MATERIAL SAFETY DATA SHEET

Product Name: Droperidol Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address
Hospira Inc.
275 North Field Drive
Lake Forest, Illinois USA
60045

Emergency Telephone
CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia (02) 8014 4880

Hospira, Inc., Non-Emergency
224-212-2000

Product Name
Droperidol Injection

Synonyms
1-[1-[3-(p-Fluorobenzoyl) propyl]-1,2,3,6-tetrahydro-4-pyridyl]-2-benzimidazolinone

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Droperidol

Chemical Formula
C₂₂H₂₂FN₃O₂

Preparation
Non-hazardous ingredients include Water for Injection. Lactic acid is added to adjust the pH.

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Droperidol</td>
<td>0.25</td>
<td>548-73-2</td>
<td>DE2100000</td>
</tr>
</tbody>
</table>

3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Droperidol</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
Droperidol Injection is a solution containing droperidol, a neuroleptic (tranquilizer) agent used clinically to reduce nausea and vomiting associated with surgical and diagnostic procedures. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract and a potent drug. Based on clinical use, possible target organs include the cardiovascular system.

Occupational Exposure Potential
Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms
None known from occupational exposures. In clinical use, the most commonly reported adverse effects include mild to moderate hypotension (decreased blood pressure) and tachycardia (increased heart rate) during anesthesia. Dysphoria, postoperative drowsiness, restlessness, hyperactivity and anxiety have also been reported. QT interval prolongation, torsade de pointes, cardiac arrest, and ventricular tachycardia have been reported in patients treated with droperidol.
Product Name: Droperidol Injection

at doses at or below recommended doses. Some of these cases were associated with death.

Medical Conditions Aggravated by Exposure
Pre-existing hypersensitivity to this material; pre-existing central nervous system or cardiovascular ailments.

4. FIRST AID MEASURES

Eye contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability
None anticipated for this aqueous product.

Fire & Explosion Hazard
None anticipated for this aqueous product.

Extinguishing media
As with any fire, use extinguishing media appropriate for primary cause of fire.

Special Fire Fighting Procedures
No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal
Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling
No special handling required under conditions of normal product use.

Storage
No special storage required for hazard control. For product protection, follow temperature storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions
No special precautions required for hazard control.
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>mg/m³</th>
<th>ppm</th>
<th>µg/m³</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Droperidol</td>
<td>Not Applicable</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>None Established</td>
</tr>
</tbody>
</table>

**Respiratory protection**

Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA’s 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

**Skin protection**

If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

**Eye protection**

Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

**Engineering Controls**

Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance/Physical State</td>
<td>Liquid</td>
</tr>
<tr>
<td>Color</td>
<td>A sterile, nonpyrogenic solution in water for injection</td>
</tr>
<tr>
<td>Odor</td>
<td>NA</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>NA</td>
</tr>
<tr>
<td>pH</td>
<td>3.4 (3.0 to 3.8)</td>
</tr>
<tr>
<td>Melting point/Freezing point:</td>
<td>NA</td>
</tr>
<tr>
<td>Initial Boiling Point/Boiling Point Range:</td>
<td>NA</td>
</tr>
<tr>
<td>Evaporation Rate:</td>
<td>NA</td>
</tr>
<tr>
<td>Flammability (solid, gas):</td>
<td>NA</td>
</tr>
<tr>
<td>Upper/Lower Flammability or Explosive Limits:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Pressure:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Density:</td>
<td>NA</td>
</tr>
<tr>
<td>Specific Gravity:</td>
<td>NA</td>
</tr>
<tr>
<td>Solubility:</td>
<td>NA</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water:</td>
<td>NA</td>
</tr>
<tr>
<td>Auto-ignition temperature:</td>
<td>NA</td>
</tr>
<tr>
<td>Decomposition temperature:</td>
<td>NA</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity
Not Determined

Chemical Stability
Stable under standard use and storage conditions

Hazardous Reactions
Not Determined

Conditions to avoid
Not Determined

Incompatibilities
Not Determined

Hazardous decomposition products
Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and hydrogen fluoride.

Hazardous Polymerization
Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity
Not determined for the product formulation. Information for the ingredients is as follows:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Droperidol</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>750</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td>Droperidol</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>30</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
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</table>

Aspiration Hazard
None anticipated from normal handling of this product.

Dermal Irritation/Corrosion
None anticipated from normal handling of this product.

Ocular Irritation/Corrosion
None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation with redness and tearing.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product.

Reproductive Effects
An oral study in rats (Segment I) revealed no impairment of fertility in either males or females at dosages of 0.63, 2.5 and 10 mg/kg. Droperidol has not been shown to be teratogenic in animals. Droperidol administered intravenously has been shown to cause a slight increase in mortality of the newborn rat at 4.4 times the upper human dose. At 44 times the upper human dose, mortality rate was comparable to that for control animals. Following intramuscular administration, increased mortality of the offspring at 1.8 times the upper human dose is attributed to CNS depression in the dams who neglected to remove placentae from their offspring.

Mutagenicity
The micronucleus test in female rats revealed no mutagenic effects in single oral doses as high as 160 mg/kg.
Product Name: Droperidol Injection

Carcinogenicity  The carcinogenic potential of droperidol has not been evaluated.

Target Organ Effects  Based on clinical use, possible target organs include the cardiovascular system.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity  Not determined for product

Persistence/Biodegradability  Not determined for product

Bioaccumulation  Not determined for product

Mobility in Soil  Not determined for product

13. DISPOSAL CONSIDERATIONS

Waste Disposal  All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal  Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS:  Not regulated

IMDG STATUS:  Not regulated

ICAO/IATA STATUS:  Not regulated

Transport Comments:  None

15. REGULATORY INFORMATION

USA Regulations

<table>
<thead>
<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Droperidol</td>
<td>Not Listed</td>
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</tr>
</tbody>
</table>

RCRA Status  Not Listed
U.S. OSHA Classification  Target Organ Toxin
Classification  Possible Irritant

GHS Classification  *In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

Hazard Class  Not Applicable
Product Name: Droperidol Injection

Hazard Category
Not Applicable

Signal Word
Not Applicable

Symbol
Not Applicable

Prevention
P260 - Do not breathe dust/fume/gas/mist/vapours/spray.

Hazard Statement
Not Applicable

Response:
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling.

Get medical attention if you feel unwell.

EU Classification*
*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Droperidol.

Classification(s):
Not Applicable

Symbol:
Not Applicable

Indication of Danger:
Not Applicable

Risk Phrases:
Not Applicable

Safety Phrases:
S23 - Do not breathe vapour.
S24 - Avoid contact with skin.
S25 - Avoid contact with eyes.
S37/39 - Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION:

Notes:
ACGIH TLV  American Conference of Governmental Industrial Hygienists – Threshold Limit Value
AIHA WEEL Workplace Environmental Exposure Level
CAS Chemical Abstracts Service Number
CERCLA US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT US Department of Transportation Regulations
EC50 Concentration in water that produces 50% inhibition of growth in algae
EEL Employee Exposure Limit
IATA International Air Transport Association
LC50 Concentration in water that produces 50% mortality in fish
LD50 Dosage producing 50% mortality
NA Not applicable/Not available
NE Not established
NIOSH National Institute for Occupational Safety and Health
OSHA PEL US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65 California Proposition 65
RCRA US EPA, Resource Conservation and Recovery Act
RTECS Registry of Toxic Effects of Chemical Substances
SARA Superfund Amendments and Reauthorization Act
STEL 15-minute Short Term Exposure Limit
Product Name: Droperidol Injection

TSCA    Toxic Substance Control Act
TWA     8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
Date Prepared: 09/16/2011
Obsolete Date: 10/21/2008

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