

# SDS: Hydromorphone Hydrochloride Injection, USP CII (High Potency Formulation)

## SAFETY DATA SHEET

### 1. Identification

**Product Identifier:** Hydromorphone Hydrochloride Injection, USP CII  
(High Potency Formulation)

**Synonyms:** Dihydromorphinone hydrochloride

**National Drug Code (NDC):** 17478-540-01  
17478-540-05  
17478-540-50

**Recommended Use:** Pharmaceutical.

**Company:** Akorn, Inc.  
1925 West Field Court, Suite 300  
Lake Forest, Illinois 60045

**Contact Telephone:** 1-800-932-5676

**E mail:** customer.service@akorn.com

**Emergency Phone Number:** CHEMTREC 1-800-424-9300 (U.S. and Canada)

### 2. Hazard(s) Identification

**Physical Hazards:** Not classifiable.

**Health Hazards:**

Skin sensitization	Category 1
Respiratory sensitization	Category 1
Specific target organ toxicity – single exposure (narcotic effects)	Category 3
Reproductive toxicity	Category 2

**Symbol(s):**



**Signal Word:** Danger.

**Hazard Statement(s):**

H317 May cause an allergic skin reaction.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H336 May cause drowsiness or dizziness.



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### Precautionary Statement(s):

- H361 Suspected of damaging fertility or the unborn child.
- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P261 Avoid breathing dust/fume/gas/mist/vapor/spray.
- P271 Use only in well-ventilated area.
- P264 Wash potentially exposed skin after handling.
- P272 Contaminated work clothing should not be allowed out of the workplace.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P284 [In case of inadequate ventilation] wear respiratory protection.
- P302 IF ON SKIN: Wash with plenty of water.  
+  
P352
- P333 If skin irritation or rash occurs; Get medical advice/attention.  
+  
P313
- P362 Take off contaminated clothing and wash it before reuse.  
+  
P364
- P304 IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
+  
P340
- P342 If experiencing respiratory symptoms: Call a POISON CENTER/doctor/physician.  
+  
P311
- P308 IF exposed or concerned: Get medical advice/attention.  
+  
P313
- P403 Store in a well-ventilated place. Keep container tightly closed.  
+  
P233



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P405 Store locked up.

P501 Dispose of contents/container in accordance with local/provincial/federal regulations.

**Hazards Not Otherwise Classified:** None.

**Supplementary Information:** None.

### 3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Hydromorphone Hydrochloride	71-68-1	Dihydromorphinone hydrochloride	$C_{17}H_{19}NO_3 \cdot HCl$	321.8	1%

\*The formula also contains Sodium Citrate, 0.2%; Citric Acid, 0.2% added as a buffer to maintain a pH of between 3.5 – 5.5 and Water for Injection.

### 4. First Aid Measures

#### **Ingestion:**

If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

#### **Eye Contact:**

Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

#### **Skin Contact:**

Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

#### **Inhalation:**

Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.



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**Protection of First-Aiders:** Use personal protective equipment (see section 8).

**Signs and Symptoms:** Dizziness; drowsiness; weakness; mood or mental changes (euphoria, agitation, confusion); nausea; vomiting; constipation; decreased or difficult urination; sweating; flushing; respiratory irritation; skin irritation; eye irritation.

Overdose effects of opioid analgesics may include severe dizziness or drowsiness; cold and clammy skin; slow or troubled breathing; low blood pressure; slow or irregular heart rate; pinpoint pupils; seizures; hypothermia; decreased mental status; loss of consciousness; and death. Possible allergic reaction to material if inhaled, ingested, or in contact with skin.

**Medical Conditions Aggravated by Exposure:**

Hypersensitivity to any of the components of the product; liver or kidney dysfunction, hypothyroidism, seizure disorders, asthma or other respiratory disorders, heart arrhythmias, acute alcoholism or history of drug abuse or dependence, gallbladder disorders, inflammatory bowel disease, urinary disorders, low blood pressure, gastrointestinal obstruction, Addison's disease.

**Notes to Physician:** Treat supportively and symptomatically.

### 5. Firefighting Measures

**Suitable Extinguishing Media:** Use water, carbon dioxide, dry chemical, foam or Halon as suitable to surrounding materials.

**Unsuitable Extinguishing Media:** Not determined.

#### Specific Hazards Arising from the Chemical:

**Hazardous Combustion Products:** These products include Carbon Oxides, Nitrogen Oxides, Hydrogen Chloride, and other hazardous products of combustion.

**Other Specific Hazards:** Closed containers may explode from the heat of fire.

**Special Protective Equipment/Precautions for Firefighters:** Wear self-contained breathing apparatus and full protective gear.

### 6. Accidental Release Measures

**Personal Precautions:** Keep unnecessary personnel away. Do not touch damaged containers or spilled materials unless wearing appropriate personal protective equipment and clothing.

**Personal Protective Equipment:** For personal protection see section 8.



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**Methods for Cleaning Up:** Absorb liquid with clay absorbent, absorbent pads or paper towels. Use disposable tools to scoop up, sweep or containerize spilled material. Wipe working surfaces to dryness, and then wash thoroughly with soap and water. Use adequate personal protective equipment to prevent any exposure to eyes, to skin, and to respiratory tract. When Hydromorphone Hydrochloride Injection (HPF) is no longer needed, any unused liquid should be destroyed by flushing it down the toilet.

**Environmental Precautions:** The material is not considered a water pollutant. However, it is recommended to prevent spilled or leaking material from entering waterways. Minimize the use of water to prevent environmental contamination.

**Reference to Other Sections:** Refer to Sections 8, 12 and 13 for further information.

### 7. Handling and Storage

**Precautions for Safe Handling:** Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

**Conditions for Safe Storage, Including Any Incompatibilities:** Store according to label and/or product insert information. Store away from oxidizing agents and acids.

**Specific End Use:** Pharmaceuticals.

### 8. Exposure Controls/Personal Protection

#### Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Hydromorphone Hydrochloride	OEL*: 2 µg/m <sup>3</sup> , 8 Hour TWA; OEL*: 7 µg/m <sup>3</sup> , 12 Hour TWA; OEL*: 10 µg/m <sup>3</sup> , 12 Hour TWA; OEL*: 19 µg/m <sup>3</sup> , 15 Minutes STEL; OEL*: 30 µg/m <sup>3</sup> , 15 Minutes STEL;
Sodium Citrate	Not established.

\*Occupational Exposure Levels (OELs) have been established by private company.

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

**Respiratory Protection:** Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).



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<b>Eyes Protection:</b>	Not required for the normal use of this product. Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
<b>Hand Protection:</b>	Not required for the normal use of this product. Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
<b>Skin Protection:</b>	Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

### 9. Physical and Chemical Properties

<b>Physical State/Color:</b>	Clear, colorless to slightly yellow solution.
<b>Odor:</b>	Odorless.
<b>Odor Threshold:</b>	No data available.
<b>pH:</b>	3.5 – 5.5.
<b>Melting Point:</b>	No data available.
<b>Freezing Point:</b>	~ 32°F (~0°C).
<b>Boiling Point:</b>	~ 212°F (~100°C).
<b>Flash Point:</b>	No data available.
<b>Evaporation Rate:</b>	No data available.
<b>Flammability (solid, gas):</b>	No data available.
<b>Flammability Limit - Lower:</b>	No data available.
<b>Flammability Limit - Upper:</b>	No data available.
<b>Vapor Pressure:</b>	No data available.
<b>Vapor Density:</b>	No data available.
<b>Relative Density:</b>	No data available.
<b>Solubility(ies):</b>	Soluble in water.
<b>Partition Coefficient (n-octanol/water):</b>	No data available.
<b>Auto-Ignition Temperature:</b>	No data available.
<b>Decomposition Temperature:</b>	No data available.
<b>Viscosity:</b>	No data available.

### 10. Stability and Reactivity

<b>Reactivity:</b>	No data available.
<b>Chemical Stability:</b>	Stable at normal temperature and pressures.
<b>Possibility of Hazardous Reactions:</b>	Reactive with oxidizers.
<b>Conditions to Avoid (e.g., static discharge, shock, or vibration):</b>	Avoid heat and light.



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**Incompatible Materials:** Reactive with strong oxidizing agents.

**Hazardous Decomposition Products:** May emit toxic fumes when heated to decomposition such as carbon monoxide, carbon dioxide, oxides of sulfur, nitrogen and sodium.

### 11. Toxicological Information

#### Information on the Likely Routes of Exposure:

**Inhalation:** Material may be irritating to mucous membranes and respiratory tract.

**Ingestion:** Narcotic. In addition to analgesic action, may cause gastric disturbances evidenced by nausea, vomiting and constipation. Ingestion of large amounts may cause central nervous system depression, respiratory or cardiac collapse, coma and death. Flush mouth with water. Do not induce vomiting. Call a physician and poison control center.

**Skin Contact:** May cause skin irritation. Product may be absorbed through the skin.

**Eye Contact:** May cause eye irritation.

**Symptoms Related to the Physical, Chemical and Toxicological Characteristics:** See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

**Delayed and Immediate Effects of Exposure:** No data available.

#### **Acute Toxicity:**

Compound	Species	Route	Test Type	Dose
Hydromorphone HCl	Rat	Subcutaneous	LD <sub>50</sub>	51 mg/kg
Hydromorphone HCl	Mouse	Subcutaneous	LD <sub>50</sub>	120 mg/kg
Hydromorphone HCl	Mouse	Intravenous	LD <sub>50</sub>	55 mg/kg
Hydromorphone HCl	Cat	Intravenous	LD <sub>Lo</sub>	3 mg/kg
Hydromorphone HCl	Rabbit	Intravenous	LD <sub>Lo</sub>	2,500 mg/kg

**Acute Toxicity – Dermal:** No data available.

**Acute Toxicity – Inhalation:** No data available.

**Corrosivity:** No data available.

**Dermal Irritation:** Skin irritation is possible.

**Eye Irritation:** Causes eye irritation.

**Sensitization:** Hypersensitivity may occur; may cause addiction.

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<b>Toxicokinetics/Metabolism:</b>	No data available.
<b>Target Organ Effects:</b>	Primarily targets the central nervous system. May also affect lungs, liver, kidneys, skin and heart.
<b>Reproductive Effects:</b>	Fertility in male and female rats was not affected after daily oral administration at doses up to 7 mg/kg/day.
<b>Mutagenicity:</b>	Not mutagenic in the in vitro Ames reverse mutation assay, in the in vitro chromosome aberration assay in human lymphocytes, or, in the in vivo mouse bone marrow micronucleus test.
<b>Developmental Effects:</b>	Classified as Pregnancy Category C. No adequate and well controlled studies in humans regarding the teratogenic effects have been conducted. Neither embryo-lethal or teratogenic effects were observed following oral administration of hydromorphone hydrochloride to rats (7 mg/kg/day) and rabbits (25 mg/kg/day). Literature reports of hydromorphone hydrochloride administered to pregnant Syrian hamsters show it to be teratogenic at 20 mg/kg/day which is 600 times the human dose.
<b>Nonteratogenic Effects:</b>	Babies born to mothers who have been taking opioids regularly prior to delivery will be physically dependent.
<b>Carcinogenicity:</b>	No data available.
National Toxicology Program (NTP):	Not considered to be a carcinogen.
International Agency for Research on Cancer (IARC):	Not considered to be a carcinogen.
Occupational Safety and Health Administration (OSHA):	Not considered to be a carcinogen.
<b>Aspiration Hazard:</b>	No data available.

### 12. Ecological Information

#### Ecotoxicity

<b>Aquatic:</b>	Can freely move through the aquatic environment.
<b>Terrestrial:</b>	No data available.
<b>Persistence and Degradability:</b>	Short term products of biodegradation are not likely. Long term degradation products may arise.
<b>Bioaccumulative Potential:</b>	No applicable bioaccumulation is expected in the environment.
<b>Mobility in Soil:</b>	No data available.
<b>Mobility in Environment:</b>	Appreciable volatilization is not expected into the air.





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**Other Adverse Effects:** No data available.

### 13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

### 14. Transport Information

**UN Number:** Not applicable.

**UN Proper Shipping Name:** Not applicable.

**Transport Hazard Class(es):** Not applicable.

**Packing Group:** Not applicable.

**Department of Transportation:** Not regulated as a hazardous material.

**International Air Transport Association (IATA):** Not regulated as a dangerous good.

**International Maritime Dangerous Good (IMDG):** Not regulated as a dangerous good.

### 15. Regulatory Information

#### US Federal Regulations:

**Toxic Substance Control Act (TSCA):** Not listed.

**CERCLA Hazardous Substance and Reportable Quantity:** Not listed.

**SARA 313:** Not listed.

**SARA 302:** Not listed.

**Drug Enforcement Agency:** Schedule II Narcotic.

#### State Regulations

**New Jersey:** Hydromorphone HCl

**Pennsylvania:** Hydromorphone HCl

**California Proposition 65:** Not listed.

### 16. Other Information

Not made with natural rubber latex.

#### **NFPA Rating:**

Health: 1

Flammability: 0

Reactivity: 0

#### **HMIS Classification:**

Health: 1

Fire: 0

Physical Hazard: 0



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**Revision Number:** 1

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