, itching, hypotension, pinpoint pupils, nausea/vomiting, constipation, and reduced urination.

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Serious overdose produces respiratory depression, extreme somnolence, stupor or coma, skeletal muscle flaccidity, cold and clammy skin, bradycardia and hypotension.

Severe overdosage produces apnea, circulatory collapse, cardiac arrest, and death.

Maternal exposure to OxyContin[®] may cause respiratory depression in the neonate. Repeated maternal exposure to oxycodone hydrochloride may produce respiratory depression and/or withdrawal in the neonate.

Talc

If crushed, exposure to talc can cause eye, skin, nose, throat and lung irritation resulting in coughing, wheezing and shortness of breath. Long term overexposure to talc is associated with talc pneumoconiosis. Symptoms include shortness of breath, clubbing of fingers, coughing with sputum, changes in lung x-ray, chronic lung disease with impaired lung function and can cause right-sided heart failure.

Conditions that may be aggravated by exposure to broken or crushed OxyContin[®] tablets include significant chronic obstructive lung disease, asthma, and hypotension.

Carcinogenicity Information

OxyContin[®] and its components are not listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

4. First Aid Measures

First Aid

INHALATION

If dusts are inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician (see notes to physician below). If allergic reactions occur (e.g., stuffy, runny or itchy nose, itchy throat, sneezing, watery/itchy eyes, etc.) see a physician.

SKIN CONTACT

Remove contaminated clothing. Flush skin with plenty of water and wash thoroughly with soap and water. If irritation (redness, itching, swelling) develops, seek medical attention. Wash contaminated clothing before reuse.

EYE CONTACT

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. See a physician.

INGESTION

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If swallowed, immediately give 2 glasses of water and induce vomiting under the direction of medical personnel. Never give anything by mouth to an unconscious person. Call a physician.

Notes to Physicians

OxyContin[®] (oxycodone hydrochloride controlled-release) Tablet is a pure opioid agonist with an analgesic potency about twice that of morphine. The extended release of oxycodone from OxyContin tablets should be taken into account when treating an overdose due to ingestion of intact tablets. Naloxone is a specific antidote against respiratory depression from opioid overdose. Opioid antagonists should not be administered in the absence of clinically significant respiratory or circulatory depression secondary to oxycodone overdose.

In cases of overdosage, 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 overdose as indicated. Cardiac arrest or arrhythmias may require cardiac massage or defibrillation.

If ingested and the patient is conscious, induction of emesis may be indicated. Gastric lavage may be indicated if the patient is unconscious.

5. Fire Fighting Measures

Flammable Properties

OxyContin[®] tablets are not considered flammable. However, concentrated dust from broken or crushed tablets may pose a dust explosion hazard. Eliminate sources of ignition. Bond and ground as necessary. Use non-sparking tools.

For Oxycodone

Minimum ignition energy: 10-25 mJ

Minimum ignition temperature – dust cloud: 420-440°C

Maximum explosion pressure (20 L sphere): 9.4 bar

Maximum rate of pressure rise: 779 bar/sec

K_{st}: 212 bar·m/sec

Extinguishing Media

Water spray, carbon dioxide, dry chemical powder, or foam as appropriate for the surrounding material.

Fire Fighting Instructions

Evacuate personnel to a safe area. Keep personnel removed and upwind of fire. Wear self-contained breathing apparatus. Wear full protective equipment.

6. Accidental Release Measures

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Safeguards (Personnel)

NOTE: Review FIRE FIGHTING MEASURES and HANDLING (PERSONNEL) sections before proceeding with clean-up. Use appropriate PERSONAL PROTECTIVE EQUIPMENT during clean-up to minimize exposure to this material. Evacuate personnel from the area.

Initial Containment

Prevent material from entering sewers, waterways, or low areas. Dike area for later disposal.

Spill Clean-up

Wear suitable protective clothing and equipment. Sweep up intact tablets or HEPA vacuum up broken or crushed tablets and place collected material into a suitable container for reclamation or disposal. Thoroughly wash area with detergent and water. Oxycodone 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

Handling (Personnel)

Do not 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.

Handling (Physical Aspects)

Close container after each use. Do not generate dust.

Storage

Oxycodone is a Schedule II controlled substance. Keep containers of OxyContin[®] tightly closed. Protect from light. To maintain potency, store at 25°C (77°F) and control temperature excursions to between 15-30°C (59-86°F).

8. Exposure Controls/Personal Protection

Engineering Controls

Handle material under adequate ventilation. Keep container tightly closed.

Personal Protective Equipment

Wear safety glasses with side shields if exposure to dust is possible. Wear full-face protection when judged that the possibility exists for eye and face contact.

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Wear an appropriate NIOSH-approved air purifying respirator or positive pressure air-supplied respirator in situations where a respirator is judged appropriate to prevent inhalation of dust.

Wear impervious clothing such as gloves, lab coat, shoe covers, apron, or jumpsuit, as appropriate, to prevent skin contact if exposure to broken or crushed tablets is possible. Consult the site safety professional for additional guidance, as needed.

Exposure Guidelines

Exposure Limits

None for OxyContin[®]

Oxycodone hydrochloride

PEL (OSHA): None established

TLV (ACGIH): None established

Purdue (Occupational Exposure Guideline): 40 µg/m³ (free base)

Talc (containing no asbestos fibers, respirable particulates):

TLV (ACGIH): 2 mg/m³ 8 hr shift

PEL (OSHA): 2 mg/m³ 8 hr shift

Talc (containing no asbestos and less than 1% quartz):

NIOSH (REL): 2 mg/m³ 10 hr shift

NIOSH (IDLH): 1,000 mg/m³

California (talc as a nuisance and particulate dust or respirable fraction)

(OEL): 5 mg/m³

Exposure Guideline Comments

For Oxycodone

May be absorbed through skin (crushed tablets); may cause skin or respiratory sensitization

9. Physical and Chemical Properties

Physical Data

For Oxycodone Hydrochloride:

Odor: odorless

Form: powder (solid)

Color: white to off-white

Vapor Pressure: no information available

Melting Point: 270-272°C

K_{ow}: <1 (pH 7); <10 (pH 9)

Solubility: 10gm in 100g of water

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10. Stability and Reactivity

Chemical Stability

Low stability hazard expected at normal operating temperatures.

Incompatibility with Other Materials

Strong oxidizers, acids, bases

Oxidizing materials will increase the risk of fire and explosion (e.g., potassium perchlorate, potassium nitrate)

Conditions to Avoid

Static charge, sparks, generation of dust, and temperatures above 200°C

Decomposition

Will not decompose under conditions of usual handling. Heating to decomposition may release acrid smoke and fumes.

Polymerization

Material will not polymerize.

11. Toxicological Information

Relevant Data

The following data for oxycodone hydrochloride are reflected as oxycodone free base. The information for talc is for non-asbestos containing material.

Skin/Eyes

Oxycodone

Oxycodone has not been evaluated in skin and eye irritation studies in animals. It is expected that oxycodone may produce mild skin irritation and may cause eye irritation.

Talc

Draize (human): 300 µg/3D mild reaction

Talc is not a primary skin irritant and it does not cause sensitization. Talc particles are physical irritants which cause inflammatory changes such as skin rash and can cause serious eye damage.

Acute

Oxycodone

LD₅₀: oral: 482 mg/kg (mouse)

LD₅₀: IP: 250 mg/kg (mouse)

LDL: IV: 20 mg/kg (rat)

Talc

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LD₅₀: oral: 920 mg/kg (rat)

Subchronic

Oxycodone

In a 10-day oral study in rats, 4.5 mg/kg/day (lowest dose tested) produced stereotypic behavior and increased activity only after 5 days of treatment. At 45 mg/kg/day, stereotypic behavior, body rigidity, labored breathing was observed on the first day of dosing. Animals that received ≥ 90 mg/kg/day did not survive past two days of dosing.

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; ≥ 22 mg/kg/day 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, and 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 ≥ 1 mg/kg/day produced effects similar to those observed in the 28-day study.

Chronic Toxicity

Oxycodone

No information available

Talc

No information available

Carcinogenicity

Oxycodone

No information available

Talc

Inhalation Studies

Purdue Pharma L.P.

Rats were exposed to non-asbestiform talc aerosols (0, 6, or 18 mg/m³) for 6 hours a day for 5 days a week for as long as 113 weeks for males and 122 weeks for females. Rats exhibited a concentration-time related increase in lung talc burden and impairment of lung function (total and vital lung capacities, compliance, gas exchange efficiency). Lung weights for rats in the 18mg/m³ group were greater than control values during and at the end of the study. Inhalation exposure produced inflammatory, reparative, and proliferative processes in the lungs. Female, but not male, rats in the 18 mg/m³ group exhibited clear evidence of carcinogenic activity in the lungs. Male, but not female, rats in the 18 mg/m³ group exhibited some evidence of carcinogenic activity in the adrenal gland (increased incidence of pheochromocytomas).

Mice were exposed to non-asbestiform talc aerosols (0, 6, 18 mg/m³) for 6 hours a day for 5 days a week for up to 104 weeks. The mice in the study exhibited a concentration-time increase in lung talc burden; lung function was not measured in this study. Talc inhalation was associated with chronic active inflammation in the lung but the proliferative changes observed in rats were not observed in the mice. There was no evidence of carcinogenic activity in the male or female mice.

Mutagenicity/Genotoxicity

Oxycodone

Bacterial mutagenicity: negative

Mouse micronucleus: negative

Human lymphocyte chromosome aberration: weakly positive

Mouse lymphoma: positive

Talc

Bacterial mutagenicity: negative

Developmental/Reproductive Toxicity

Oxycodone

Oxycodone administration to rats at dosages as high as 8 mg/kg/day had no effect on fertility or general reproductive performance.

Oxycodone did not produce developmental toxicity in rats or rabbits at dosages as high as 8 and 125 mg/kg/day, respectively.

Pups born to rats treated with oxycodone at a dosage of 6 mg/kg/day during late gestation through weaning had low body weight through lactation and the early growth phase. There was no effect on survival of the offspring. The no adverse effect level for the finding was 2 mg/kg/day.

Repetitive maternal exposure to opioids has been associated with respiratory depression and/or withdrawal symptoms in neonates.

Purdue Pharma L.P.

Oxycodone has been detected in breast milk.

Talc

Mice and rats were fed up to 1,600 mg/kg/day during pregnancy. Hamsters received 1,200 mg/kg/day during pregnancy and rabbits received 90-900 mg/kg/day orally during pregnancy. There was no evidence of teratogenicity or embryotoxicity in these species at these dosages.

12. Ecological Information

Ecotoxicological Information

Oxycodone HCl

24 hr LC₅₀: Daphnia magna: 300 mg/mL

Microbial Growth Inhibition EC₁₀: 7 species: > 1,000 mg/mL

Chemical Fate Information

Oxycodone HCl

Aerobic biodegradation: sewer sludge: est. t_{1/2}: 276 days

13. Disposal Considerations

Disposal

This material is not listed under US RCRA. It is a Schedule II drug. Disposal of this material must be in accordance with federal, state/provincial, and local regulations.

14. Transportation Information

Shipping Information

This material is non-hazardous under US DOT.

15. Regulatory/Statutory Information

US Federal: OxyContin[®] (Oxycodone preparations) are subject to control under the US Federal Controlled Substances Act of 1970 as schedule II (C-II) drugs.

California Hazardous Substance List: Talc (exempt if no inhalable dust is present or can be generated through use), polyvinylpyrrolidone

Illinois Toxic Substance Disclosure to Employees Act: Talc as a nuisance dust

Indiana OSHA Approved Implementation Plan: Talc, nuisance dust

Kentucky OSHA Approved Implementation Plan: Talc, nuisance dust

Massachusetts Right-to-Know Substance List: Talc (exempt if encapsulated or if particulates are not present or cannot be generated through use of this product)

Minnesota Hazardous Substance List: Talc as a nuisance dust

New Jersey Right-to-Know Substance List: Talc

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North Carolina: Talc as a nuisance dust

Pennsylvania Right-to-Know Hazardous Substance List: Talc @ 1% or greater

Rhode Island Hazardous Substances Right-to-Know Act: Talc

16. Other Information

The information contained in this Material 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 Material Safety Data Sheet relate only to the specific material designated herein and does not relate to use in combination with any other material. The data in this Material Safety Data Sheet are subject to revision as additional knowledge and experience are gained.

This MSDS was prepared for Purdue Pharma L.P. by the Occupational and Environmental Assessment Section of Purdue Pharma L.P. and Ariel Research Corporation.

Purdue Pharma L.P.

Material Safety Data Sheet

OxyContin[®] 60mg
(oxycodone hydrochloride
controlled release) Tablets

Version: 29-Jan-08

1. CHEMICAL PRODUCT/COMPANY IDENTIFICATION

Material Identification: OxyContin[®] 60mg Tablets

Chemical Name: mixture, not applicable

Active Ingredient:

4, 5-epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-one hydrochloride

Synonyms

Active Ingredient:

14-hydroxydihydrocodeinone hydrochloride

Molecular Formula: mixture

Molecular Weight: mixture

Active Ingredient: C₁₈H₂₁NO₄·HCl

Active Ingredient: 351.83

CAS Number: mixture, N/A

Active Ingredient: 124-90-3

Product Use: opioid analgesic

Company Identification:

Responsible Party

Purdue Pharma, L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901-3431
Telephone: (888) 726-7535

EMERGENCY CONTACT

Chemtrec (800) 424- 9300. For all international transportation emergencies call
Chemtrec collect at (703) 527-3887.

2. HAZARDOUS COMPONENTS

<u>Material</u>	<u>CAS Number</u>	<u>%</u>
Oxycodone Hydrochloride	124-90-3	30.7
Talc	14807-96-6	1.9

3. Hazards Identification

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Emergency Overview

Green unscored, film-coated, controlled-release tablet
Slight, varnish-like odor

Target organs: central nervous system, gastrointestinal tract, cardiovascular system, respiratory tract

Serious overdosage of oxycodone produces respiratory depression, extreme somnolence, stupor or coma, skeletal muscle flaccidity, cold and clammy skin, bradycardia and hypotension.

Severe overdosage produces apnea, circulatory collapse, cardiac arrest, and death.

OxyContin[®] tablets do not pose a significant workplace hazard unless tablets are broken or crushed. The following information is provided for those circumstances where uncontrolled exposure to oxycodone may occur due to breakage or crushing of the OxyContin[®] tablet.

Broken or crushed tablets, may be fatal if ingested.

Broken or crushed tablets, may be harmful by inhalation or skin contact.

Contact with broken or crushed tablets, may cause eye and skin irritation.

Repetitive contact with broken or crushed tablets may cause allergic skin reactions.

Exposure to broken or crushed tablets may cause pinpoint pupils.

Potential Health Effects

OxyContin[®] is a film-coated, controlled-release tablet product. It does not pose a significant hazard under normal workplace handling conditions.

The active ingredient of OxyContin[®] is oxycodone, an orally active opioid analgesic approximately twice the potency of morphine. OxyContin[®] is designed to provide controlled release of oxycodone in the body. If OxyContin[®] tablets are broken or crushed, workplace exposure to oxycodone may occur. The following information is provided for those circumstances where uncontrolled exposure to the hazardous components in OxyContin[®] may occur due to breakage or crushing of the tablet.

Oxycodone

Oxycodone hydrochloride may cause eye irritation and mild skin irritation.

Repetitive exposure to oxycodone hydrochloride may cause skin and/or respiratory allergies. Systemic absorption may occur through skin.

Overdosage may cause dizziness, euphoria, flushing, itching, hypotension, pinpoint pupils, nausea/vomiting, constipation, and reduced urination.

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Serious overdose produces respiratory depression, extreme somnolence, stupor or coma, skeletal muscle flaccidity, cold and clammy skin, bradycardia and hypotension.

Severe overdosage produces apnea, circulatory collapse, cardiac arrest, and death.

Maternal exposure to OxyContin[®] may cause respiratory depression in the neonate. Repeated maternal exposure to oxycodone hydrochloride may produce respiratory depression and/or withdrawal in the neonate.

Talc

If crushed, exposure to talc can cause eye, skin, nose, throat and lung irritation resulting in coughing, wheezing and shortness of breath. Long term overexposure to talc is associated with talc pneumoconiosis. Symptoms include shortness of breath, clubbing of fingers, coughing with sputum, changes in lung x-ray, chronic lung disease with impaired lung function and can cause right-sided heart failure.

Conditions that may be aggravated by exposure to broken or crushed OxyContin[®] tablets include significant chronic obstructive lung disease, asthma, and hypotension.

Carcinogenicity Information

OxyContin[®] and its components are not listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

4. First Aid Measures

First Aid

INHALATION

If dusts are inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician (see notes to physician below). If allergic reactions occur (e.g., stuffy, runny or itchy nose, itchy throat, sneezing, watery/itchy eyes, etc.) see a physician.

SKIN CONTACT

Remove contaminated clothing. Flush skin with plenty of water and wash thoroughly with soap and water. If irritation (redness, itching, swelling) develops, seek medical attention. Wash contaminated clothing before reuse.

EYE CONTACT

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. See a physician.

INGESTION

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If swallowed, immediately give 2 glasses of water and induce vomiting under the direction of medical personnel. Never give anything by mouth to an unconscious person. Call a physician.

Notes to Physicians

OxyContin[®] (oxycodone hydrochloride controlled-release) Tablet is a pure opioid agonist with an analgesic potency about twice that of morphine. The extended release of oxycodone from OxyContin tablets should be taken into account when treating an overdose due to ingestion of intact tablets. Naloxone is a specific antidote against respiratory depression from opioid overdose. Opioid antagonists should not be administered in the absence of clinically significant respiratory or circulatory depression secondary to oxycodone overdose.

In cases of overdosage, 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 overdose as indicated. Cardiac arrest or arrhythmias may require cardiac massage or defibrillation.

If ingested and the patient is conscious, induction of emesis may be indicated. Gastric lavage may be indicated if the patient is unconscious.

5. Fire Fighting Measures

Flammable Properties

OxyContin[®] tablets are not considered flammable. However, concentrated dust from broken or crushed tablets may pose a dust explosion hazard. Eliminate sources of ignition. Bond and ground as necessary. Use non-sparking tools.

For Oxycodone

Minimum ignition energy: 10-25 mJ

Minimum ignition temperature – dust cloud: 420-440°C

Maximum explosion pressure (20 L sphere): 9.4 bar

Maximum rate of pressure rise: 779 bar/sec

K_{st}: 212 bar·m/sec

Extinguishing Media

Water spray, carbon dioxide, dry chemical powder, or foam as appropriate for the surrounding material.

Fire Fighting Instructions

Evacuate personnel to a safe area. Keep personnel removed and upwind of fire. Wear self-contained breathing apparatus. Wear full protective equipment.

6. Accidental Release Measures

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Safeguards (Personnel)

NOTE: Review FIRE FIGHTING MEASURES and HANDLING (PERSONNEL) sections before proceeding with clean-up. Use appropriate PERSONAL PROTECTIVE EQUIPMENT during clean-up to minimize exposure to this material. Evacuate personnel from the area.

Initial Containment

Prevent material from entering sewers, waterways, or low areas. Dike area for later disposal.

Spill Clean-up

Wear suitable protective clothing and equipment. Sweep up intact tablets or HEPA vacuum up broken or crushed tablets and place collected material into a suitable container for reclamation or disposal. Thoroughly wash area with detergent and water. Oxycodone 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

Handling (Personnel)

Do not 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.

Handling (Physical Aspects)

Close container after each use. Do not generate dust.

Storage

Oxycodone is a Schedule II controlled substance. Keep containers of OxyContin[®] tightly closed. Protect from light. To maintain potency, store at 25°C (77°F) and control temperature excursions to between 15-30°C (59-86°F).

8. Exposure Controls/Personal Protection

Engineering Controls

Handle material under adequate ventilation. Keep container tightly closed.

Personal Protective Equipment

Wear safety glasses with side shields if exposure to dust is possible. Wear full-face protection when judged that the possibility exists for eye and face contact.

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Wear an appropriate NIOSH-approved air purifying respirator or positive pressure air-supplied respirator in situations where a respirator is judged appropriate to prevent inhalation of dust.

Wear impervious clothing such as gloves, lab coat, shoe covers, apron, or jumpsuit, as appropriate, to prevent skin contact if exposure to broken or crushed tablets is possible. Consult the site safety professional for additional guidance, as needed.

Exposure Guidelines

Exposure Limits

None for OxyContin[®]

Oxycodone hydrochloride

PEL (OSHA): None established

TLV (ACGIH): None established

Purdue (Occupational Exposure Guideline): 40 µg/m³ (free base)

Talc (containing no asbestos fibers, respirable particulates):

TLV (ACGIH): 2 mg/m³ 8 hr shift

PEL (OSHA): 2 mg/m³ 8 hr shift

Talc (containing no asbestos and less than 1% quartz):

NIOSH (REL): 2 mg/m³ 10 hr shift

NIOSH (IDLH): 1,000 mg/m³

California (talc as a nuisance and particulate dust or respirable fraction)

(OEL): 5 mg/m³

Exposure Guideline Comments

For Oxycodone

May be absorbed through skin (crushed tablets); may cause skin or respiratory sensitization

9. Physical and Chemical Properties

Physical Data

For Oxycodone Hydrochloride:

Odor: odorless

Form: powder (solid)

Color: white to off-white

Vapor Pressure: no information available

Melting Point: 270-272°C

K_{ow}: <1 (pH 7); <10 (pH 9)

Solubility: 10gm in 100g of water

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10. Stability and Reactivity

Chemical Stability

Low stability hazard expected at normal operating temperatures.

Incompatibility with Other Materials

Strong oxidizers, acids, bases

Oxidizing materials will increase the risk of fire and explosion (e.g., potassium perchlorate, potassium nitrate)

Conditions to Avoid

Static charge, sparks, generation of dust, and temperatures above 200°C

Decomposition

Will not decompose under conditions of usual handling. Heating to decomposition may release acrid smoke and fumes.

Polymerization

Material will not polymerize.

11. Toxicological Information

Relevant Data

The following data for oxycodone hydrochloride are reflected as oxycodone free base. The information for talc is for non-asbestos containing material.

Skin/Eyes

Oxycodone

Oxycodone has not been evaluated in skin and eye irritation studies in animals. It is expected that oxycodone may produce mild skin irritation and may cause eye irritation.

Talc

Draize (human): 300 µg/3D mild reaction

Talc is not a primary skin irritant and it does not cause sensitization. Talc particles are physical irritants which cause inflammatory changes such as skin rash and can cause serious eye damage.

Acute

Oxycodone

LD₅₀: oral: 482 mg/kg (mouse)

LD₅₀: IP: 250 mg/kg (mouse)

LDL: IV: 20 mg/kg (rat)

Talc

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LD₅₀: oral: 920 mg/kg (rat)

Subchronic

Oxycodone

In a 10-day oral study in rats, 4.5 mg/kg/day (lowest dose tested) produced stereotypic behavior and increased activity only after 5 days of treatment. At 45 mg/kg/day, stereotypic behavior, body rigidity, labored breathing was observed on the first day of dosing. Animals that received ≥ 90 mg/kg/day did not survive past two days of dosing.

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; ≥ 22 mg/kg/day 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, and 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 ≥ 1 mg/kg/day produced effects similar to those observed in the 28-day study.

Chronic Toxicity

Oxycodone

No information available

Talc

No information available

Carcinogenicity

Oxycodone

No information available

Talc

Inhalation Studies

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Rats were exposed to non-asbestiform talc aerosols (0, 6, or 18 mg/m³) for 6 hours a day for 5 days a week for as long as 113 weeks for males and 122 weeks for females. Rats exhibited a concentration-time related increase in lung talc burden and impairment of lung function (total and vital lung capacities, compliance, gas exchange efficiency). Lung weights for rats in the 18mg/m³ group were greater than control values during and at the end of the study. Inhalation exposure produced inflammatory, reparative, and proliferative processes in the lungs. Female, but not male, rats in the 18 mg/m³ group exhibited clear evidence of carcinogenic activity in the lungs. Male, but not female, rats in the 18 mg/m³ group exhibited some evidence of carcinogenic activity in the adrenal gland (increased incidence of pheochromocytomas).

Mice were exposed to non-asbestiform talc aerosols (0, 6, 18 mg/m³) for 6 hours a day for 5 days a week for up to 104 weeks. The mice in the study exhibited a concentration-time increase in lung talc burden; lung function was not measured in this study. Talc inhalation was associated with chronic active inflammation in the lung but the proliferative changes observed in rats were not observed in the mice. There was no evidence of carcinogenic activity in the male or female mice.

Mutagenicity/Genotoxicity

Oxycodone

Bacterial mutagenicity: negative

Mouse micronucleus: negative

Human lymphocyte chromosome aberration: weakly positive

Mouse lymphoma: positive

Talc

Bacterial mutagenicity: negative

Developmental/Reproductive Toxicity

Oxycodone

Oxycodone administration to rats at dosages as high as 8 mg/kg/day had no effect on fertility or general reproductive performance.

Oxycodone did not produce developmental toxicity in rats or rabbits at dosages as high as 8 and 125 mg/kg/day, respectively.

Pups born to rats treated with oxycodone at a dosage of 6 mg/kg/day during late gestation through weaning had low body weight through lactation and the early growth phase. There was no effect on survival of the offspring. The no adverse effect level for the finding was 2 mg/kg/day.

Repetitive maternal exposure to opioids has been associated with respiratory depression and/or withdrawal symptoms in neonates.

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Oxycodone has been detected in breast milk.

Talc

Mice and rats were fed up to 1,600 mg/kg/day during pregnancy. Hamsters received 1,200 mg/kg/day during pregnancy and rabbits received 90-900 mg/kg/day orally during pregnancy. There was no evidence of teratogenicity or embryotoxicity in these species at these dosages.

12. Ecological Information

Ecotoxicological Information

Oxycodone HCl

24 hr LC₅₀: Daphnia magna: 300 mg/mL

Microbial Growth Inhibition EC₁₀: 7 species: > 1,000 mg/mL

Chemical Fate Information

Oxycodone HCl

aerobic biodegradation: sewer sludge: est. t_{1/2}: 276 days

13. Disposal Considerations

Disposal

This material is not listed under US RCRA. It is a Schedule II drug. Disposal of this material must be in accordance with federal, state/provincial, and local regulations.

14. Transportation Information

Shipping Information

This material is non-hazardous under US DOT.

15. Regulatory/Statutory Information

US Federal: OxyContin[®] (Oxycodone preparations) are subject to control under the US Federal Controlled Substances Act of 1970 as schedule II (C-II) drugs.

California Hazardous Substance List: Talc (exempt if no inhalable dust is present or can be generated through use); polyvinylpyrrolidone

Illinois Toxic Substance Disclosure to Employees Act: Talc as a nuisance dust

Indiana OSHA Approved Implementation Plan: Talc, nuisance dust

Kentucky OSHA Approved Implementation Plan: Talc, nuisance dust

Massachusetts Right-to-Know Substance List: Talc (exempt if encapsulated or if particulates are not present or cannot be generated through use of this product)

Minnesota Hazardous Substance List: Talc as a nuisance dust

New Jersey Right-to-Know Substance List: Talc

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North Carolina: Talc as a nuisance dust

Pennsylvania Right-to-Know Hazardous Substance List: Talc @ 1% or greater

Rhode Island Hazardous Substances Right-to-Know Act: Talc

16. Other Information

The information contained in this Material 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 Material Safety Data Sheet relate only to the specific material designated herein and does not relate to use in combination with any other material. The data in this Material Safety Data Sheet are subject to revision as additional knowledge and experience are gained.

This MSDS was prepared for Purdue Pharma L.P. by the Occupational and Environmental Assessment Section of Purdue Pharma L.P. and Ariel Research Corporation.

Purdue Pharma L.P.

Material Safety Data Sheet

OxyContin[®] 80mg
(oxycodone hydrochloride
controlled release) Tablets

Version: 3-Jan-08

1. CHEMICAL PRODUCT/COMPANY IDENTIFICATION

Material Identification: OxyContin[®] 80mg Tablets

Chemical Name: mixture, not applicable

Active Ingredient:

4, 5-epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-one hydrochloride

Synonyms

Active Ingredient:

14-hydroxydihydrocodeinone hydrochloride

Molecular Formula: mixture

Molecular Weight: mixture

Active Ingredient: C₁₈H₂₁NO₄·HCl

Active Ingredient: 351.83

CAS Number: mixture, N/A

Active Ingredient: 124-90-3

Product Use: opioid analgesic

Company Identification:

Responsible Party

Purdue Pharma, L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901-3431
Telephone: (888) 726-7535

EMERGENCY CONTACT

Chemtrec (800) 424- 9300. For all international transportation emergencies call
Chemtrec collect at (703) 527-3887.

2. HAZARDOUS COMPONENTS

<u>Material</u>	<u>CAS Number</u>	<u>%</u>
Oxycodone Hydrochloride	124-90-3	30.7
Talc	14807-96-6	1.9

3. Hazards Identification

Purdue Pharma L.P.

Emergency Overview

Green unscored, film-coated, controlled-release tablet
Slight, varnish-like odor

Target organs: central nervous system, gastrointestinal tract, cardiovascular system, respiratory tract

Serious overdosage of oxycodone produces respiratory depression, extreme somnolence, stupor or coma, skeletal muscle flaccidity, cold and clammy skin, bradycardia and hypotension.

Severe overdosage produces apnea, circulatory collapse, cardiac arrest, and death.

OxyContin[®] tablets do not pose a significant workplace hazard unless tablets are broken or crushed. The following information is provided for those circumstances where uncontrolled exposure to oxycodone may occur due to breakage or crushing of the OxyContin[®] tablet.

Broken or crushed tablets, may be fatal if ingested.

Broken or crushed tablets, may be harmful by inhalation or skin contact.

Contact with broken or crushed tablets, may cause eye and skin irritation.

Repetitive contact with broken or crushed tablets may cause allergic skin reactions.

Exposure to broken or crushed tablets may cause pinpoint pupils.

Potential Health Effects

OxyContin[®] is a film-coated, controlled-release tablet product. It does not pose a significant hazard under normal workplace handling conditions.

The active ingredient of OxyContin[®] is oxycodone, an orally active opioid analgesic approximately twice the potency of morphine. OxyContin[®] is designed to provide controlled release of oxycodone in the body. If OxyContin[®] tablets are broken or crushed, workplace exposure to oxycodone may occur. The following information is provided for those circumstances where uncontrolled exposure to the hazardous components in OxyContin[®] may occur due to breakage or crushing of the tablet.

Oxycodone

Oxycodone hydrochloride may cause eye irritation and mild skin irritation.

Repetitive exposure to oxycodone hydrochloride may cause skin and/or respiratory allergies. Systemic absorption may occur through skin.

Overdosage may cause dizziness, euphoria, flushing, itching, hypotension, pinpoint pupils, nausea/vomiting, constipation, and reduced urination.

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Serious overdose produces respiratory depression, extreme somnolence, stupor or coma, skeletal muscle flaccidity, cold and clammy skin, bradycardia and hypotension.

Severe overdosage produces apnea, circulatory collapse, cardiac arrest, and death.

Maternal exposure to OxyContin[®] may cause respiratory depression in the neonate. Repeated maternal exposure to oxycodone hydrochloride may produce respiratory depression and/or withdrawal in the neonate.

Talc

If crushed, exposure to talc can cause eye, skin, nose, throat and lung irritation resulting in coughing, wheezing and shortness of breath. Long term overexposure to talc is associated with talc pneumoconiosis. Symptoms include shortness of breath, clubbing of fingers, coughing with sputum, changes in lung x-ray, chronic lung disease with impaired lung function and can cause right-sided heart failure.

Conditions that may be aggravated by exposure to broken or crushed OxyContin[®] tablets include significant chronic obstructive lung disease, asthma, and hypotension.

Carcinogenicity Information

OxyContin[®] and its components are not listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

4. First Aid Measures

First Aid

INHALATION

If dusts are inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician (see notes to physician below). If allergic reactions occur (e.g., stuffy, runny or itchy nose, itchy throat, sneezing, watery/itchy eyes, etc.) see a physician.

SKIN CONTACT

Remove contaminated clothing. Flush skin with plenty of water and wash thoroughly with soap and water. If irritation (redness, itching, swelling) develops, seek medical attention. Wash contaminated clothing before reuse.

EYE CONTACT

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. See a physician.

INGESTION

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If swallowed, immediately give 2 glasses of water and induce vomiting under the direction of medical personnel. Never give anything by mouth to an unconscious person. Call a physician.

Notes to Physicians

OxyContin[®] (oxycodone hydrochloride controlled-release) Tablet is a pure opioid agonist with an analgesic potency about twice that of morphine. The extended release of oxycodone from OxyContin tablets should be taken into account when treating an overdose due to ingestion of intact tablets. Naloxone is a specific antidote against respiratory depression from opioid overdose. Opioid antagonists should not be administered in the absence of clinically significant respiratory or circulatory depression secondary to oxycodone overdose.

In cases of overdosage, 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 overdose as indicated. Cardiac arrest or arrhythmias may require cardiac massage or defibrillation.

If ingested and the patient is conscious, induction of emesis may be indicated. Gastric lavage may be indicated if the patient is unconscious.

5. Fire Fighting Measures

Flammable Properties

OxyContin[®] tablets are not considered flammable. However, concentrated dust from broken or crushed tablets may pose a dust explosion hazard. Eliminate sources of ignition. Bond and ground as necessary. Use non-sparking tools.

For Oxycodone

Minimum ignition energy: 10-25 mJ

Minimum ignition temperature – dust cloud: 420-440°C

Maximum explosion pressure (20 L sphere): 9.4 bar

Maximum rate of pressure rise: 779 bar/sec

K_{st}: 212 bar·m/sec

Extinguishing Media

Water spray, carbon dioxide, dry chemical powder, or foam as appropriate for the surrounding material.

Fire Fighting Instructions

Evacuate personnel to a safe area. Keep personnel removed and upwind of fire. Wear self-contained breathing apparatus. Wear full protective equipment.

6. Accidental Release Measures

Purdue Pharma L.P.

Safeguards (Personnel)

NOTE: Review FIRE FIGHTING MEASURES and HANDLING (PERSONNEL) sections before proceeding with clean-up. Use appropriate PERSONAL PROTECTIVE EQUIPMENT during clean-up to minimize exposure to this material. Evacuate personnel from the area.

Initial Containment

Prevent material from entering sewers, waterways, or low areas. Dike area for later disposal.

Spill Clean-up

Wear suitable protective clothing and equipment. Sweep up intact tablets or HEPA vacuum up broken or crushed tablets and place collected material into a suitable container for reclamation or disposal. Thoroughly wash area with detergent and water. Oxycodone 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

Handling (Personnel)

Do not 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.

Handling (Physical Aspects)

Close container after each use. Do not generate dust.

Storage

Oxycodone is a Schedule II controlled substance. Keep containers of OxyContin[®] tightly closed. Protect from light. To maintain potency, store at 25°C (77°F) and control temperature excursions to between 15-30°C (59-86°F).

8. Exposure Controls/Personal Protection

Engineering Controls

Handle material under adequate ventilation. Keep container tightly closed.

Personal Protective Equipment

Wear safety glasses with side shields if exposure to dust is possible. Wear full-face protection when judged that the possibility exists for eye and face contact.

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Wear an appropriate NIOSH-approved air purifying respirator or positive pressure air-supplied respirator in situations where a respirator is judged appropriate to prevent inhalation of dust.

Wear impervious clothing such as gloves, lab coat, shoe covers, apron, or jumpsuit, as appropriate, to prevent skin contact if exposure to broken or crushed tablets is possible. Consult the site safety professional for additional guidance, as needed.

Exposure Guidelines

Exposure Limits

None for OxyContin[®]

Oxycodone hydrochloride

PEL (OSHA): None established

TLV (ACGIH): None established

Purdue (Occupational Exposure Guideline): 40 µg/m³ (free base)

Talc (containing no asbestos fibers, respirable particulates):

TLV (ACGIH): 2 mg/m³ 8 hr shift

PEL (OSHA): 2 mg/m³ 8 hr shift

Talc (containing no asbestos and less than 1% quartz):

NIOSH (REL): 2 mg/m³ 10 hr shift

NIOSH (IDLH): 1,000 mg/m³

California (talc as a nuisance and particulate dust or respirable fraction)

(OEL): 5 mg/m³

Exposure Guideline Comments

For Oxycodone

May be absorbed through skin (crushed tablets); may cause skin or respiratory sensitization

9. Physical and Chemical Properties

Physical Data

For Oxycodone Hydrochloride:

Odor: odorless

Form: powder (solid)

Color: white to off-white

Vapor Pressure: no information available

Melting Point: 270-272°C

K_{ow}: <1 (pH 7); <10 (pH 9)

Solubility: 10gm in 100g of water

Purdue Pharma L.P.

10. Stability and Reactivity

Chemical Stability

Low stability hazard expected at normal operating temperatures.

Incompatibility with Other Materials

Strong oxidizers, acids, bases

Oxidizing materials will increase the risk of fire and explosion (e.g., potassium perchlorate, potassium nitrate)

Conditions to Avoid

Static charge, sparks, generation of dust, and temperatures above 200°C

Decomposition

Will not decompose under conditions of usual handling. Heating to decomposition may release acrid smoke and fumes.

Polymerization

Material will not polymerize.

11. Toxicological Information

Relevant Data

The following data for oxycodone hydrochloride are reflected as oxycodone free base. The information for talc is for non-asbestos containing material.

Skin/Eyes

Oxycodone

Oxycodone has not been evaluated in skin and eye irritation studies in animals. It is expected that oxycodone may produce mild skin irritation and may cause eye irritation.

Talc

Draize (human): 300 µg/3D mild reaction

Talc is not a primary skin irritant and it does not cause sensitization. Talc particles are physical irritants which cause inflammatory changes such as skin rash and can cause serious eye damage.

Acute

Oxycodone

LD₅₀: oral: 482 mg/kg (mouse)

LD₅₀: IP: 250 mg/kg (mouse)

LDL: IV: 20 mg/kg (rat)

Talc

Purdue Pharma L.P.

LD₅₀: oral: 920 mg/kg (rat)

Subchronic

Oxycodone

In a 10-day oral study in rats, 4.5 mg/kg/day (lowest dose tested) produced stereotypic behavior and increased activity only after 5 days of treatment. At 45 mg/kg/day, stereotypic behavior, body rigidity, labored breathing was observed on the first day of dosing. Animals that received ≥ 90 mg/kg/day did not survive past two days of dosing.

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; ≥ 22 mg/kg/day 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, and 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 ≥ 1 mg/kg/day produced effects similar to those observed in the 28-day study.

Chronic Toxicity

Oxycodone

No information available

Talc

No information available

Carcinogenicity

Oxycodone

No information available

Talc

Inhalation Studies

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Rats were exposed to non-asbestiform talc aerosols (0, 6, or 18 mg/m³) for 6 hours a day for 5 days a week for as long as 113 weeks for males and 122 weeks for females. Rats exhibited a concentration-time related increase in lung talc burden and impairment of lung function (total and vital lung capacities, compliance, gas exchange efficiency). Lung weights for rats in the 18mg/m³ group were greater than control values during and at the end of the study. Inhalation exposure produced inflammatory, reparative, and proliferative processes in the lungs. Female, but not male, rats in the 18 mg/m³ group exhibited clear evidence of carcinogenic activity in the lungs. Male, but not female, rats in the 18 mg/m³ group exhibited some evidence of carcinogenic activity in the adrenal gland (increased incidence of pheochromocytomas).

Mice were exposed to non-asbestiform talc aerosols (0, 6, 18 mg/m³) for 6 hours a day for 5 days a week for up to 104 weeks. The mice in the study exhibited a concentration-time increase in lung talc burden; lung function was not measured in this study. Talc inhalation was associated with chronic active inflammation in the lung but the proliferative changes observed in rats were not observed in the mice. There was no evidence of carcinogenic activity in the male or female mice.

Mutagenicity/Genotoxicity

Oxycodone

Bacterial mutagenicity: negative

Mouse micronucleus: negative

Human lymphocyte chromosome aberration: weakly positive

Mouse lymphoma: positive

Talc

Bacterial mutagenicity: negative

Developmental/Reproductive Toxicity

Oxycodone

Oxycodone administration to rats at dosages as high as 8 mg/kg/day had no effect on fertility or general reproductive performance.

Oxycodone did not produce developmental toxicity in rats or rabbits at dosages as high as 8 and 125 mg/kg/day, respectively.

Pups born to rats treated with oxycodone at a dosage of 6 mg/kg/day during late gestation through weaning had low body weight through lactation and the early growth phase. There was no effect on survival of the offspring. The no adverse effect level for the finding was 2 mg/kg/day.

Repetitive maternal exposure to opioids has been associated with respiratory depression and/or withdrawal symptoms in neonates.

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Oxycodone has been detected in breast milk.

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Mice and rats were fed up to 1,600 mg/kg/day during pregnancy. Hamsters received 1,200 mg/kg/day during pregnancy and rabbits received 90-900 mg/kg/day orally during pregnancy. There was no evidence of teratogenicity or embryotoxicity in these species at these dosages.

12. Ecological Information

Ecotoxicological Information

Oxycodone HCl

24 hr LC₅₀: Daphnia magna: 300 mg/mL

Microbial Growth Inhibition EC₁₀: 7 species: > 1,000 mg/mL

Chemical Fate Information

Oxycodone HCl

aerobic biodegradation: sewer sludge: est. t_{1/2}: 276 days

13. Disposal Considerations

Disposal

This material is not listed under US RCRA. It is a Schedule II drug. Disposal of this material must be in accordance with federal, state/provincial, and local regulations.

14. Transportation Information

Shipping Information

This material is non-hazardous under US DOT.

15. Regulatory/Statutory Information

US Federal: OxyContin[®] (Oxycodone preparations) are subject to control under the US Federal Controlled Substances Act of 1970 as schedule II (C-II) drugs.

California Hazardous Substance List: Talc (exempt if no inhalable dust is present or can be generated through use); polyvinylpyrrolidone

Illinois Toxic Substance Disclosure to Employees Act: Talc as a nuisance dust

Indiana OSHA Approved Implementation Plan: Talc, nuisance dust

Kentucky OSHA Approved Implementation Plan: Talc, nuisance dust

Massachusetts Right-to-Know Substance List: Talc (exempt if encapsulated or if particulates are not present or cannot be generated through use of this product)

Minnesota Hazardous Substance List: Talc as a nuisance dust

New Jersey Right-to-Know Substance List: Talc

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North Carolina: Talc as a nuisance dust

Pennsylvania Right-to-Know Hazardous Substance List: Talc @ 1% or greater

Rhode Island Hazardous Substances Right-to-Know Act: Talc

16. Other Information

The information contained in this Material 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 Material Safety Data Sheet relate only to the specific material designated herein and does not relate to use in combination with any other material. The data in this Material Safety Data Sheet are subject to revision as additional knowledge and experience are gained.

This MSDS was prepared for Purdue Pharma L.P. by the Occupational and Environmental Assessment Section of Purdue Pharma L.P. and Ariel Research Corporation.