



SAFETY DATA SHEET

Issue Date 13-Oct-2009

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Version 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION

Product Name Dilaudid® (hydromorphone hydrochloride) Oral Solution C-II

Synonyms Dilaudid® 1 mg/mL Oral Solution

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

Recommended Use Opioid analgesic

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

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

2. HAZARDS IDENTIFICATION

This product contains a chemical which is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

Specific target organ toxicity (single exposure)

Category 3

Emergency Overview

Signal Word

Warning

Hazard Statements

May cause drowsiness or dizziness



Appearance Clear, colorless solution

Physical state Liquid

Odor Characteristic sweet odor

Hazards Not Otherwise Classified (HNOC)

Not Applicable.

Other Information

Acute oral toxicity for hydromorphone hydrochloride ranged from 50-300 mg/kg.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No	Weight %
Hydromorphone hydrochloride	71-68-1	0.1-1
Water	7732-18-5	90-100
Glycerin	56-81-5	5-10
Methylparaben	99-76-3	0.1-1

4. FIRST AID MEASURES

First aid measures

Eye contact	In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.
Skin contact	In case of contact, remove contaminated clothing. Immediately flush skin with copious amounts of water for at least 15 minutes. Obtain medical attention if skin reaction occurs.
Inhalation	In case of inhalation, remove to fresh air. If not breathing, provide artificial respiration. If breathing is difficult, administer oxygen. Seek medical attention immediately.
Ingestion	In case of accidental ingestion, wash out mouth with copious amounts of water. Seek medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
Self-protection of the first aider	Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Most important symptoms and effects, both acute and delayed

Symptoms	Overdose may cause dizziness, euphoria, flushing, itching, hypotension, pinpoint pupils, nausea/vomiting, constipation, and reduced urination. Serious overdose produces respiratory depression, extreme somnolence, stupor or coma, skeletal muscle flaccidity, cold and clammy skin, bradycardia, and hypotension. Severe overdose produces apnea, circulatory collapse, cardiac arrest, and death.
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Indication of any immediate medical attention and special treatment needed

Note to physicians	<p>Hydromorphone hydrochloride is a pure opioid agonist with an analgesic potency about 8 times that of morphine. 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 hydromorphone hydrochloride overdose.</p> <p>In cases of overdose, 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.</p>
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5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media

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

Unsuitable Extinguishing Media No information available.

Specific hazards arising from the chemical

No information available.

Explosion Data

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None.

Protective equipment and precautions for firefighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

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

Other Information Not Applicable.

Environmental precautions

Environmental precautions See section 12 for additional Ecological Information.

Methods and material for containment and cleaning up

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

Methods for cleaning up Pick up and transfer to properly labeled containers.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling Avoid contact with skin, eyes or clothing. Wash thoroughly after handling. Wash contaminated clothing before reuse.

Conditions for safe storage, including any incompatibilities

Storage conditions Hydromorphone hydrochloride is a Schedule II Controlled Substance and requires DEA-compliant storage. Keep containers 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).

Incompatible materials Strong oxidizers, acids, bases.
Oxidizing materials will increase the risk of fire and explosion (e.g., potassium perchlorate, potassium nitrate).

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Glycerin 56-81-5	-	TWA: 15 mg/m ³ mist, total particulate TWA: 5 mg/m ³ mist, respirable fraction	-

Chemical Name	Performance-Based Exposure Band (PBEB)	Company OEG (ug/m ³)
Hydromorphone hydrochloride	None	2

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

Individual Protection Measures (Personal Protective Equipment)

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

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

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

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical and Chemical Properties

Physical state Liquid
Appearance Clear, colorless solution
Odor Characteristic sweet odor
Color Colorless
Odor threshold No information available.

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	No information available.	
Melting point / melting range	No information available.	
Boiling point / boiling range	No information available.	
Flash point	No information available.	
Evaporation rate	No information available.	
Flammability (solid, gas)	No information available.	
Flammability limits in air		
Upper flammability limits		
Lower flammability limits		
Vapor pressure	No information available.	
Vapor density	No information available.	
Specific gravity	No information available.	
Water solubility	No information available.	
Solubility in other solvents	No information available.	
Partition coefficient (n-	No information available.	

octanol/water)

Autoignition temperature	No information available.
Decomposition temperature	No information available.
Kinematic viscosity	No information available.
Dynamic viscosity	No information available.
Explosive properties	No information available.
Oxidizing properties	No information available.

Other Information

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

10. STABILITY AND REACTIVITY

Chemical stability	Low stability hazard expected at normal operating temperatures.
Possibility of hazardous reactions	No information available.
Hazardous polymerization	Hazardous polymerization does not occur.
Conditions to avoid	None known based on available information.
Incompatible materials	Strong oxidizers, acids, bases. Oxidizing materials will increase the risk of fire and explosion (e.g., potassium perchlorate, potassium nitrate).
Hazardous decomposition products	None known based on available information.

11. TOXICOLOGICAL INFORMATION**Information on likely routes of exposure**

Product Information	No data available.
Inhalation	No data available.
Eye contact	No data available.
Skin contact	No data available.
Ingestion	No data available.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Glycerin	12600 mg/kg (Rat)	10 g/kg (Rabbit)	570 mg/m ³ (Rat) 1 h
Methylparaben	2100 mg/kg (Rat)	-	-
Water	90 mL/kg (Rat)	-	-
Hydromorphone hydrochloride	51 mg/kg (Rat)	-	-

Information on toxicological effects

Symptoms	Overdose may cause dizziness, euphoria, flushing, itching, hypotension, pinpoint pupils, nausea/vomiting, constipation, and reduced urination. Serious overdose produces respiratory depression, extreme somnolence, stupor or coma, skeletal muscle flaccidity, cold and clammy skin, bradycardia, and hypotension. Severe overdose produces apnea, circulatory collapse, cardiac arrest, and death.
Sensitization	Hydromorphone in a patch is negative in skin sensitizing test.

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

Germ cell mutagenicity	Hydromorphone was not genotoxic in the Ames bacterial mutagenicity test, in the chromosome aberration assay in human lymphocytes, or in the mouse bone marrow micronucleus test.
Carcinogenicity	Not listed by IARC, NTP or US OSHA.
Reproductive toxicity	
Developmental Toxicity	Embryo-fetal toxicity effects were not produced following administration of hydromorphone hydrochloride at oral doses up to 7 mg/kg/day in rats from day 6 to day 17 of gestation and up to 25 mg/kg/day in rabbits from day 6 to day 20 of gestation.
Teratogenicity	Teratogenic effects were not produced following administration of hydromorphone hydrochloride at oral doses up to 7 mg/kg/day in rats from day 6 to day 17 of gestation and up to 25 mg/kg/day in rabbits from day 6 to day 20 of gestation. Administration to Syrian hamsters shows that hydromorphone is teratogenic at a dose of 20 mg/kg. However, in these studies, profound sedation and hypoxia/hypercarbia in pregnant animals is believed to be the cause of the teratogenic effects, not the direct effect of hydromorphone hydrochloride on the fetus.
STOT-single exposure	No information available.
STOT-repeated exposure	No information available.
Aspiration hazard	Due to the physical form of the product it is not an aspiration hazard.
Acute toxicity	Acute oral toxicity for hydromorphone hydrochloride ranged from 50-300 mg/kg.

12. ECOLOGICAL INFORMATION**Ecotoxicity**

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Glycerin		LC50 96 h 51 - 57 mL/L (Oncorhynchus mykiss - static)		EC50 24 h > 500 mg/L (Daphnia magna)
Hydromorphone hydrochloride		Chronic NOEL 5.4 mg/L (Fathead minnow)		

Persistence and degradability No information available.

Bioaccumulation No information available.

Chemical Name	Partition coefficient
Hydromorphone hydrochloride	-0.37
Glycerin	-1.76

Other adverse effects No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

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

Contaminated Packaging Do not reuse container.

14. TRANSPORT INFORMATION

DOT Not regulated.

IATA Not regulated.

15. REGULATORY INFORMATION

Hydromorphone hydrochloride preparations are subject to control under the US Federal Controlled Substances Act of 1970 as schedule II (C-II) drugs.

International Inventories

TSCA Not determined.
 DSL Not determined.

Legend:

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

US Federal Regulations

SARA 313

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

SARA 311/312 Hazard Categories

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

CWA (Clean Water Act)

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

CERCLA

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

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

US State Right-to-Know Regulations

US EPA Label Information

EPA Pesticide Registration Number Not Applicable.

16. OTHER INFORMATION

<u>NFPA</u>	Health Hazards 0	Flammability 0	Instability 0	Physical and Chemical Properties -
<u>HMIS</u>	Health Hazards 0	Flammability 0	Physical Hazards 0	Personal protection X

General Information

Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for Safe Handling.

Prepared By

This SDS was prepared by the Environmental, Health, and Safety & Toxicology Departments of Purdue Pharma L.P.

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07-Feb-2017

Revision Note

(M)SDS sections updated. 2. 8. 11.

Disclaimer

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End of Safety Data Sheet