

**Product Name:**  
**Issued:**

**Hydromorphone Hydrochloride**  
**Nov-13-2007**



## MATERIAL SAFETY DATA SHEET

### 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

**Manufacturer Name and Address:** Abbott Laboratories  
Global Pharmaceuticals Operations  
1401 N. Sheridan Rd.  
North Chicago, IL 60064

**Customer Service Telephone:** 1-800-255-5162 (USA Only)

**Emergency Telephone:** CHEMTREC: 1(800) 424-9300 (in USA and Canada) or Access Code + (703) 527-3887

**Product Name:** Hydromorphone Hydrochloride

**Synonyms:** Dihydromorphinone Hydrochloride

**List Number:** 3728

**Drug Code Number:** 86751; 93581; 35992; 235318; 259984; 235082; 259915

### 2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	Percent	OSHA PEL	ACGIH TLV	AIHA WEEL	Abbott EEL	Skin Notation
Hydromorphone Hydrochloride 71-68-1	100	Not Listed	Not Listed	Not Applicable	2 mcg/m <sup>3</sup> TWA	None

**Notes:**

OSHA PEL: US Occupational Safety and Health Administration- Permissible Exposure Limit.

ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value.

AIHA WEEL: American Industrial Hygiene Association - Workplace Environmental Exposure Level.

Abbott EEL: Abbott Laboratories Employee Exposure Limit.

TWA: 8-hour Time Weighted Average.

STEL: 15-minute Short Term Exposure Limit.

C: Ceiling Limit.

Abbott : Hazardous per OSHA criteria

### 3. HAZARDS IDENTIFICATION

#### Emergency Overview:

White to off-white crystalline powder.  
Odorless.  
Reproductive hazard. Potent compound. Toxic by ingestion.

#### Routes of Exposure:

**Oral:** Yes

**Dermal:** Not determined.

**Inhalation:** Yes

#### Hazard Information:

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### 3. HAZARDS IDENTIFICATION

**Ingestion Rating:** Toxic  
**Skin Absorption Rating:** Not determined.  
**Inhalation Rating:** Not determined.  
**Corrosiveness Rating:** Not determined.  
**Skin Contact Rating:** Not determined.  
**Skin Sensitization Rating:** Not determined.  
**Eye Contact Rating:** Not determined.  
**Target Organs:** Nervous System, Respiratory System, Fetus.

#### Carcinogenicity Rating:

Ingredients	Percent	OSHA:	NTP:	IARC:	ACGIH:
Hydromorphone Hydrochloride	100	Not Listed	Not Listed	Not Listed	Not Listed

#### NFPA Rating:

Health: 2  
Fire: 1  
Reactivity: 0

**Signs and Symptoms:** Clinical data suggests the following: sedation, drowsiness, lethargy, cognitive dysfunction, vomiting, nausea, decreased blood pressure, slow heart rate, respiratory distress, anorexia.

**Medical Conditions Aggravated by Exposure:** Data suggest any preexisting ailments in the following organs: central nervous system, kidney, liver. Hypersensitivity to the material and/or similar materials. Pregnancy. Concurrent intake of depressants like alcohol.

### 4. FIRST AID MEASURES

**Eye Contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Skin Contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Inhalation:** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Ingestion:** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

### 5. FIRE FIGHTING MEASURES

#### Flammability:

**Lower Explosive Limit:** Not determined.  
**Autoignition Temp. (°C):** Not determined.

#### Fire-Fighting Information:

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**Suitable Extinguishing Media:** Use appropriate medium for the underlying cause of the fire.

**Special Exposure Hazards:** Avoid inhalation of combustion products.

**Min. Ignition Energy-Cloud (mJ):** 3-10 mJ

## 6. ACCIDENTAL RELEASE MEASURES

**Methods of Cleaning and Collecting:** Recover product. Place into appropriate container for disposal. Clean area with suitable cleaning materials. Dispose of as directed in Section 13.

**Personal Precautions:** Use personal protective equipment identified in Section 8.

**Environmental Precautions:** Not determined.

## 7. HANDLING AND STORAGE

**Handling:** Not determined.

**Storage:** Store according to label instructions.

**Special Precautions:** Not applicable.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Engineering Controls:** Use inside a hood, glovebox or process enclosure.

**Respiratory Protection:** An approved respirator (i.e. NIOSH, etc.) should be worn when exposures are expected to exceed the applicable limits.

**Eyes:** Wear eye protection appropriate to handling activities.

**Gloves:** Impervious gloves.

**Other PPE Data:** Not determined.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance:** White to off-white crystalline powder.

**Odor:** Not determined.

**Boiling Pt. @ 760 mm Hg (°C):** Not determined.

**Melting/Freezing Point (°C):** 263-268 (with decomposition)

**Vapor Pressure (mm Hg)** Not determined.

**Bulk Density at 20°C:** Not determined.

**Solubility:** Soluble in: water.

**Specific Gravity:** Not determined.

**pH:** Not determined.

**Viscosity (centipoise):** Not determined.

## 10. STABILITY AND REACTIVITY

**Chemical Stability:** Not determined.

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**Self-Heating Tendency:** Thermally stable to 300 deg C in a DSC study.

**Materials to Avoid:** Not determined.

**Hazardous Decomposition Products:** Not determined.

**Hazardous Polymerization:** Not determined.

**Conditions to Avoid:** Not determined.

## 11. TOXICOLOGICAL INFORMATION

**Acute Toxicity - Oral:** Data for component (s) given below.

Ingredients	Percent	Acute Test	Value	Units	Species
Hydromorphone Hydrochloride	100	LD50 =	199	mg/kg	Male Rats
			172	mg/kg	Female Rats

**Notes to Toxicologist:** Estimated human lethal dose = 120 - 250 mg.

**Acute Toxicity - Dermal:** Not determined.

**Acute Toxicity - Inhalation:** Not determined.

**Other Toxicology Data:** Data for component (s) given below:

Ingredients	Percent	Test Type	Value	Units	Species	Comments
Hydromorphone Hydrochloride	100	LD50 (iv) =	2.5 - 61	mg/kg	Rabbits	None.
		LD50 (sc) =	51 - 120	mg/kg	Mice	
					Rats	

**Corrosivity:** Not determined.

**Dermal Irritation:** Not determined.

**Eye Irritation:** Not determined.

**Sensitization:** Not determined.

**Target Organ Effects:** In clinical use target organ effects include: central nervous system, respiratory system. Clinical dose is less than (<) 10 mg/day.

Hydromorphone is a narcotic analgesic used to treat pain. It can also produce physical and psychological dependence and respiratory dyspnea.

**Reproductive Effects:** In animals adverse reproductive effects include: fetal abnormalities. In clinical use adverse reproductive effects include: fetal behavior abnormalities.

**Carcinogenicity:** Not determined.

**Mutagenicity:** Not determined.

**Notes:**

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

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## 12. ECOLOGICAL INFORMATION

**Aquatic Toxicity:** Not determined.

**Biodegradation:** Not determined.

**General Notes:** Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

**Notes:**

1. EC50: Concentration in water that produces 50% mortality in *Daphnia* sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

## 13. DISPOSAL CONSIDERATIONS

**Waste Disposal Methods:** Disposal should be made in accordance with federal, state and local regulations. This material is not a RCRA hazardous waste.

## 14. TRANSPORT INFORMATION

**DOT/ADR:**

**Status:** Regulated.  
**DG Description:** UN3249, Medicine, solid, toxic, n.o.s., 6.1, III

**ICAO/IATA:**

**Status:** Regulated.  
**Proper Shipping Name:** UN3249, Medicine, solid, toxic, n.o.s., 6.1, III

**IMDG:**

**Status:** Regulated.  
**Dangerous Goods Description:** UN3249, Medicine, solid, toxic, n.o.s., 6.1, III

**TDG (Canada):**

**Status:** Regulated.

## 15. REGULATORY INFORMATION

**SARA 313 Information**

Ingredients	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Hydromorphone Hydrochloride	100	No	Not Applicable	Not applicable

**SARA 311/312 Hazard Categories:**

**Immediate Health:** Yes  
**Delayed Health:** No  
**Fire:** No

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**Sudden Pressure:** No  
**Reactivity:** No

**TSCA Inventory Status:** Exempt.

**CERCLA Status:** Not determined.

**RCRA Status:** Not determined.

**Proposition 65 Status:** Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

#### EC HAZARD CLASSIFICATION:

**Category of Danger:** Exempt.  
**Indication of danger:** Exempt.  
**GHS Classification:** Not determined.

#### CANADIAN REGULATIONS:

**Canadian Inventory:** Not determined.  
**Canadian NDSL:** Not determined.  
**WHMIS Hazard Class:** Not determined.  
(Bad file name or number)

#### Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

## 16. OTHER INFORMATION

**Document Authored By:** Global Occupational Toxicology (D-05TX)

**Supersedes the MSDS dated:** Apr-19-2007

#### Disclaimer:

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