



300 Northfield Road
 Bedford, OH 44146
 Telephone: (440) 232-3320
 -or- (800) 562-4797

MATERIAL SAFETY DATA SHEET

Section I - IDENTITY

Common/Trade Name: Haloperidol Lactate 5mg/mL (1mL/vial and 10mL/vial)
Chemical Names: 4-[4-(p-chlorophenyl)-4-hydroxypiperidino]-4'-fluorobutyrophenone)
Synonyms: Haldol®, Aldoperiden, Dozic, Einalon S, Galoperidol, Fortunan, Linton, Pernox, Serenace
Manufacturer's Name: BEN VENUE LABORATORIES, INC.
Address: 300 NORTHFIELD ROAD
 BEDFORD, OH 44146
Emergency Telephone Number: Chemtrec: (800) 424-9300
Telephone Number for Info.: (440) 232-3320 or (800) 562-4797
Medical Emergency: Professional Services: (800) 521-5169
Date Prepared: March 14, 2001
Date Revised: December 18, 2001
Date Revised: July 16, 2007

Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

<u>Component</u>	<u>%</u>	<u>CAS#</u>	<u>OSHA PEL</u>	<u>ACGIH TLV</u>	<u>Other Limits Recommended</u>
Haloperidol USP	0.5	52-86-8	NONE	NONE	NONE
Methylparaben	0.18	99-76-3	NONE	NONE	NONE
Propylparaben	0.02	94-13-3	NONE	NONE	NONE
Lactic Acid/adjust pH	0.38	50-21-5	NONE	NONE	NONE
Water for Injection	98.92	7732-18-5	NONE	NONE	NONE

Haloperidol Lactate is a sterile injectable liquid drug provided in a vial.

Section III - HEALTH HAZARD DATA

Routes of Entry: Product may be absorbed via inhalation, ingestion, or skin contact.
Health Hazard (Acute & Chronic): 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.
Carcinogenicity: NTP? NO IARC Monographs? NONE
 OSHA Regulated? NO

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.

Medical Conditions Generally Aggravated by Exposure: Active alcoholism, severe cardiovascular disease, epilepsy, glaucoma, impaired liver or kidney function, hyperthyroidism, thyrotoxicosis, Parkinsons disease, asthma, and other respiratory illnesses.

BVL Hazard Category: 3

Section IV - 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.

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.

Section V - FIRE AND EXPLOSION HAZARD DATA

Flash Point (Method Used): >200°F Cleveland Closed Cup **LEL:** not available **UEL:** not available

Flammable Limits: Not Available

Extinguishing Media: Use a multi-purpose ABC extinguisher.

Special Fire Fighting Procedures: As with all fires, evacuate personnel to a safe area. Fire fighters must wear self-contained breathing apparatus to avoid inhalation of smoke.

Unusual Fire/Explosion Hazards: None

Section VI - ACCIDENTAL RELEASE INFORMATION

Release to Land: Prevent entry of Haloperidol Lactate into waterways. Use absorbents to wipe up spills. Soap and water may be used to decontaminate surfaces.

Release to Air: If aerosols are generated, reduce exposures by ventilating area and wear respiratory protection.

Release to Water: Refer to local water authority; drain disposal is not recommended. Refer to local, state and federal guidelines.

Section VII - PRECAUTIONS FOR SAFE HANDLING AND USE

Steps to be taken in case material is released or spilled: See Section VI above. Wear all necessary protective equipment including nitrile gloves, protective clothing, safety glasses and an air-purifying respirator with HEPA (P100) and organic vapor cartridges.

Waste Disposal Method: Dispose of waste according to local, state, and federal guidelines. Incineration is recommended.

Precautions to be taken in handling and storing: Store product at 15-30°C or 59-86°F. Protect from light. Do not freeze.

Other Precautions: None

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

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 CFR 1910.134.

Ventilation: Use with adequate ventilation.

Protective Gloves: Latex or nitrile

Eye Protection: Safety glasses or goggles

Other Protective Clothing or Equipment: Lab coat

Work/Hygienic Practices: Wash hands following use. No eating, drinking, or smoking while handling this product.

Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical State: Liquid

Appearance and Odor: Pale yellow, clear with odor

Boiling Point: Approximate to water

Vapor Pressure: Approximate to water

Vapor Density: Approximate to water

Specific Gravity: Approximate to water

Melting Point: Liquid at room temperature

Evaporation Rate: Approximate to water

Solubility in Water: Soluble

pH: 3.0-3.6

Section X - STABILITY AND REACTIVITY DATA

Stability: Stable

Incompatibility (Materials to Avoid): Oxidizers

Hazardous Decomposition or Byproducts: Decomposition products of this compound may include potentially hazardous byproducts of nitrogen oxides, carbon monoxide, and sulfur dioxide.

Hazardous Polymerization: Will not occur

Conditions to Avoid: Avoid contact with oxidizers

Section XI - TOXICOLOGICAL INFORMATION

Toxicity data is for the active ingredient, Haloperidol: RTECS # EU1575000

LD₅₀ oral, rat = 128 mg/kg

LD₅₀ oral, mouse = 71 mg/kg

LD₅₀ intraperitoneal, rat = 27 mg/kg

LD₅₀ intraperitoneal, mouse = 30 mg/kg

LD₅₀ subcutaneous, mouse = 41 mg/kg

LD₅₀ intravenous, mouse = 13 mg/kg

LD₅₀ oral, dog = 90 mg/kg

TDLo multiple man = 343 ug/kg

LD₅₀ intravenous, dog = 18 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 XII - ENVIRONMENTAL IMPACT INFORMATION

Information is currently not available on the environmental impact of Haloperidol. Handle in a manner to prevent spills or releases to the environment.

Section XIII - DISPOSAL INFORMATION

Dispose of according to local, state, and federal guidelines. Recommend disposal via incineration

in an approved, licensed incinerator.

Section XIV - TRANSPORTATION INFORMATION

Haloperidol Lactate is not D.O.T. hazardous according to 49 CFR 172.101

Haloperidol Lactate not a Marine Pollutant

Section XV - REGULATORY INFORMATION

SARA 313 listed?: NO

CERCLA listed?: NO

RCRA listed?: NO

Listed on California's Proposition 65 as Code DF

Section XVI - OTHER DATA

1. Use of this product should be through or under the direction of a physician. This MSDS does not address the therapeutic use of this material.
2. Persons administering this drug to patients must be careful to avoid needle sticks to syringes and other sharps used in the administration. All needle sticks must be reported to your company management.
3. BVL Hazard Category Definitions (internal hazard ranking used by Ben Venue Laboratories):
1 = Low Toxicity
2 = Moderate Toxicity
3 = Potent or Toxic
4 = Highly Potent or Toxic
5 = Extremely Potent or Toxic
4. OEL=Occupational Exposure Limit. An internal limit set by Ben Venue Laboratories for the recommended limit of employee exposure to airborne dusts or aerosols that should not be exceeded over an eight-hour time-weighted average.
5. Haloperidol Lactate may be considered a Hazardous Drug as described in the NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings. Employees who prepare or administer hazardous drugs or who work in areas where these drugs are used should follow specific handling guidelines in order to prevent exposure to these agents in the air or on work surfaces, clothing, or equipment.
6. **The Following Guidance Information is excerpted from the NIOSH Alert:**

Elements of a Hazardous Drug Handling Program include:

- Establishment and implementation of written policies and protocols to ensure the safe handling of oncolytic and/or potent drugs, including receipt of product.
- Training and education of employees on the recognition, evaluation and control of Hazardous Drugs
- Effective Planning and design of the workplace
- Use of best practice control measures and specialized equipment such as ventilated cabinets or isolators designed for worker protection
- Wearing recommended personal protective equipment
- An integrated health surveillance program that: includes the assessment and counseling of prospective employees before they commence any work involving oncolytic and/or potent drugs and related waste

7. **Published guidance on the handling and transport of cytotoxic drugs:**

NIOSH Alert – Preventing occupational exposures to antineoplastic and other hazardous drugs in health care settings

<http://www.cdc.gov/niosh/docs/2004-165/>

National Study Commission on Cytotoxic Exposure: Recommendation for handling Cytotoxic Agents:

<http://www.nih.gov/od/ors/ds/pubs/cyto/index.htm>

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