

# Safety Data Sheet



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Version: 1.0  
Issued: 24 Feb 2022

## 1. Identification

<b>Product Identifier</b>	Hydromorphone Hydrochloride
<b>Other means of identification</b>	
Internal item number	82393-0119
CAS number	71-68-1
Synonyms	Dihydromorphinone hydrochloride
Chemical name	Morphinan-6-one, 4,5-epoxy-3-hydroxy-17-methyl-, hydrochloride, (5alpha)-

**Relevant use and restrictions:** No further information available.


**Application of substance:** Active pharmaceutical ingredient.

### Manufacturer/Supplier information

<b>Company name</b>	Pharma Source Direct
<b>Address</b>	8591 Prairie Trail Drive, Ste C-600 Englewood, CO 80112
<b>Website</b>	www.pharmasd.com

**Emergency phone number** Infotrac: 1-800-535-5053

## 2. Hazard(s) Identification

<b>Physical hazards</b>	Not classified	
<b>Health hazards</b>	Acute toxicity, oral	Category 3
	Specific target organ toxicity, single exposure	Category 3 narcotic effects
<b>Environmental hazards</b>	Not classified	
<b>OSHA defined hazards</b>	Not classified	
<b>Label elements</b>		

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<b>Signal word</b>	Danger
<b>Hazard statement</b>	Toxic if swallowed. May cause drowsiness or dizziness.
<b>Precautionary statement</b>	
<b>Prevention</b>	Wash thoroughly after handling. Use only outdoors or in a well-ventilated area.
<b>Response</b>	If swallowed: Immediately call a poison center/doctor. Rinse mouth. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell.
<b>Storage</b>	Store in a well-ventilated place. Keep container tightly closed. Store locked up.

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## Disposal

Dispose of contents/container in accordance with local/regional/national/ international regulations.

## Hazards not otherwise classified (HNOC)

The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.

## Supplemental information

Potent pharmacologically active material.

### 3. Composition/Information on Ingredients

#### Substance

Chemical name	Common name and synonyms	CAS number	%
Hydromorphone Hydrochloride	Dihydromorphinone hydrochloride	71-68-1	100

### 4. First-aid Measures

#### Inhalation

Move to fresh air. Oxygen or artificial respiration if needed. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Do not use mouth-to-mouth method if the substance is inhaled. Call a physician if symptoms develop or persist.

#### Skin contact

Wash off with soap and water. Get medical attention if irritation develops and persists.

#### Eye contact

Rinse with water. Get medical attention if irritation develops and persists.

#### Ingestion

Rinse mouth. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if substance is ingested. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

#### Most important symptoms/effects, acute and delayed

Central nervous system depression. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

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

Treat symptomatically. Treatment of opioid analgesic overdose may include the following: Do not induce vomiting. Administer activated charcoal as a slurry. Monitor vital signs, pulse oximetry, and cardiac function. Monitor for CNS and respiratory depression. For respiratory depression, administer oxygen and assist ventilation. Protect airway with orotracheal intubation. For coma and respiratory depression, reverse with naloxone. Administer intravenously, intramuscularly, intratracheally, intranasally, or subcutaneously. A continuous infusion might be needed for long-acting opioids. For seizures, treat with intravenous benzodiazepines. If seizures persist, administer propofol or barbiturates. For hypotension, treat with an infusion of isotonic fluid. If hypotension persists, administer dopamine or norepinephrine. Hemodialysis and hemoperfusion are not recommended.

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## General Information

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

## 5. Fire-fighting Measures

### Suitable extinguishing media

Water. Foam. Dry chemical or CO<sub>2</sub>. Use fire-extinguishing media appropriate for surrounding materials.

### Unsuitable extinguishing media

None known.

### Specific hazards arising from the chemical

Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.

### Special protective equipment and precautions for firefighters

Wear suitable protective equipment.

### Fire fighting equipment/instructions

Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

### Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

### General fire hazards

No unusual fire or explosion hazards noted.

## 6. Accidental Release Measures

### Personal precautions, protective equipment and emergency procedures

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Keep unnecessary personnel away. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS. Wear appropriate protective equipment and clothing during clean-up.

### Methods and materials for containment and cleaning up

Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.

### Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and Storage

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## Precautions for safe handling

As a general rule, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

## Conditions for safe storage, including any incompatibilities

Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

## 8. Exposure Controls & Personal Protection

### Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

### Exposure limit values

#### Industrial Use

Material	Type	Value
Hydromorphone Hydrochloride (CAS 71-68-1)	STEL	20 micrograms/m3
	TWA	4 micrograms/m3

### Biological limit values

No biological exposure limits noted for the ingredient(s)

### Appropriate engineering controls

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

#### Skin protection

##### Hand protection

Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

##### Other

Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

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## Respiratory protection

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Chose respiratory protection appropriate to the task and the level of existing engineering controls.

## Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

## General hygiene considerations

Pharmacological effects may be seen with occupational exposure. Procedures for any use or quantity should be determined after an appropriate assessment.

## 9. Physical and Chemical Properties

### Appearance

Appearance descriptions are general information and not specific to any lot.

#### Physical state

Solid.

#### Form

Powder.

#### Color

White.

### Odor

Odorless.

### Odor threshold

Not available.

### pH

Not available.

### Melting point/freezing point

581 - 599 °F (305 - 315 °C) (decomposes)

### Initial boiling point and boiling range

Not available.

### Flash point

Not available.

### Evaporation rate

Not available.

### Flammability (solid, gas)

Not available.

### Upper/lower flammability or explosive limits

#### Flammability limit - lower (%)

Not available.

#### Flammability limit - upper (%)

Not available.

#### Explosive limit - lower (%)

Not available.

#### Explosive limit - upper (%)

Not available.

### Vapor pressure

Not available.

### Vapor density

Not available.

### Relative density

Not available.

### Solubility(ies)

#### Solubility (water)

Freely soluble.

#### Solubility (other)

Alcohol: Sparingly soluble.

Ether: Practically insoluble.

### Auto-ignition temperature

> 752 °F (> 400 °C)

### Decomposition temperature

599 °F (315 °C)

### Viscosity

Not available.

### Other information

#### Chemical family

Morphinan derivative.

#### Molecular formula

C17H19NO3.ClH

#### Molecular weight

321.8

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## 10. Stability and Reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Oxidizers. Alkalies. Tannins. Borax. Ferric chloride. Iodides. Mercuric chloride. Gold salts. Metals.
<b>Hazardous decomposition products</b>	NO <sub>x</sub> . Cl <sup>-</sup> . Br <sup>-</sup> . Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological Information

### Information on likely routes of exposure

<b>Inhalation</b>	May cause drowsiness or dizziness.
<b>Skin contact</b>	Knowledge about health hazard is incomplete.
<b>Eye contact</b>	Knowledge about health hazard is incomplete.
<b>Ingestion</b>	Toxic if swallowed.

**Symptoms related to the physical, chemical, and toxicological characteristics**  
Opioids: Respiratory depression. Central nervous system depression. Gastrointestinal disturbances. Mood or mental changes. Pinpoint pupils. Muscle rigidity. Seizures.

### Information on toxicological effects

**Acute toxicity**  
Toxic if swallowed.

Product	Species	Test Results
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Hydromorphone Hydrochloride (CAS 71-68-1)

#### Acute

##### Oral

Rat	51 mg/kg
Rat	199 mg/kg

LD50

**Skin corrosion/irritation**  
Knowledge about health hazard is incomplete.

**Serious eye damage/eye irritation**  
Knowledge about health hazard is incomplete.

### Respiratory or skin sensitization

**Respiratory sensitization**  
Knowledge about health hazard is incomplete.

**Skin sensitization**  
Based on available data, the classification criteria are not met.

Sensitization Patch test  
Result: Negative.

**Germ cell mutagenicity**  
Knowledge about mutagenicity is incomplete.

#### Mutagenicity

Human lymphocyte chromosome aberration assay  
Result: Negative.  
In vitro Ames reverse mutation assay  
Result: Negative.  
In vivo mouse micronucleus assay  
Result: Negative.

**Carcinogenicity**  
Knowledge about carcinogenicity is incomplete

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0 - 15 mg/kg/day Carcinogenicity  
Result: No evidence of carcinogenic potential.  
Species: Mouse  
Test Duration: 2 years  
2 - 75 mg/kg/day Carcinogenicity  
Result: Increased incidences of hibernoma in females. No evidence of carcinogenicity in males.  
Species: Rat  
Test Duration: 2 years

## IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

## OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

## US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

## Reproductive toxicity

Knowledge about health hazard is incomplete. Maternal use of opioids during pregnancy may cause physical dependence in the fetus leading to respiratory difficulties and withdrawal symptoms (dehydration, irritability, tremors, excessive crying, diarrhea) in the newborn.

## Reproductivity

0 - 7 mg/kg/day Reproductivity  
Result: No evidence of embryo toxicity or increased incidence of birth defects.  
Species: Rat  
14 - 258 mg/kg Reproductivity  
Result: Skull malformations produced in offspring.  
Species: Syrian hamster  
25 mg/kg/day Reproductivity  
Result: No evidence of teratogenicity.  
Species: Rabbit

## Specific target organ toxicity - single exposure

May cause drowsiness and dizziness.

## Specific target organ toxicity - repeated exposure

Knowledge about health hazard is incomplete.

## Aspiration hazard

Based on available data, the classification criteria are not met.

## Further information

Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

## 12. Ecological Information

### Ecotoxicity

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

### Persistence and degradability

No data is available on the degradability of this product.

### Bioaccumulative potential

No data available.

### Mobility in soil

No data available.

### Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

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## 13. Disposal Considerations

<b>Disposal instructions</b>	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
<b>Contaminated packaging</b>	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport Information

### DOT

<b>UN number</b>	UN2811
<b>UN proper shipping name</b>	Toxic solid, organic, n.o.s. (Hydromorphone hydrochloride)
<b>Transport hazard class(es)</b>	
<b>Class</b>	6.1
<b>Subsidiary risk</b>	-
<b>Packing group</b>	III

### IATA

<b>UN number</b>	UN2811
<b>UN proper shipping name</b>	Toxic solid, organic, n.o.s. (Hydromorphone hydrochloride)
<b>Transport hazard class(es)</b>	
<b>Class</b>	6.1
<b>Subsidiary risk</b>	-
<b>Packing group</b>	III

### Other information

<b>Passenger and cargo aircraft</b>	Allowed with restrictions.
<b>Cargo aircraft only</b>	Allowed with restrictions.

<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not applicable
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DOT; IATA

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## General information

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

## 15. Regulatory Information

### US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

#### Toxic Substances Control Act (TSCA)

##### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

#### CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

#### SARA 304 Emergency release notification

Not regulated.

#### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

#### SARA 302 Extremely hazardous substance

Not listed.

#### SARA 311/312 Hazardous chemical

Yes

##### Classified hazard categories

Acute toxicity (any route of exposure)  
Specific target organ toxicity (single or repeated exposure)

#### SARA 313 (TRI reporting)

Not regulated.

### Other federal regulations

#### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

#### Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

#### Safe Drinking Water Act (SDWA)

Not regulated.

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## US state regulation

### California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

## International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Phillipines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
Unites States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other Information

### Disclaimer

The information in this SDS has been compiled from sources considered dependable, but has not been independently verified. The company cannot guarantee the accuracy of information herein, and the statements contained should not be considered an official expression. The company will not assume liability for any loss, damage, and/or expense resulting from the use and/or misuse of this product in regards to handling, storage, and/or disposal.

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