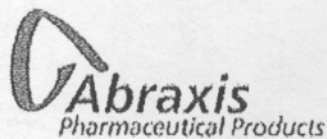


373474



## 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.

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

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**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.

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**SECTION 5 - FIRE FIGHTING MEASURES**

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**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<sub>2</sub>, Cl<sub>2</sub>, and NO<sub>x</sub>.

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**SECTION 6 - ACCIDENTAL RELEASE MEASURES**

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**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.

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**SECTION 7 - HANDLING AND STORAGE**

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**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.

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**SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION**

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**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

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**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES**

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**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

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**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES...continued**

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

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**SECTION 10 - STABILITY AND REACTIVITY**

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

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**SECTION 11 - TOXICOLOGY INFORMATION**

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**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 <sub>50</sub>	Oral	Rat	128 mg/kg
	LD <sub>50</sub>	Oral	Mouse	71 mg/kg
	LD <sub>50</sub>	IP	Rat	27 mg/kg
	LD <sub>50</sub>	IP	Mouse	30 mg/kg
	LD <sub>50</sub>	SC	Mouse	41 mg/kg
	LD <sub>50</sub>	IV	Mouse	15 mg/kg
	LD <sub>50</sub>	Oral	Dog	90 mg/kg
	TD <sub>L0</sub>	Multiple	Man	343 mcg/kg
	LD <sub>50</sub>	IV	Dog	18 mg/kg

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**SECTION 11 - TOXICOLOGY INFORMATION...continued**

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

  DELAYED EFFECTS:  
  Possible hypersensitization.

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**SECTION 12 - TRANSPORTATION INFORMATION**

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**UN/NA Number:**                    NA  
**U.S. DOT Hazard Class:**         NA  
**Proper Shipping Name:**        NA  
**Shipping Label:**                 NA

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**SECTION 13 - DISPOSAL INFORMATION**

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

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**SECTION 14 - OTHER**

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**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

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SECTION 14 - OTHER...continued

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