## SECTION 1: PRODUCT IDENTIFICATION

<table>
<thead>
<tr>
<th>PRODUCT NAME</th>
<th>HALOPERIDOL, USP</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRODUCT CODE</td>
<td>0330</td>
</tr>
<tr>
<td>SUPPLIER</td>
<td>MEDISCA Inc.</td>
</tr>
<tr>
<td></td>
<td>Tel.: 1.800.932.1039</td>
</tr>
<tr>
<td></td>
<td>661 Route 3, Unit C, Plattsburgh, NY, 12901</td>
</tr>
<tr>
<td></td>
<td>3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118</td>
</tr>
<tr>
<td></td>
<td>6641 N. Belt Line Road, Suite 130, Irving, TX, 75063</td>
</tr>
<tr>
<td></td>
<td>MEDISCA Pharmaceutique Inc.</td>
</tr>
<tr>
<td></td>
<td>Tel.: 1.800.665.6334</td>
</tr>
<tr>
<td></td>
<td>4509 Rue Dobrin, St. Laurent, QC, H4R 2L8</td>
</tr>
<tr>
<td></td>
<td>21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2</td>
</tr>
<tr>
<td></td>
<td>MEDISCA Australia PTY LTD</td>
</tr>
<tr>
<td></td>
<td>Tel.: 1.300.786.392</td>
</tr>
<tr>
<td></td>
<td>Unit 7, Heritage Business Park</td>
</tr>
<tr>
<td></td>
<td>5-9 Ricketty Street, Mascot, NSW 2020</td>
</tr>
<tr>
<td>EMERGENCY PHONE</td>
<td>CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300</td>
</tr>
<tr>
<td></td>
<td>NSW Poisons Information Centre: 131 126</td>
</tr>
<tr>
<td>USES</td>
<td>Antipsychotic; Antidiabetic; Antiemetic</td>
</tr>
</tbody>
</table>

## SECTION 2: HAZARDS IDENTIFICATION

### GHS CLASSIFICATION
- Acute Toxicity - Oral (Category 3)
- Toxic to Reproduction (Category 2)
- Chronic Aquatic Toxicity (Category 1)
- Specific Target Organ Toxicity - Repeated Exposure (Category 1) - (nervous system)

### PICTOGRAM

### SIGNAL WORD
Danger

### HAZARD STATEMENT(S)
- Toxic if swallowed
- Causes skin and eye irritation
- May cause an allergic skin reaction
- May cause respiratory irritation if inhaled
- Suspected of damaging fertility or the unborn child
- Very toxic to aquatic life with long lasting effects
- Causes damage to organs through prolonged or repeated exposure.

### AUSTRALIA-ONLY HAZARDS
Repeated exposure may cause skin dryness or cracking.

### PRECAUTIONARY STATEMENT(S)
**Prevention**
- Wash thoroughly after handling.
- Do not eat, drink or smoke when using this product.
- Obtain special instructions before use.
- Do not handle until all safety precautions have been read and understood.
- Wear protective gloves, protective clothing, eye protection, face protection.
- Do not breathe dust/fume/gas/mist/ vapors/spray.
- Avoid release to the environment.

**Response**
- IF SWALLOWED: Immediately call a poison center or medical professional; Rinse mouth.
- IF EXPOSED OR CONCERNED: Get medical advice/attention.
- COLLECT SPILLAGE

**Storage**
Store locked up.
SAFETY DATA SHEET

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME
4-[4-(4-Chlorophenyl)-4-hydroxypiperidino]-4'-fluorobutyrophenone

BOTANICAL NAME
Not applicable

SYNONYM
Not applicable

CHEMICAL FORMULA
C₂₁H₂₃ClFNO₂

CAS NUMBER
52-86-8

ALTERNATE CAS NUMBER
Not applicable

MOLECULAR WEIGHT
375.8687

COMPOSITION

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>% BY WEIGHT</th>
</tr>
</thead>
<tbody>
<tr>
<td>HALOPERIDOL</td>
<td>52-86-8</td>
<td>100</td>
</tr>
</tbody>
</table>

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

NOTES
Chemical family: Butyrophenone derivative.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT
Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

IN CASE OF SKIN CONTACT
Wash with soap & water for 15 minutes. If irritation persists seek medical aid.

IF SWALLOWED
Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

IF INHALED
Not expected to present a significant hazard under anticipated conditions of normal use.

SYMPTOMS AND EFFECTS

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL
Not applicable

FLAMMABLE PROPERTIES
May be combustible at high temperature

Hazardous Combustion Products
Under fire conditions, hazardous fumes will be present.

Extinguishing Media
Small fire: dry chemical, CO₂ or water spray. Large fire: dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

Protective Equipment and Precautions for Firefighters
Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES
PERSONAL PRECAUTIONS

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT

On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Do not store in unlabelled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: HALOPERIDOL CAS #: 52-86-8

<table>
<thead>
<tr>
<th></th>
<th>TWA</th>
<th>Ceiling</th>
<th>STEL</th>
<th>REL</th>
<th>IDLH</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA PEL</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>ACGIH TLV</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>NIOSH</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td></td>
</tr>
<tr>
<td>AIHA WEEL</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Safe Work Australia HSIS</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>HSE</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

N/L = Not Listed

EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. Skin: Wear appropriate gloves to prevent skin exposure. Clothing: Wear appropriate protective clothing to minimize contact with skin. Respirators: Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

NOTES

USP: ELV: Industrial: TWA: 1 micrograms/m³

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE

Solid
<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>White to faintly yellowish, amorphous or microcrystalline powder.</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOLUBILITY</td>
<td>Practically insoluble in water; soluble in chloroform; sparingly soluble in alcohol; slightly soluble in ether.</td>
</tr>
<tr>
<td>ODOR</td>
<td>Odorless</td>
</tr>
<tr>
<td>FLAMMABILITY</td>
<td>May be combustible at high temperature.</td>
</tr>
<tr>
<td>ODOR THRESHOLD</td>
<td>Not available</td>
</tr>
<tr>
<td>pH</td>
<td>Neutral to litmus (saturated solution)</td>
</tr>
<tr>
<td>MELTING POINT</td>
<td>(148 - 150)°C, (298.4-302)°F</td>
</tr>
<tr>
<td>BOILING POINT</td>
<td>Not available</td>
</tr>
<tr>
<td>FREEZING POINT</td>
<td>(148 - 150)°C, (298.4-302)°F</td>
</tr>
<tr>
<td>SPECIFIC GRAVITY</td>
<td>Not available</td>
</tr>
<tr>
<td>EVAPORATION RATE</td>
<td>Not available</td>
</tr>
<tr>
<td>EXPLOSIVE LIMIT</td>
<td>Not available</td>
</tr>
<tr>
<td>UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)</td>
<td>Not available</td>
</tr>
<tr>
<td>LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)</td>
<td>Not available</td>
</tr>
<tr>
<td>VAPOR DENSITY (AIR = 1)</td>
<td>Not available</td>
</tr>
<tr>
<td>RELATIVE DENSITY (WATER = 1)</td>
<td>Not available</td>
</tr>
<tr>
<td>log P (OCTANOL-WATER)</td>
<td>4.3</td>
</tr>
<tr>
<td>AUTO-IGNITION TEMPERATURE</td>
<td>Not available</td>
</tr>
<tr>
<td>DECOMPOSITION TEMPERATURE</td>
<td>Not available</td>
</tr>
<tr>
<td>VISCOSITY</td>
<td>Not available</td>
</tr>
</tbody>
</table>

**NOTES**
The physical data presented above are typical values and should not be construed as a specification.

**SECTION 10: STABILITY AND REACTIVITY**

**REACTIVITY**
Not established.

**STABILITY**
Stable under recommended storage conditions.

**MATERIALS TO AVOID**
Strong oxidants.

**HAZARDOUS DECOMPOSITION PRODUCTS**
Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur.

**HAZARDOUS POLYMERIZATION**
Will not occur.

**POSSIBILITY OF HAZARDOUS REACTION**
Not established.

**CONDITIONS TO AVOID**
Moisture, sunlight and extreme temperatures.

**SECTION 11: TOXICOLOGICAL INFORMATION**

**ACUTE TOXICITY**
- Oral: Rat: LD50: (mg/kg): 128
- Dermal: Rabbit LD50: (mg/kg): Not available
- Inhalation: Rat: LC50: (mg/L/4hr): Not available

**SKIN CORROSION/IRRITATION**
Due to lack of data the classification is not possible.

**SERIOUS EYE DAMAGE/EYE IRRITATION**
Due to lack of data the classification is not possible.

**RESPIRATORY OR SKIN SENSITIZATION**
Due to lack of data the classification is not possible.
**SAFETY DATA SHEET**

**GERM CELL MUTAGENICITY**
Due to lack of data the classification is not possible.

**CARCINOGENICITY**

<table>
<thead>
<tr>
<th>Agency</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA</td>
<td>HALOPERIDOL is not listed.</td>
</tr>
<tr>
<td>NTP</td>
<td>HALOPERIDOL is not listed.</td>
</tr>
<tr>
<td>IARC</td>
<td>HALOPERIDOL is not evaluated.</td>
</tr>
</tbody>
</table>

**California Proposition 65**
This product contains the following chemical known to the State of California to cause birth defects or other reproductive harm: HALOPERIDOL.

**ADDITIONAL CARCINOGENICITY INFORMATION**
Suspected carcinogen: The Toolbox profiler 'Carcinogenicity (genotox and nongenotox) alerts by ISS' gives an alert for carcinoenicity.

**REPRODUCTIVE TOXICITY**
Suspected toxic for reproduction: The Toolbox profiler 'DART scheme v.1.0' gives an alert for toxicity to reproduction; CAESAR developmental toxicity model in VEGA (Q)SAR platform predicts that the chemical is Toxicant (EXPERIMENTAL value); Developmental/Reproductive Toxicity library (PG) in VEGA (Q)SAR platform predicts that the chemical is Toxicant (good reliability).

In humans, exposure to haloperidol during late pregnancy may cause extrapyramidal side effects in the newborn. A retrospective study of 100 pregnancies in which the mothers received 0.6 mg of haloperidol twice daily showed no adverse effects on the pregnancies and no increased incidence of birth defects in the offspring. 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.

**SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE**
Due to lack of data the classification is not possible.

**SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE**
Causes damage to organs (nervous system) through prolonged or repeated exposure.

**ASPIRATION HAZARDS**
Based on available data, the classification criteria are not met.

**SIGNS AND SYMPTOMS OF EXPOSURE**
Symptoms related to the physical, chemical, and toxicological characteristics:
- Irregular heartbeat
- Restlessness
- Hallucinations
- Tiredness
- Dizziness
- Lightheadedness
- Drowsiness
- Blurred vision
- Uncontrolled movements
- Difficulty breathing
- Change in menstrual cycle
- Swelling or tenderness of breasts
- Unusual secretion of milk
- Painful or difficult urination
- Constipation
- Nausea
- Vomiting
- Loss of appetite
- Dry mouth
- Weight gain
- Skin sensitivity to sunlight
- Skin rash

Delayed and immediate effects of exposure:
- Coma
- Tardive dyskinesia
- High blood pressure
- Low blood pressure
- Tachycardia

Medical conditions aggravated by exposure:
- Active alcoholism
- Cardiovascular disorders
- History of seizures
- Parkinson's disease
- Urinary retention
- Electrolyte imbalance
- Long-QT syndrome
- Thyroid problems
- Porphyria
- Bipolar disorder

**POTENTIAL HEALTH EFFECTS**

<table>
<thead>
<tr>
<th>Route</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>May be harmful if inhaled. May cause respiratory tract irritation.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Toxic if swallowed. Readily absorbed from the gastrointestinal.</td>
</tr>
<tr>
<td>Skin</td>
<td>May be harmful if absorbed through skin. Causes skin irritation. May cause an allergic skin reaction.</td>
</tr>
<tr>
<td>Eyes</td>
<td>Causes eye irritation.</td>
</tr>
</tbody>
</table>

**SECTION 12: ECOLOGICAL INFORMATION**

**TOXICITY**

<table>
<thead>
<tr>
<th>Test Method</th>
<th>EC50 (mg/L)</th>
<th>EC50 (mg/L)</th>
<th>LC50 (mg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>48 Hr: Crustacea: Daphnia Magna</td>
<td>0.1382**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>96 Hr: Fish</td>
<td>1.31**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>96 Hr: Algae</td>
<td>&lt;1**</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**PERSISTENCE AND DEGRADABILITY**
Suspected persistent in the environment: The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable.

**BIOACCUMULATIVE POTENTIAL**
Has the potential to bioaccumulate: LogPow: 4.3 (20°C).

**MOBILITY IN SOIL**
Practically insoluble in water: 14 mg/L (25°C)
Henry's Law Constant: 2.26E-14 atm-m³/mole (25°C)
SAFETY DATA SHEET

OTHER ADVERSE EFFECTS

Not available

This product is not intended to be released into the environment.

NOTES

*(Q)SAR platform prediction (moderate reliability)
**Danish QSAR database

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION

UNITED STATES & CANADA

UN PROPER SHIPPING NAME

TOXIC SOLID, ORGANIC, N.O.S.

UN NUMBER

2811

CLASS

6.1

PACKING GROUP

III

AUSTRALIA

UN PROPER SHIPPING NAME

TOXIC SOLID, ORGANIC, N.O.S.

UN NUMBER

2811

CLASS

6.1

PACKING GROUP

2X

ENVIRONMENTAL HAZARDS

Not available

SPECIAL SHIPPING INFORMATION

Not applicable

SECTION 15: REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>CERCLA 40 CFR Part 302.4</th>
<th>SARA (Title III) 40 CFR Part 372.85</th>
<th>EPA 40 CFR Part 355 Appendix A</th>
<th>Pennsylvania</th>
<th>Right-to-know New Jersey</th>
<th>Massachusetts</th>
<th>California Prop 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>HALOPERIDOL 52-86-8</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>X</td>
</tr>
</tbody>
</table>

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>Poisons and Therapeutic Goods Regulation</th>
<th>Therapeutic Goods Act</th>
<th>Code of Practices - Illicit Drug Precursors</th>
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</thead>
<tbody>
<tr>
<td>HALOPERIDOL 52-86-8</td>
<td>N/L</td>
<td>Listed as Schedule 4</td>
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</tr>
</tbody>
</table>

SECTION 16: OTHER INFORMATION

Last Revision: 10/2018

HALOPERIDOL, USP
REFERENCES
Available upon request

ABBREVIATIONS AND ACRONYMS
CAS – Chemical Abstract Service; GHS – Global Harmonized System; OSHA PEL – Occupational Safety & Health Administration Permissible Exposure Limits; TWA – Time Weighted Average; HSIS – Hazardous Substances Information System; STEL – Short Term Exposure Limit; AIHA WEEL – American Industrial Hygiene Association Workplace Environment Exposure Levels; LD50 – Lethal Dose, 50%; IARC – International Agency for Research on Cancer; NTP – National Toxicology Program; WHMIS – Workplace Hazardous Materials Information System; SARA – Superfund Amendments and Reauthorization Act; EPA – Environmental Protection Agency; CERCLA – Comprehensive Environmental Response, Compensation, and Liability Act; HMIS – Hazardous Materials Information System; NIOSH – National Institute for Occupational Safety and Health; MSHA - Mine Safety and Health Administration; ACGIH - American Conference of Governmental Industrial Hygienists; IDHL - Immediately Dangerous to Health or Life; TLV – Threshold Limit Value; HSE – Health and Safety Executive; REL - Recommended Exposure Limit

LAST REVISION
10/2018

SUPERSEDES
05/2015

DISCLAIMER
This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.