Material Safety Data Sheet

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Rockville, MD 20852 USA

Phone Calls: 301-816-8129
8 a.m. to 5 p.m. EST Mon. - Fri.

HALOPERIDOL

Catalog Number: 1303002 **Revision Date:** October 4, 2005

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Common Name: Haloperidol

Manufacturer: U. S. Pharmacopeia

Responsible Party: Reference Standards Technical Services

Mailing Address: 12601 Twinbrook Parkway, Rockville, MD 20852 USA

Phone: 301-816-8129

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Product Use: USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

SECTION 2 - HAZARD INFORMATION

EMERGENCY OVERVIEW - Toxic.

Adverse Effects: Adverse effects may include restlessness or need to keep moving; skin rash; difficult urination; hallucinations; decreased thirst; unusual tiredness or weakness; dizziness, lightheadedness, or fainting; blurred vision; changes in menstrual period; constipation; decreased sweating; nasal congestion; dry mouth; swelling or soreness of breasts; unusual secretion of milk; weight gain; decreased sexual ability; drowsiness; increased sensitivity of skin to sun; nausea or vomiting; and extrapyramidal effects (muscle spasms, uncontrollable body movements, inability to move eyes, weakness or stiffness in arms or legs, difficulty speaking or swallowing, loss of balance, mask-like face, shuffling walk). Possible allergic reaction to material if inhaled, ingested, or in contact with skin.

Overdose Effects: Symptoms of overdose may include an exaggeration of adverse effects, including severe breathing difficulty; severe drowsiness; coma or shock-like state; and severe, uncontrolled muscle movements.

Acute: Possible eye, skin, gastrointestinal, and/or respiratory tract irritation.

Chronic: Possible hypersensitization and tardive dyskinesia (lip smacking or puckering, puffing of cheeks, rapid or worm-like movement of tongue, uncontrolled chewing movements, uncontrolled movement of arms and legs).

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, active alcoholism, cardiovascular disease, epilepsy, Parkinson's disease, and urinary retention.

Cross Sensitivity: n/f

Target Organs: Central nervous system

For additional information on toxicity, see Section 11.

n/f = not found

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Common Name: Haloperidol

Formula: C21H23ClFNO2

Synonym: n/f

Chemical Name: 1-Butanone, 4-[4-(4-chlorophenyl)-4-hydroxy-1-piperidinyl]-1-(4-fluorophenyl)-

CAS: 52-86-8

RTECS Number: EU1575000

Chemical Family: Butyrophenone derivative

Therapeutic Category: Antidyskinetic; antipsychotic

Composition: Pure Material

SECTION 4 - FIRST AID MEASURES

Inhalation: May cause irritation. Remove to fresh air.

Eye: May cause irritation. Flush with copious quantities of water.

Skin: May cause irritation or contact dermatitis. Flush with copious quantities of water.

Ingestion: May cause irritation and toxicity. Avoid ingestion. Flush out mouth with water. This material is readily absorbed from the gastrointestinal tract.

General First Aid Procedures: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen. Obtain medical attention.

Note to Physicians

Overdose Treatment: Treatment is essentially symptomatic and supportive and may include the following:

1. Induce vomiting or perform gastric lavage, immediately followed by administration of activated charcoal.
2. Establish a patent airway and mechanically assist respiration, if necessary.
3. Counteract hypotension and circulatory collapse by use of intravenous fluids, plasma, or concentrated albumin, and vasopressor agents such as norepinephrine. Epinephrine should NOT be used.
4. Administer benztropine or diphenhydramine to manage severe extrapyramidal reactions.
5. Monitor ECG and treat severe arrhythmias.
6. Dialysis is not effective in removing excess systemic haloperidol. [USP DI 2005]

SECTION 5 - FIREFIGHTING MEASURES

Extinguisher Media: Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

Fire and Explosion Hazards: This material is assumed to be combustible. As with all dry powders, it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

Firefighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Spill Response: Wear approved respiratory protection, chemically compatible gloves, and protective clothing. Wipe up spillage or collect spillage using a high-efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labeled container for disposal. Wash spill site.

SECTION 7 - HANDLING AND STORAGE

Handling: As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors

n/f = not found

associated with the material. Wash thoroughly after handling.

Storage: Store in tight, light-resistant container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION

Engineering Controls: Engineering controls such as exhaust ventilation are recommended.

Respiratory Protection: Use a NIOSH-approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

Gloves: Chemically compatible

Eye Protection: Safety goggles or glasses

Protective Clothing: Protect exposed skin.

Exposure Limits: n/f

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.

Appearance and Odor: White to faintly yellow amorphous or microcrystalline powder; odorless.

Odor Threshold: n/f

pH: n/f

Melting Range: 148 - 150° C

Boiling Point: n/f

Flash Point: n/f

Autoignition Temperature: n/f

Evaporation Rate: n/f

Upper Flammability Limit: n/f

Lower Flammability Limit: n/f

Vapor Pressure: n/f

Vapor Density: n/f

Specific Gravity: n/f

Solubility in Water: Practically insoluble

Fat Solubility: n/f

Other Solubility: Sparingly soluble in alcohol; freely soluble in chloroform, methanol, acetone, benzene, and diluted acids.

Partition Coefficient: n-octanol/water: 4.30

Percent Volatile: n/f

Reactivity in Water: n/f

Explosive Properties: n/f

Oxidizing Properties: n/f

Formula: C21H23ClFNO2

Molecular Weight: 375.86

SECTION 10 - STABILITY AND REACTIVITY

Conditions to Avoid: Avoid exposure to light.

Incompatibilities: n/f

Decomposition Products: When heated to decomposition, material emits very toxic fumes of F-, Cl-, and NOx. Emits toxic fumes under fire conditions.

Stable? Yes **Hazardous Polymerization?** No

SECTION 11 - TOXICOLOGICAL PROPERTIES

Oral Rat: LD50: 128 mg/kg; 165 mg/kg

Oral Mouse: LD50: 71 mg/kg

Other Toxicity Data: Oral Dog: LD50: 90 mg/kg

Irritancy Data: n/f

Corrosivity: n/f

Sensitization Data: n/f

Listed as a Carcinogen by: **NTP:** No **IARC:** No **OSHA:** No

Other Carcinogenicity Data: Neuroleptic medications (including haloperidol) elevate prolactin concentrations; the elevation persists during chronic administration. Tissue culture experiments indicate that approximately 1/3 of human breast cancers are prolactin dependent in vitro. The clinical significance of raised serum prolactin concentrations is unknown for most patients. An increase in mammary neoplasms has been found in rodents after chronic administration of neuroleptic medications. However, neither clinical nor epidemiologic studies conducted to date have shown an association between chronic administration of these drugs and mammary tumorigenesis; the available evidence is considered too limited to be conclusive at this time. [USP DI 2005]

Mutagenicity Data: Positive in human fibroblast and sister-chromatid exchange assays; negative in Ames assay.

Reproductive and Developmental Effects: There are reports of cases of limb malformations observed following maternal use of haloperidol, along with other drugs that are suspected to cause birth defects during the first trimester of pregnancy. Exposure during later pregnancy may cause extrapyramidal side effects in the newborn as in the adult. Some rodent studies have shown an increase in incidence of fetal resorptions, delayed delivery, and newborn death with haloperidol doses 2 to 20 times the usual maximum human dose. Cleft palate has been observed in mice given haloperidol at 15 times the usual maximum human dose.

SECTION 12 - ECOLOGICAL INFORMATION

Ecological Information: n/f

SECTION 13 - DISPOSAL CONSIDERATIONS

Disposal: Dispose of waste in accordance with all applicable Federal, State, and local laws.

SECTION 14 -TRANSPORT INFORMATION

Shipping Name: Toxic solid, organic, n.o.s. (Haloperidol)

Class: 6.1

UN Number: UN2811

Packing Group: III

Additional Transport Information: n/f

SECTION 15 - REGULATORY INFORMATION

U.S. Regulatory Information: California Proposition 65 Developmental Toxicity
California Proposition 65 Reproductive Toxicity Female

International Regulatory Information: EINECS #: 200-155-6

SECTION 16 - OTHER INFORMATION

Revision: 04-Oct-05

Previous Revision Date: 19-Feb-02

n/f = not found