

373474



MATERIAL SAFETY DATA SHEET

SECTION 1 - PRODUCT & COMPANY IDENTIFICATION

1501 East Woodfield Road Emergency Telephone (800) 551-7176
Suite 300 East
Schaumburg, IL 60173
(847) 969-2700

Product Identifier: Haloperidol Injection, USP
Chemical Name: Haloperidol Lactate
Category: Antipsychotic

SECTION 2 - COMPOSITION

<u>Ingredient</u>	<u>CAS Number</u>	<u>Amount</u>
Haloperidol Lactate	52-86-8	5 mg/mL
Methylparaben	99-76-3	1.8 mg/mL
Propylparaben	94-13-3	0.2 mg/mL

SECTION 3 - HAZARDS IDENTIFICATION

Route of Entry: Inhalation, eye/skin contact, or ingestion

Chemical Listing as Carcinogen

NTP: No

IARC: No

OSHA: No

Note: NA

SECTION 4 - EMERGENCY & FIRST AID MEASURES

Eyes: Immediately flush eyes with water for at least 15 minutes. Seek medical attention.

Skin: Remove contaminated clothing immediately. Flush area with water for at least 15 minutes. Wash exposed area with soap and water. Seek medical attention.

Inhalation: Move exposed subject to fresh air immediately. Give artificial respiration and cardiopulmonary resuscitation (CPR) if required. Seek medical attention.

SECTION 4 - EMERGENCY & FIRST AID MEASURES...continued

Ingestion: If individual is conscious, induce vomiting or perform gastric lavage. Immediately follow with administration of activated charcoal. Seek medical attention.

Note: If necessary, counteract hypotension and circulatory collapse with intravenous fluids, plasma, or concentrated albumin, and vasopressor agents such as metaraminol, phenylephrine, and norepinephrine. Epinephrine should not be used. In cases of severe extrapyramidal reactions, antiparkinson medication should be administered. ECG and vital signs should be monitored especially for signs of QT prolongation or dysrhythmias.

Contact Info: For Adverse Event Information, please call (800) 551-7176 or (847) 969-2700.

SECTION 5 - FIRE FIGHTING MEASURES

Fire and Explosion Data

Closed Cup Flash Point:	NE
Open Cup Flash Point:	NE
Fire Point:	NE
Autoignition:	NE
Lower Explosion Limit:	NE
Upper Explosion Limit:	NE
General Hazard:	When heated to decomposition, toxic fumes may be emitted.
Fire Fighting Instructions:	Water spray, dry chemical, carbon dioxide, or foam as appropriate to surroundings.
Fire Fighting Equipment:	Wear self-containing breathing apparatus and protective clothing.
Hazardous Combustion Products:	Toxic fumes of F ₂ , Cl ₂ , and NO _x .

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Clean-Up: Wear recommended personal protective equipment (See Section 8 - Exposure Controls/Personal Protection). Use absorbent towels or brooms to clean-up spill. Wipe surface area clean with soap and water.

SECTION 7 - HANDLING AND STORAGE

General Handling: When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product.

Storage Conditions: Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F) [see USP Controlled Room Temperature]. Do not freeze. Protect from light.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: General room ventilation is usually satisfactory. Use local exhaust ventilation if necessary.

Personal Protective Equipment

Eye Protection: Safety glasses or goggles recommended.

Hand Protection: Disposable latex gloves recommended.

Respiratory Protection: With satisfactory ventilation, respiratory protection is usually not required.

Skin Protection: Disposable garments if direct skin contact is anticipated.

Exposure Limits:

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Haloperidol Lactate	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	STEL	NE
Methylparaben	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	STEL	NE
Propylparaben	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	STEL	NE

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

**Physical Form/
Appearance:** Clear, colorless solution.

**Boiling Point/Boiling
Range:** NE

**Melting Point/Melting
Range:** 147 - 152°C

Freezing Point: NE

Vapor Pressure: NE

Relative Vapor Density: NE

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES...continued

Percent Volatiles: NE
pH: 3.0 - 3.8
Molecular Weight: 375.86
Solvent Solubility: Insoluble in water.
Note: NA

SECTION 10 - STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: Protect from freezing, extreme heat, and light.
Hazardous Polymerization: Will not occur

SECTION 11 - TOXICOLOGY INFORMATION

Signs & Symptoms of Exposure & Overexposure: This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Adverse reactions from therapeutic doses include: extrapyramidal symptoms, tardive dyskinesia, tardive dystonia, insomnia, restlessness, anxiety, neuroleptic malignant syndrome (NMS), tachycardia, hypotension, hypertension, leukopenia, leukocytosis, impaired liver function, maculopapular skin reactions, lactation, breast engorgement, anorexia, dry mouth, blurred vision, laryngospasm, and bronchospasm. Occupational exposure has not been fully investigated.

Medical Conditions Aggravated by Accidental Exposure: Individuals with severe toxic central nervous system depression, hypersensitivity to this drug, or have Parkinson's disease.

Acute Toxicity:

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dosage</u>
Haloperidol Lactate	LD ₅₀	Oral	Rat	128 mg/kg
	LD ₅₀	Oral	Mouse	71 mg/kg
	LD ₅₀	IP	Rat	27 mg/kg
	LD ₅₀	IP	Mouse	30 mg/kg
	LD ₅₀	SC	Mouse	41 mg/kg
	LD ₅₀	IV	Mouse	15 mg/kg
	LD ₅₀	Oral	Dog	90 mg/kg
	TD _{1,0}	Multiple	Man	343 mcg/kg
	LD ₅₀	IV	Dog	18 mg/kg

SECTION 11 - TOXICOLOGY INFORMATION...continued

Other: IMMEDIATE EFFECTS:
Eye, skin, and respiratory irritation.

DELAYED EFFECTS:
Possible hypersensitization.

SECTION 12 - TRANSPORTATION INFORMATION

UN/NA Number: NA

U.S. DOT Hazard Class: NA

Proper Shipping Name: NA

Shipping Label: NA

SECTION 13 - DISPOSAL INFORMATION

Disposal Procedure : Treatment, storage, transportation, and disposal must be in accordance with applicable federal, state, and local regulations.

SECTION 14 - OTHER

Key to Abbreviations: ACGIH - American Conference of Governmental Industrial Hygienists
HEPA - High Efficiency Particulate Air
IARC - International Agency for Research on Cancer
NA - Not Applicable
NE - Not Established
NG - Not Given
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OEL - Occupational Exposure Limit
OSHA - Occupational Safety and Health Administration
PEL - Permissible Exposure Limit
PPM - Parts Per Million
QS - Quantity Sufficient
RCRA - Resource Conservation and Recovery Act
STEL - Short Term Exposure Limit
TLV - Threshold Limit Value
USP - United States Pharmacopeia

SECTION 14 - OTHER...continued

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