	<b>Sagent Pharmaceuticals, Inc.</b>				
	<b>Haloperidol Injection, USP</b>			<b>Material Safety Data Sheet (MSDS)</b>	
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### Section 1 - Chemical Product and Company

**Distributor:**

Sagent Pharmaceuticals, Inc.  
1901 N. Roselle Rd, Suite 700  
Schaumburg, IL 60195  
847-908-1600

**Emergency Telephone:** 866-625-1618

**Product Identifier:** Haloperidol Injection, USP  
**Product Code:** 25021-806  
 25021-823  
**Common/Trade Name:** Haldol®  
**Chemical Name:** 4-[4-(p-chlorophenyl)-4-hydroxypiperidino]-4'-fluorobutyrophenone.  
**Chemical Family:** Antipsychotic  
**Product Use:** Pharmaceutical  
**Product Type:** Regulated Prescription Drug  
**Container Information:** Vials

### Section 2 - Composition / Information on Ingredients

Ingredient	Weight %	CAS No.
Haloperidol	.5	52-86-8
Lactic Acid	q.s. for pH adjustment	50-21-5
Methylparaben*	0.18	99-76-3
Propylparaben*	0.02	94-13-3
Water for Injection	Balance	7732-18-5

(\*25021-806 is Preservative-free and does not contain these ingredients)


### Section 3 - Hazards Identification

**Primary Physical and Health Hazards:**

Haloperidol is a drug used in the treatment of psychotic disorders. Irritation of eyes, skin, and respiratory system may result. Product affects the central nervous, cardiovascular and digestive systems. Allergic reactions may occur. Haloperidol is teratogenic and may have adverse affects on a developing fetus. Chronic exposures may cause mammary tumors or breast cancer.

**Routes of Entry:**

Product may be absorbed via inhalation, ingestion or skin contact.

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**Signs & Symptoms of Exposure:**

Excessive exposure may cause restlessness, blurred vision, constipation, dry mouth, muscle twitching and spasms, weakness/stiffness in arms or legs, secretion of breast milk, breathing difficulty, rapid heart rate and muscle spasms. Irritation may also occur.

**Chemical Listed as Carcinogen:**

**NTP:** No **IARC:** No **OSHA:** No

**Medical Conditions Generally Aggravated by Exposure:**

Active alcoholism, severe cardiovascular disease, epilepsy, glaucoma, impaired liver or kidney function, hyperthyroidism, thyrotoxicosis, Parkinsons disease, asthma, or other respiratory illnesses.

#### Section 4 - First Aid Measures

**Eye Exposure:**

Flush eyes with large volumes of water for 15 or more minutes.

**Skin Exposure:**

Wash skin with cool, soapy water.

**Ingestion:**

If ingestion occurs, flush mouth with water and seek medical attention immediately. If person is conscious, induce vomiting. Never induce vomiting on an unconscious person.

**Injection:**

Not established

**Inhalation:**

If difficulty breathing, administer oxygen. Seek attention of a physician immediately.  
\*If necessary, counteract hypotension and circulatory collapse by use of intravenous fluids, plasma, or concentrated albumin and vasopressor agents such as norepinephrine. Administer benztropine or diphenhydramine to manage severe extrapyramidal reactions. Epinephrine should not be used.

**Notes to Physician:**

See patient package insert in shipping carton for complete information.

#### Section 5 - Fire Fighting Measures

**Flash Point:**

>200°F (Cleveland Closed Cup Method)

**Auto-ignition Temperature:**


Not established

**Flammable Limits in Air:**

Lower %: Not established  
Upper %: Not established

**Flammable Limits:**

Not established

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<b>Extinguishing Media:</b>	Use a multipurpose ABC extinguisher.
<b>Special Fire Fighting Procedures:</b>	As with all fires, evacuate personnel to a safe area. Fire fighters must wear self-contained breathing apparatus to avoid inhalation of smoke.
<b>Unusual Fire/Explosion Hazards:</b>	None

### Section 6 - Accidental Release Measures

<b>Spill:</b>	Prevent entry of Haloperidol into waterways. Use absorbents to wipe up spills. Soap and water may be used to decontaminate surfaces.
<b>Release to Air:</b>	If aerosols are generated, reduce exposure by ventilating area and wear respiratory protection.
<b>Release to Water:</b>	Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

### Section 7 - Handling and Storage

<b>General Handling:</b>	When handling pharmaceutical products, avoid all contact or inhalation of dust, fumes, mist and/or vapors associated with the product.
<b>Waste Disposal Method:</b>	Dispose of waste according to local, state and federal guidelines. Incineration is recommended.
<b>Storage Conditions:</b>	Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.] Follow instructions provided in packaging.

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**Section 8 - Exposure Controls / Personal Protection**

**Respiratory Protection:** Under normal use, respirators are not required. If aerosols are generated, an air-purifying respirator with HEPA (P100) and organic vapor cartridges may be worn. For large spill emergencies, SCBA may be required. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR1910.134.

**Eye Protection:** Safety glasses or goggles

**Ventilation:** Use with adequate ventilation


**Skin Protection:** Latex or nitrile gloves

**Other Protective Equipment:** Lab coat

**Additional Exposure Precautions:** Wash hands following use. No eating, drinking, or smoking while handling this product.

**Exposure Limits**

<b><u>Compound</u></b>	<b><u>Issuer</u></b>	<b><u>Type</u></b>	<b><u>OEL</u></b>
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


<b>Physical State:</b>	Liquid	<b>Specific Gravity:</b>	Approx. to water
<b>Appearance and Odor:</b>	Pale yellow, clear with odor	<b>Evaporation Rate:</b>	Approx. to water
<b>Boiling Point:</b>	Approx. to water	<b>Melting Point:</b>	Liquid at room temperature
<b>Vapor Pressure:</b>	Approx. to water	<b>Solubility in Water:</b>	Soluble
<b>Vapor Density:</b>	Approx. to water	<b>pH:</b>	3.0-3.8
		<b>Molecular Weight:</b>	375.86

### Section 10 - Stability and Reactivity

<b>Stability:</b>	Stable
<b>Incompatibility (Materials to avoid):</b>	Oxidizers
<b>Hazardous Decomposition:</b>	Decomposition products of this compound may include potentially hazardous byproducts of nitrogen oxides, carbon monoxide, and sulfur dioxide.
<b>Hazardous Polymerization:</b>	Will not occur
<b>Conditions to Avoid:</b>	Avoid contact with oxidizers.

### Section 11 - Toxicological Information

<b>Signs &amp; Symptoms of Exposure:</b>	Excessive exposure may cause restlessness, blurred vision, constipation, dry mouth, muscle twitching and spasms, weakness/stiffness in arms or legs, secretion of breast milk, breathing difficulty, rapid heart rate and muscle spasms. Irritation may also occur.
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### Acute Toxicity

Component	Type	Route	Species	Dosage
Haloperidol	LD <sub>50</sub>	Oral	Rat	128 mg/kg
Haloperidol	LD <sub>50</sub>	Oral	Mouse	71 mg/kg
Haloperidol	LD <sub>50</sub>	Intraperitoneal	Rat	27 mg/kg
Haloperidol	LD <sub>50</sub>	Intraperitoneal	Mouse	30 mg/kg
Haloperidol	LD <sub>50</sub>	Subcutaneous	Mouse	41 mg/kg
Haloperidol	LD <sub>50</sub>	Intravenous	Mouse	13 mg/kg

Additional reproductive health data is available from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS)

### Section 12 - Ecological Information

No applicable ecological information found.

### Section 13 - Disposal Considerations

**Waste Disposal:** Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.


### Section 14 - Transport Information

**Regulatory Organizations:**

**DOT:** Not Regulated

**ICAO/IATA:** Not established

**IMO:** Not established

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### Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

#### **U.S. Regulations**

RCRA - *No*

CERCLA - *Not on this list*

SARA 302 - *Not on this list*

SARA 313 - *Not on this list*

TSCA - *Not on this list*


Listed on California's Proposition 65 as Code DF

### Section 16 - Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

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**Glossary:** This glossary contains definitions of general terms used in MSDSs. Not all of these Glossary Terms will apply to this MSDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)