## 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.<br><br>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:**

| | | |
|---|---|---|
| **Issued Date** | : | 08.08.24 |
| **Revision Date** | : | NA |
| **Version** | : | 00 |
| **Prepared By** | : | Caplin Steriles Limited |

**----End of SDS---**