

MSDS: Hydromorphone HCl High Potency Injection, USP (High Potency Formulation) 10 mg/mL

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Section 1 - IDENTIFICATION

TRADE NAME: Hydromorphone Hydrochloride High Potency Injection USP, 10mg/mL
Description: Hydromorphone Hydrochloride High Potency Injection USP is indicated for the relief of moderate-to-severe pain in opioid-tolerant patients.

Composition	CAS#	TLV (mg/m³)	PEL (mg/m³)	% Content
Hydromorphone Hydrochloride, USP	71-68-1	Not Established	Not Established	1
Sodium Citrate	6132-04-3	Not Established	Not Established	0.2
Citric Acid	77-92-9	Not Established	Not Established	0.2
Water for Injection	7732-18-5	Not Established	Not Established	QS

Common name of active ingredient: Hydromorphone Hydrochloride
Chemical Formula (s): C₁₇H₁₉NO₃·HCl
Molecular Weight: 321.80 g/mole
Legal Category: Prescription Only, Schedule II narcotic opiate

Section 2 - HAZARDOUS INGREDIENTS

Principal Hazardous Ingredient: Hydromorphone Hydrochloride
This material is a strong sensitizer.

Persons developing hypersensitivity (anaphylactic) reactions must receive immediate medical attention. Material may be irritating to mucous membranes and respiratory tract. Risk-benefit must be considered because opioid analgesics cross the placenta. Regular use during pregnancy may cause physical dependency in the fetus, leading to withdrawal symptoms in the neonate. Although teratogenic effects in humans have not been documented, controlled studies have not been done. Studies in animals have shown hydromorphone to be teratogenic at very high doses. As a general rule, when handling hydromorphone hydrochloride, avoid all contact and inhalation of dust, fumes, mists and/or vapors associated with the material. Keep container tightly closed and use with adequate ventilation; wash thoroughly after handling.



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Section 3 - PHYSICAL AND CHEMICAL CHARACTERISTICS

Appearance	Clear, colorless to slightly yellow solution
Physical State	Liquid
Odor	Odorless
Boiling Point	~ 212°F (~100°C)
Freezing Point	~ 32°F (~0°C)
Vapor Pressure (mmHg at 20°C)	Not applicable
Vapor Density (g/m³)	Not applicable
Specific Gravity	~ 1.0 g/mL
pH	3.5 to 5.5
Solubility in Water	Freely Soluble
Latex Free:	Yes

Section 4 - FIRST AID MEASURES

General:	Remove from exposure. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.
Eyes:	May cause irritation. Hold eyelids open and flush with copious quantities of water. May cause narcotic effect exhibited by pupil contraction. See a physician immediately.
Skin:	May cause irritation. Product may be absorbed through the skin. Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with soap and water. Seek medical attention.
Inhalation:	May cause irritation of respiratory tract. Readily absorbable by inhalation and may cause narcotic effect. Move individual to fresh air. Obtain medical attention.
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.

Section 5 - FIRE AND EXPLOSION HAZARD DATA

Flash point:	Not Established	Method: Not Established
UEL:	No applicable information found	
LEL:	No applicable information found	
Auto-ignition Temperature:	Not applicable	
Extinguishing Media:	Use water, carbon dioxide, dry chemical, foam, or Halon as suitable to surrounding materials. Thermally decomposes to form toxic vapors which may be irritating to eyes and skin and toxic to the respiratory tract. Firefighters should wear self-contained breathing apparatus and full protective gear.	



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Section 6 - STABILITY AND REACTIVITY DATA

Stability:	Stable at normal temperatures and pressures
Conditions to avoid:	Heat, Light
Incompatibility:	Reactive with strong oxidizing agents
Hazardous Decomposition:	May emit toxic fumes when heated to decomposition such as carbon monoxide, carbon dioxide, oxides of sulfur, nitrogen and sodium
Hazardous Polymerization:	Will not occur

Section 7 - PROTECTION INFORMATION

Respiratory Protection:	Under normal conditions of product use, respiratory protection is not required.
Eye Protection:	Wear chemical splash goggles or safety glasses.
Ventilation:	Local exhaust or general ventilation at maximum levels is recommended.
Skin Protection:	When administering this product to patients, wear nitrile or latex gloves. Use respiratory protection, goggles, impervious coveralls, shoe covers and gloves for clean-up activities.

Section 8 - HANDLING AND STORAGE

Handling:	No special protective equipment or procedures are required in the clinical or home environment. Hydromorphone Hydrochloride High Potency Injection poses little risk of direct exposure to healthcare personnel and should be handled and disposed of prudently, in accordance with hospital or institutional policy.
Storage:	Store at controlled room temperature 20° to 25°C (68° to 77°F).

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN

Section 9 - ACCIDENTAL RELEASE MEASURES

Method of Spill Clean 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.
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Section 10 - TOXICOLOGY INFORMATION

Active ingredient LD₅₀ :	Subcutaneous (rat)	51 mg/kg
	Subcutaneous (mouse)	120 mg/kg
	Intravenous (mouse)	55 mg/kg
Active ingredient LD_{Lo} :	Intravenous (cat)	3 mg/kg
	Intravenous (rabbit)	2500 µg/kg
Inhalation:	Causes respiratory irritation	
Eye Irritation:	Causes eye irritation	
Skin Irritation:	Skin irritation is possible	
Sensitization:	Hypersensitivity may occur; may cause addiction	
Organ Systems:	Primarily targets the central nervous system. May also affect lungs, liver, kidneys, skin and heart.	
Carcinogenicity:	Unknown	
Mutagenicity:	Not mutagenic in the <i>in vitro</i> Ames reverse mutation assay, in the <i>in vitro</i> chromosome aberration assay in human lymphocytes, or, in the <i>in vivo</i> mouse bone marrow micronucleus test	
Reproductive Effects:	Fertility in male and female rats was not affected after daily oral administration at doses up to 7 mg/kg/day.	
Developmental Effects:	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.	
Nonteratogenic Effects:	Babies born to mothers who have been taking opioids regularly prior to delivery, will be physically dependent.	

Section 11 - ECOLOGICAL INFORMATION

Ecotoxicity Data:	No data available
Persistence / Degradability:	Short term products of biodegradation are not likely. Long term degradation products may arise.
Bioaccumulation / Accumulation:	No applicable bioaccumulation is expected in the environment.
Mobility in Environment:	Appreciable volatilization is not expected into the air. Can freely move through the aquatic environment



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Section 12 - REGULATORY INFORMATION

Carcinogenicity:

NTP:	No
IARC Monographs:	No
OSHA:	No
U.S. Regulations	
DEA:	Schedule II narcotic
RTECS #:	QD2625000
TSCA:	Not Available
HMIS Classification:	Health -3, Fire- 1, Reactivity-0
NFPA Rating:	Not Determined

California Safe Drinking Water & Toxic Enforcement Act (Prop 65):

This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins under California Proposition 65.

Section 13 - DISPOSAL INFORMATION

Dispose of material according to Federal, State, and Local regulations. The method typically used is incineration. Additionally, because this is a controlled substance, notify the local DEA office for appropriate disposal procedures.

Section 14 - TRANSPORTATION INFORMATION

DOT:	Not classified as hazardous by Department of Transportation regulations. This product does not pose an unreasonable risk to health and safety or property when transported in commerce.
ICAO/IATA:	Not Regulated

Section 15 - OTHER INFORMATION

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