SECTION 1: IDENTIFICATION

Product Identifier

Product Name	:	Haloperidol Decanoate Injection
Product Use	:	Pharmaceutical product used as antipsychotic.
Supplier Details	:	Caplin Steriles Limited, Survey No. 895 & 897, Guruvarajakandigai, Sirupuzhalpettai (Post), Gummidipoondi (Taluk), Thiruvallur (District), Pin Code: 601 201, Tamil Nadu (State), INDIA.
Emergency Telephone Number	:	+91-4467901901/02/03

SECTION 2: HAZARDS IDENTIFICATION

(a) Classification: GHS Classification**:**
Reproductive toxicity - category 2
Acute oral toxicity – category 4
Specific organ toxicity – STOT, single exposure SE – category 3
Reproductive toxicity; effects on or via lactation

(b) Signal word: Danger

Hazard statement (s): May cause respiratory irritation. Harmful if swallowed. May cause respiratory irritation. May damage fertility or an unborn child. May be harmful to breast-fed children.

Symbols :	

Precautionary Statement(s): Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapors/spray.

(c) Description of Hazards: Not available

(d) Unknown Acute Toxicity: N/A

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS Number	% Composition	Functionality
Haloperidol Decanoate	74050-97-8	5-10%	N/A
Benzyl Alcohol	100-51-6	1.2 -1.5%	Preservative
Sesame Oil	8008-74-0	Quantity sufficient	Vehicle
*Percentages are listed in weight by volume percentage (w/v%).			

SECTION 4: FIRST AID MEASURES

Eye Exposure	:	If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel.
Skin Exposure	:	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel.
Ingestion	:	Do not eat, drink or smoke when using this product. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person.
Inhalation	:	Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel.
Notes to Physician	:	See patient package insert in shipping carton for complete information.

SECTION 5: FIRE FIGHTING MEASURES

Extinguishing media	:	Use water spray, alcohol- resistant foam, dry chemical or carbon dioxide.
Hazardous Combustion Products	:	Not available; May produce toxic fumes of carbon monoxide, carbon dioxide and oxides of nitrogen. Not considered to be a fire hazard. High concentrations of finely divided airborne organic particles could possibly explode if ignited.
Special Protective Equipment/ Precautions	:	As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke and protective clothing.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Spill	:	Take precautions to minimize exposure by using appropriate personal protective equipment (PPE), including nitrile gloves, protective clothing, etc. Avoid release to environment. DO NOT RAISE DUST. Surround spill or powder with absorbents and place a damp cloth or towel over the area to minimize entry of powder into the air. Add excess liquid to allow the material to enter solution. Capture remaining liquid onto spill absorbents. Place spill materials into a leak-proof container suitable for disposal in accordance with applicable waste disposal regulations. Decontaminate the area twice.
Release to Air	:	N/A
Release to Water	:	N/A

SECTION 7: HANDLING AND STORAGE

General Handling : Use adequate ventilation. Wear appropriate personal protective equipment (PPE). Follow recommendations for handling potent cytotoxic pharmaceutical agents. Wash thoroughly after handling.

Storage Conditions : Store at 20º to 25ºC (68º to 77ºF); excursions permitted between 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Do not refrigerate or freeze. Protect from Light. Keep in carton until empty. Keep out of reach of children.

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Haloperidol Decanoate	OSHA	PEL	NE
	ACGIH	TLV	NE
Benzyl Alcohol	OSHA	PEL	NE
	ACGIH	TLV	NE
Sesame Oil	OSHA	PEL	NE
	ACGIH	TLV	NE

(b) Engineering Controls

Ventilation : Use with adequate ventilation Material should be handled inside a closed process, ventilated enclosure, isolator or device of equivalent or better control that is suitable for dusts and/or aerosols.

(c) Individual Protection Measures

Respiratory Protection: : For routine powder handling tasks, an approved and properly worn powered air-purifying respirator equipped with HEPA filters.

Eye Protection : Safety glasses, and side shields, chemical splash goggles or full face shield if necessary.

Skin Protection : Wear Latex or Nitrile gloves, lab coat, or other protective over garment.

Other Protective Equipment : Protective Latex or Nitrile gloves

Additional Exposure Precautions : Wash hands following use. No eating, drinking, or smoking while handling this product. Protective equipment not to be worn outside the work area.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	Clear colorless/pink to yellow amber oily liquid
Odor	:	Not available
Odor Threshold	:	Not available
pH	:	3.0 - 3.8
Melting Point	:	225 - 230 °C
Initial Boiling Point	:	Not available
Flash Point	:	200°C
Evaporation Rate	:	Not available
Flammability	:	Not considered to be a fire hazard
Upper Lower Flammability or Explosion Limits	:	Not available
Vapor Pressure	:	Not applicable
Vapor Density	:	Not available
Relative Density	:	Not available
Solubility(ies)	:	Insoluble in water (0.01 mg/mL). Soluble in most organic solvents.
Partition Coefficient: n-octanol/water	:	Not available
Auto-ignition Temperature	:	Not available
Decomposition Temperature	:	Not available
Viscosity	:	Not available

SECTION 10: STABILITY AND REACTIVITY

Reactivity	:	Not available
Chemical Stability	:	Stable under normal conditions.
Possibility of Hazardous Reactions	:	Hazardous polymerization will not occur.
Conditions to Avoid	:	Avoid extreme temperatures, direct sunlight, any conditions that are incompatible with water and mixing the product with incompatible chemicals
Incompatible Materials	:	Not available
Hazardous Decomposition Products	:	Carbon oxides, nitrogen oxides

SECTION 11: TOXICOLOGICAL INFORMATION

Likely Routes of Exposure	Ingestion, Inhalation, skin, eye, injection
Symptoms related to the physical, chemical and toxicological characteristics	This product is intended for therapeutic use only when prescribed by a physician. May cause irritation of respiratory tract, skin and eyes. Adverse effects from therapeutic doses include: extrapyramidal symptoms, tardive dyskinesia, insomnia, anxiety, euphoria, agitation, vertigo, blurred vision. Aggravation for pre-existing conditions: individuals who are hypersensitive to this drug or have Parkinson's Disease. See package insert for complete list of adverse effects.

Delayed and immediate effects and also chronic effects from short and long term exposure	Acute effects: eye, skin and respiratory irritation may occur. Moderately toxic by ingestion. Chronic effects: hypersensitivity reactions ranging from mild to severe may occur.

Acute Toxicity:

Component	Type	Route	Species	Dosage
Haloperidol Decanoate	LD50	IP	Rat	27 mg/kg
	LD50	IP	Mouse	30 mg/kg
	LD50	SC	Mouse	41 mg/kg
	LD50	IV	Dog	18 mg/kg

Hazardous Chemical Listings

NTP : Not Listed
IARC : Not Listed
OSHA : Not Listed
NIOSH List : Not Listed
DOT : Not regulated

SECTION 12: ECOLOGICAL INFORMATION

Eco Toxicity : No ecotoxicity was found for this product
Persistence and Biodegradability : No further relevant information available
Bio accumulative Potential : No further relevant information available
Mobility in Soil : No further relevant information available
Other Adverse Effects : No further relevant information available

SECTION 13: DISPOSAL CONSIDERATIONS

Dispose of wastes according to prescribed federal, state and local guidelines e.g. appropriately permitted chemical waste incinerator.

SECTION 14: TRANSPORT INFORMATION

UN Number	UN2811
UN Proper Shipping Name	2811 Toxic Solid, Organic, N.O.S Toxic Solid, Organic, N.O.S
Transport Hazard Class(s)	6.1 toxic substances
Packing Group	III
Environmental Hazards	NO
Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not Applicable
Special Precautions	Warning-Toxic Substances

SECTION 15: REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible Caplin 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:

TSCA : Not listed
CERCLA : Not on this list
SARA 302 : Not on this list
SARA 313 : Not on this list

SECTION 16: OTHER INFORMATION

16.1. Other Information: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

16.2. Key or legend to abbreviations and acronyms used in the safety data sheet

ACGIH	American Conference of Governmental Industrial Hygienists
CAS	Chemical Abstract Service Registry
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
DOT	Department of Transportation
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
NA	Not Applicable
NE	Not Established
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
PEL	Permissible Exposure Limit (OSHA)
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
TLV	Threshold Limit Value (ACGIH)
TSCA	Toxic Substances Control Act
UN	United Nations
USP	United States Pharmacopeia

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

History:

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Prepared By	:	Caplin Steriles Limited

----End of SDS---