1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Material Name: Haloperidol Tablets
Trade Name: Brotopon(R) Tablets
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antipsychotic

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haloperidol</td>
<td>52-86-8</td>
<td>200-155-6</td>
<td>0.5-1.4</td>
</tr>
<tr>
<td>Corn Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dibasic calcium phosphate, dihydrate USP</td>
<td>7789-77-7</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Lactose</td>
<td>63-42-3</td>
<td>200-559-2</td>
<td>*</td>
</tr>
</tbody>
</table>

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

3. HAZARDS IDENTIFICATION

Appearance: White tablets
Signal Word: DANGER

Statement of Hazard:
May be harmful if swallowed.
May cause nervous system, cardiovascular system and reproductive effects
May damage the unborn child.

Additional Hazard Information:
Short Term: Overdose: Seizure and/or coma may occur.
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system. Animal studies have shown a potential to cause adverse effects on the fetus. 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: Toxic to Reproduction: Category 2

EU Hazard Symbols: 

EU Risk Phrases: 
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

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.

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.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: May burn emitting oxides of: chlorine nitrogen and hydrogen fluoride

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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.

7. HANDLING AND STORAGE

General Handling: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Haloperidol
Pfizer OEL TWA-8 Hr: 1 ug/m³

Corn Starch
OSHA - Final PELS - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA)
Australia TWA = 10 mg/m³ TWA

Magnesium stearate
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA

The exposure limit(s) listed for solid components are only relevant if dust may be generated.


Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands: Not required for the normal use of this product. Wear protective gloves when working with large quantities.

Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.

Respiratory protection: Not required for the normal use of this product. 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.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State: Tablets
Molecular Formula: Mixture
Color: White
Molecular Weight: Mixture
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.

11. TOXICOLOGICAL 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 LD50 128 mg/kg
- Rat Subcutaneous Minimum Symptomatic Dose 1 mg/kg

Magnesium stearate
- Rat Oral LD50 > 2000 mg/kg
- Rat Inhalation LC50 > 2000 mg/m³

Lactose
- Rat Oral LD50 > 10 g/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.

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

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

Haloperidol
- Bacterial Mutagenicity (Ames) Bacteria Positive
- Sister Chromatid Exchange Rat Positive
- Mammalian Cell Mutagenicity Rat Positive

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.

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Toxic to Reproduction: Category 2
EU Risk Phrases: R60 - May impair fertility.
R61 - May cause harm to the unborn child.
EU Safety Phrases: S53 - Avoid exposure - obtain special instructions before use.
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:
DANGER
May be harmful if swallowed.
May cause nervous system, cardiovascular system and reproductive effects
May damage the unborn child.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A
Haloperidol
California Proposition 65   developmental toxicity, initial date 1/29/99
Australia (AICS):       female reproductive toxicity, initial date 1/29/99
Standard for the Uniform Scheduling   Schedule 4
for Drugs and Poisons:
EU EINECS List   200-155-6

Corn Starch
Inventory - United States TSCA - Sect. 8(b)   XU
Australia (AICS):       Present
EU EINECS List   232-679-6

Magnesium stearate
Inventory - United States TSCA - Sect. 8(b)   Present
Australia (AICS):       Present
EU EINECS List   209-150-3

Dibasic calcium phosphate, dihydrate USP
Australia (AICS):       Present

Lactose
Inventory - United States TSCA - Sect. 8(b)   Present
Australia (AICS):       Present
EU EINECS List   200-559-2

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations.

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

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End of Safety Data Sheet