Product Name: Ondansetron Injection, USP

MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

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

Emergency Telephone Hospira, Inc.
CHEMTREC: 800-424-9300
224 212-2055

Product Names Ondansetron Injection, USP Hydrochloride Products include the following:
Multi-Dose 20 mL Glass Vial (MDV), Single Dose 2 mL Glass Vial (SDV) and Premix in 5% Dextrose.

Synonyms 1,2,3,9-Tetrahydro-90methyl-3-[{(2-methyl-1H-imidazol-1-yl)methyl]-4H-carbazol-4-one hydrochloride

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name Ondansetron Hydrochloride Dihydrate
Chemical Formula C18H19N3O * HCL * 2H2O

<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>Ondansetron Hydrochloride Dihydrate</td>
<td>&lt;0.20%</td>
<td>103639-04-9</td>
<td>FE6375500</td>
</tr>
</tbody>
</table>

SDV Non-hazardous ingredients include: Water, and NaCl, and Citric Acid.
MDV Non-hazardous ingredients include: Water, NaCl, Citric Acid, Methyl Paraben, Propyl Paraben
Premix in 5% Dextrose Non-hazardous ingredients include: Water, Dextrose, Citric Acid and Sodium Citrate

3. HAZARD INFORMATION

Emergency Overview Caution – Potent pharmaceutical agent. Health effects information is based on hazards of components.

Occupational Exposure Handling this product in its final form presents minimal risk from occupational exposure.

Signs and Symptoms Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing); headache; constipation; flushing; abnormal nervous system sensations.

Medical Conditions Aggravated by Exposure Hypersensitivity to material and impaired liver function.
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  Physical form suggests that risk of inhalation exposure is negligible. 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  Non-Flammable

Fire & Explosion Hazard  Not expected for the product.

Extinguishing Media  Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.

Special Fire Fighting Procedures  No special requirements needed for single units or packages. For larger amounts self contained breathing apparatus and full protective equipment is recommended.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal  Absorb liquid with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling  No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.

Storage  No special storage required for hazard control. Refer to the product insert for product storage information.

Special Precautions  None
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>OSHA-PEL</th>
<th>ACGIH-TLV</th>
<th>Hospira EEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ondansetron Hydrochloride</td>
<td>N/E</td>
<td>N/E</td>
<td>0.02 mg/m³</td>
</tr>
</tbody>
</table>

Notes:  
OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit  
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.  
EEL: Employee Exposure Limit.  
TWA: 8 hour Time Weighted Average.  
STEL: 15-minute Short Term Exposure Limit.

Respiratory Protection
None, physical form suggests that risk of inhalation exposure is negligible.

Skin Protection
If contact with unprotected skin is likely, glove use is prudent practice.

Eye Protection
Eye protection is not required during expected product use conditions but may be warranted if eye contact is likely.

Engineering Controls
Engineering controls are not needed during normal product use conditions.

9. PHYSICAL/CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Appearance/Physical State</th>
<th>Clear, Colorless Liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor</td>
<td>Odorless</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>N/E</td>
</tr>
<tr>
<td>Melting Point</td>
<td>177 – 179 °C</td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>N/E</td>
</tr>
<tr>
<td>Vapor Density (Air =1)</td>
<td>N/E</td>
</tr>
<tr>
<td>Evaporation Rate</td>
<td>N/E</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>0.39 g/cm³ (poured bulk density), 0.59 g/cm³ (tapped bulk density)</td>
</tr>
<tr>
<td>Solubility</td>
<td>4% in Water, Active Ingredient</td>
</tr>
<tr>
<td>pH</td>
<td>4.5 based upon a 1% aqueous solution</td>
</tr>
</tbody>
</table>
Product Name: Ondansetron Injection, USP

10. STABILITY AND REACTIVITY

Chemical Stability Stable

Incompatibilities Strong Oxidizing Agents

Hazardous Decomposition

Products Toxic fumes of NOx and HCl

Hazardous Polymerization No

11. TOXICOLOGICAL INFORMATION:

Acute Toxicity – Oral:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Test Type</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ondansetron Hydrochloride</td>
<td>LD₅₀</td>
<td>95</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td>Ondansetron Hydrochloride</td>
<td>LD₅₀</td>
<td>45</td>
<td>mg/kg</td>
<td>Dog</td>
</tr>
</tbody>
</table>

LD₅₀ is the dosage producing 50% mortality. Product contains approximately 1% 2,6-Diisopropylphenol.

Mutagenicity

Negative in the following in vitro tests. Ames bacteria test with and without activation, modified Ames bacteria test with and without activation, Bacteria Fluctuation test and yeast gene conversion assay. Caused no chromosomal damage in mouse micronucleus test.

Dermal Irritation
Corrosive to skin.

Ocular Irritation
Severe eye irritant.

Target Organ Effects
Liver

Carcinogenicity

No evidence of carcinogenic effects in rats or mice at oral dosages up to 10 or 30 mg/kg (700 or 2100 mg in a 70kg adult) respectively.

Sensitization
Potential to produce respiratory sensitization.

Genetic Toxicity
Not expected to be genotoxic under occupational exposure conditions.

Reproductive Effects

No evidence of adverse effects on reproductive performance or fertility in rats at oral dosages up to 15 mg/kg (1050 mg in a 70 kg adult).

Other Adverse Effects

Overexposure in the workplace might have the following effects: symptoms of hypersensitivity (such as skin rash, hives, itching, and/or difficulty breathing); headache; constipation; flushing; activity in the nervous system.
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12. ECOLOGICAL INFORMATION:

Aquatic Toxicity

This material contains an active pharmaceutical ingredient that is very toxic to algae.

LC₅₀: 0.87 mg/L, 72 Hours, Selenastrum capricornutum, green algae, Measured
NOEL: 0.31 mg/L, 72 Hours, Static Test.

This material contains an active pharmaceutical ingredient that is harmful to daphnids.

EC₅₀: 28 mg/l, 48 Hours, Daphnia pulex, Static Test
NOEL: 16 mg/l, 48 Hours, Daphnia pulex, Static Test

This material contains an active pharmaceutical ingredient that is toxic to fish. Adult Oncorhyncus mykiss, rainbow trout.

EC₅₀: 6.5 mg/l, 96 Hours, Static Test
NOEL: 2.6 mg/l, 96 Hours, Measured

13. DISPOSAL CONSIDERATIONS:

Waste Disposal
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

DOT Status
Not regulated in its current form.

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

TSCA Status
Not Listed

CERCLA Status
Not Listed

SARA Status
Not Listed

RCRA Status
Not Listed

PROP 65 (Calif.)
Not Listed

Notes: TSCA, Toxic Substance Control Act
CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
SARA, Superfund Amendments and Reauthorization Act
RCRA, US EPA, Resource Conservation and Recovery Act
Prop 65, California Proposition 65
16. OTHER INFORMATION:

Notes:
ACGIH TLV American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS Chemical Abstracts Service Number
CERCLA US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT US Department of Transportation Regulations
EC50 Effect Concentration affecting 50% of tested individuals
EEL Employee Exposure Limit
IATA International Air Transport Association
LC50 Dosage producing 50% mortality. For inhalation experiments, the concentration of the chemical in air that kills 50% of the test animals in a given time (usually four hours) is the LC50 value. Environmental studies it can also mean the concentration of a chemical in water.
LD50 Dosage producing 50% mortality
NA Not applicable/Not available
NE Not established
NIOSH National Institute for Occupational Safety and Health
NOEL No Observable Effect Level
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
TSCA Toxic Substance Control Act
TWA 8-hour Time Weighted Average

MSDS Coordinator: Gregory R. Gerhartz
Date Prepared: 10/30/2006

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