



# SAFETY DATA SHEET

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Version 1

## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION

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

**Synonyms** Dilaudid® 1 mg/mL Oral Liquid

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

**Recommended Use** Opioid analgesic

**Uses advised against** No information available.

**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 chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

### Emergency Overview

**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

|   |  |
|---|--|
| <b>Eye contact</b>                        | 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.                                   |
| <b>Skin contact</b>                       | 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.  |
| <b>Inhalation</b>                         | In case of inhalation, remove to fresh air. If not breathing, provide artificial respiration. If breathing is difficult, administer oxygen. Seek medical attention immediately.  |
| <b>Ingestion</b>                          | 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. |
| <b>Self-protection of the first aider</b> | 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**

|                 |   |
|-----------------|---|
| <b>Symptoms</b> | 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. |
|-----------------|---|

#### **Indication of any immediate medical attention and special treatment needed**

|                           |   |
|---------------------------|---|
| <b>Note to physicians</b> | <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> |
|---------------------------|---|

## 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<br>56-81-5 | -         | TWA: 15 mg/m <sup>3</sup> mist, total particulate<br>TWA: 5 mg/m <sup>3</sup> mist, respirable fraction | -          |

| Chemical Name               | Performance-Based Exposure Band (PBEB) | Company OEG (ug/m <sup>3</sup> ) |
|-----------------------------|--|----------------------------------|
| Hydromorphone hydrochloride | None                                   | 10                               |

**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. |                         |

|  |                           |
|--|---------------------------|
| <b>Solubility in other solvents</b>            | No information available. |
| <b>Partition coefficient (n-octanol/water)</b> | No information available. |
| <b>Autoignition temperature</b>                | No information available. |
| <b>Decomposition temperature</b>               | No information available. |
| <b>Kinematic viscosity</b>                     | No information available. |
| <b>Dynamic viscosity</b>                       | No information available. |
| <b>Explosive properties</b>                    | No information available. |
| <b>Oxidizing properties</b>                    | No information available. |

**Other Information**

|                         |                           |
|-------------------------|---------------------------|
| <b>Softening point</b>  | No information available. |
| <b>Molecular weight</b> | No information available. |
| <b>VOC content; (%)</b> | No information available. |
| <b>Density</b>          | No information available. |
| <b>Bulk density</b>     | No information available. |

## 10. STABILITY AND REACTIVITY

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

## 11. TOXICOLOGICAL INFORMATION

**Information on likely routes of exposure**

|                            |                    |
|----------------------------|--------------------|
| <b>Product Information</b> | No data available. |
| <b>Inhalation</b>          | No data available. |
| <b>Eye contact</b>         | No data available. |
| <b>Skin contact</b>        | No data available. |
| <b>Ingestion</b>           | No data available. |

| Chemical Name | Oral LD50           | Dermal LD50        | Inhalation LC50                   |
|---------------|---------------------|--------------------|-----------------------------------|
| Glycerin      | 12600 mg/kg ( Rat ) | 10 g/kg ( Rabbit ) | 570 mg/m <sup>3</sup> ( Rat ) 1 h |
| Water         | 90 mL/kg ( Rat )    | -                  | -                                 |
| Methylparaben | 2100 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** No information available.

**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** No information available.

**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<br>(Oncorhynchus mykiss - static) |                            | EC50 24 h > 500 mg/L<br>(Daphnia magna) |
| Hydromorphone hydrochloride |                      | Chronic NOEL 5.4 mg/L<br>(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**

|  |    |
|--|----|
| <b>Acute Health Hazard</b>               | No |
| <b>Chronic Health Hazard</b>             | No |
| <b>Fire Hazard</b>                       | No |
| <b>Sudden Release of Pressure Hazard</b> | No |
| <b>Reactive Hazard</b>                   | 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**

|                    |                         |                       |                           |   |
|--------------------|-------------------------|-----------------------|---------------------------|---|
| <b><u>NFPA</u></b> | <b>Health Hazards</b> 0 | <b>Flammability</b> 0 | <b>Instability</b> 0      | <b>Physical and Chemical Properties -</b> |
| <b><u>HMIS</u></b> | <b>Health Hazards</b> 0 | <b>Flammability</b> 0 | <b>Physical Hazards</b> 0 | <b>Personal protection</b> 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 Occupational and Environmental Assessment Section of Purdue Pharma L.P.

**Issue Date**

13-Oct-2009

**Revision Date**

05-May-2015

**Revision Note**

SDS reformated for OSHA (GHS) 2012.

**Disclaimer**

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

**End of Safety Data Sheet**