

SAFETY DATA SHEET

PRODUCT: Haloperidol Injection

Section 1: PRODUCT AND COMPANY INFORMATION

Wintac Limited 54/1, Boodhihal village, Nelamangala, Bangalore, India-562123. PRODUCT NAME: Haloperidol Injection

Section 2: HAZARD(S) IDENTIFICATION

EMERGENCY OVERVIEW	
Appearance	Clear, pale yellow solution, free from visible extraneous matter.
Classification of the substance or Mixture	
Statement of Hazard:	May be harmful if swallowed. May damage the unborn child. May cause nervous system, cardiovascular system and reproductive effects
Additional Hazard Information:	
Short Term:	Overdose: Seizure and/or coma may occur.
Long Term:	Animal studies have shown a potential to cause adverse effects on the fetus. Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system. Can cause effects on central nervous system, gastrointestinal, cardiovascular system and respiratory system.
Known Clinical Effects:	Therapeutic use of this substance has resulted in weakness, dizziness, drowsiness, ataxia, confusion, tremors, headache, and gastrointestinal disturbances. As with all antipsychotic agents, tardive dyskinesia may appear. This syndrome is characterized by rhythmical involuntary movements of the tongue, face, mouth, or jaw. Higher doses may cause CNS stimulation and/or depression, and impairment of motor and cognitive skills.
EU Indication of danger:	Not classified

Section 3: COMPOSITION AND INFORMATION ON INGREDIENTS

Chemical Name	CAS Number
Haloperidol Decanoate USP	74050-97-8
Benzyl Alcohol NF	100-51-6
Sesame Oil NF	8008-74-0

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. * Proprietary

Section 4: FIRST AID MEASURES

Eye Contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If irritation occurs or persists, get medical attention.
Skin Contact:	Wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance if irritation occurs.
Inhalation:	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
Ingestion:	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Section 5: FIRE FIGHTING MEASURES

Extinguishing Media:	Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products:	Formation of toxic gases is possible during heating or fire.
Fire Fighting Procedures:	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Fire / Explosion Hazards:	Not applicable

Section 6: ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Measures for Cleaning / Collecting:	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Additional Consideration for Large Spills	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

Section 7: HANDLING AND STORAGE

Handling	Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.
Storage	Store at controlled room temperature.

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits	The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.
Hands:	Wear protective gloves when working with large quantities
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Wear protective clothing when working with large quantities.
Respiratory protection:	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

<p>Appearance Clear, pale yellow solution,</p> <p>Decomposition Temperature (°C): No data available.</p> <p>Evaporation Rate (Gram/s): No data available</p> <p>Vapour Pressure (kPa): No data available</p> <p>Vapour Density (g/ml): No data available</p> <p>Relative Density: No data available</p> <p>Viscosity: No data available</p> <p>Flammability: Auto ignition Temperature (Solid) (°C): No data available</p> <p>Flammability (Solids): No data available</p> <p>Flash Point (Liquid) (°C): No data available</p> <p>Upper Explosive Limits (Liquid) (% by Vol.): No data available</p> <p>Lower Explosive Limits (Liquid) (% by Vol.): No data available</p>
--

Section 10: STABILITY AND REACTIVITY

Stability:	Stable at normal conditions
Conditions to Avoid:	None known
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers.

Section 11: TOXICOLOGY INFORMATION

General Information:

The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)**Haloperidol**

Rat Oral LD 50 128 mg/kg

Rat Subcutaneous Minimum Symptomatic Dose 1 mg/kg

Lactic acid

Rat Oral
LD50

3543 mg/kg

Rabbit

Dermal

LD50

>2000 mg/kg

Glucose

Rat Oral LD50 25800 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)**Lactic acid**

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Moderate Severe

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**Haloperidol**

13 Week(s) Rat Oral 10 mg/kg

NOAEL None identified
 6 Month(s) Dog 2 mg/kg LOEL
 Central Nervous System
 1 Year(s) Rat 10 mg/kg LOEL Central Nervous System
 80 Week(s) Rat Oral 0.34-1.11 mg/kg LOEL Central Nervous System

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Haloperidol

Reproductive & Fertility Rat Oral 0.5-5 mg/kg LOAEL Developmental toxicity, Fetotoxicity, Fertility Reproductive & Fertility Mouse Intraperitoneal
 0.5-5 mg/kg

LOAEL Developmental toxicity, Fetotoxicity, Fertility Reproductive & Fertility Rat Oral
 30 mg/kg/day

LOAEL Fertility

Embryo / Fetal Development Rat Oral 15 mg/kg
 LOAEL Developmental toxicity

Embryo / Fetal Development Rat Oral 0.5-5 mg/kg
 LOAEL Teratogenic,

Fetotoxicity

Lactic acid

Reproductive & Fertility Rat Oral 6.25 mg/kg/day NOEL Fertility, Not teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Haloperidol

Bacterial Mutagenicity
 (Ames)

B

acteria

P

ositive Sister Chromatid
 Exchange

R

at

P

ositive Mammalian Cell
 Mutagenicity

at R
P
ositive

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Haloperidol

2 Year(s) Rat Oral 5 mg/kg/day NOEL Not carcinogenic
2 Year(s) Female Mouse Oral 1.25 mg/kg/day LOEL Tumors, Mammary gland
2 Year(s) Female Mouse Oral 5 LOEL Tumors, Endocrine system, Mammary gland

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview:	Environmental properties have not been thoroughly
--------------------------------	---

Section 13: DISPOSAL CONDITIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

Section 14: TRANSPORTATION INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations

Section 15: REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:

DANGER

May be harmful if swallowed. May damage the unborn child.

May cause nervous system, cardiovascular system and reproductive effects.

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 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.