MATERIAL SAFETY DATA SHEET

Product Name: Ondansetron Hydrochloride Injection, Solution

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

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

Hospira Australia Pty Ltd
1 Lexia Place
Mulgrave, VIC 3170
Australia

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
Ondansetron Hydrochloride Injection, Solution

Synonyms
Ondansetron Hydrochloride Dihydrate; (±) 1, 2, 3, 9-tetrahydro-9-methyl-3-[(2-methyl-1H-imidazol-1-yl)methyl]-4H-carbazol-4-one, monohydrochloride, dihydrate.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Ondansetron Hydrochloride Dihydrate

Chemical Formula
C_{18}H_{19}N_{3}O \cdot \cdot HCl \cdot 2H_{2}O

Preparation
Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% may include sodium chloride, methylparaben, NF and propylparaben, NF. Sodium citrate dihydrate and citric acid anhydrous are added as buffers.

<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>0.2</td>
<td>103639-04-9</td>
<td>FE6375500</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>Ondansetron Hydrochloride Dihydrate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
ONDANSETRON - ondansetron hydrochloride injection, is a solution containing ondansetron hydrochloride, a serotonin-blocking drug used intravenously or orally to prevent nausea and vomiting associated with the use of emetogenic cancer chemotherapy drugs, radiation induced nausea and vomiting, and to prevent post-operative nausea and vomiting. In the workplace, ondansetron hydrochloride should be considered a potent drug, possibly irritating to skin, and possibly severely irritating to the eyes and respiratory tract. Possible target organs include the central nervous system and liver.
### Product Name: Ondansetron Hydrochloride Injection, Solution

<table>
<thead>
<tr>
<th>Occupational Exposure Potential</th>
<th>Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signs and Symptoms</td>
<td>In the workplace, this material should be considered potentially irritating to the skin, and possibly severely irritating to the eyes and respiratory tract. Respiratory sensitization and allergy-like effects have also been reported following occupational exposures. In clinical use, adverse effects may include headache, restlessness, dizziness, hypotension, fever, malaise, fatigue, and diarrhea or constipation. Infrequently, elevations in liver function parameters and extrapyramidal symptoms have been reported. Also, rash, hypersensitivity, fever, bronchospasm and wheezing have been reported.</td>
</tr>
<tr>
<td>Medical Conditions Aggravated by Exposure</td>
<td>Pre-existing hypersensitivity to ondansetron hydrochloride or other components in this product. Pre-existing central nervous system or liver ailments.</td>
</tr>
</tbody>
</table>

### 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 from this aqueous product.
- **Fire & Explosion Hazard** None anticipated from 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. Prevent entry into sewers and surface drainage systems. Dispose of spill materials according to the applicable federal, state, or local regulations.
7. HANDLING AND STORAGE

Handling
No special handling is required for hazard control under conditions of normal product use.

Storage
No special storage required for hazard control. For product protection, follow 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

Exposure Guidelines

<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>Ondansetron Hydrochloride Dihydrate</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 solution 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 intended use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Appearance/Physical State</th>
<th>Liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>Clear, Colorless</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>Not determined</td>
</tr>
<tr>
<td>pH:</td>
<td>3.3 to 4.0</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>
</tbody>
</table>
Product Name: Ondansetron Hydrochloride Injection, Solution

Vapor Pressure: NA
Vapor Density: NA
Specific Gravity: NA
Solubility: Soluble in water
Partition coefficient: n-octanol/water: Not determined
Auto-ignition temperature: NA
Decomposition temperature: NA

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 Strong oxidizers.
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 chloride.
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>Ondansetron Hydrochloride Dihydrate</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>95</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&gt;45</td>
<td>mg/kg</td>
<td>Dog</td>
</tr>
<tr>
<td>Ondansetron Hydrochloride Dihydrate</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>20.1</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&gt;15</td>
<td>mg/kg</td>
<td>Dog</td>
</tr>
</tbody>
</table>

Aspiration Hazard
None anticipated from normal handling of this product.

Dermal Irritation/Corrosion
None anticipated from normal handling of this product. Aqueous solutions of the active ingredient, ondansetron hydrochloride, are reported to be severely irritating/corrosive to the skin. Inadvertent contact of this product with skin may produce mild irritation.

Ocular Irritation/Corrosion
None anticipated from normal handling of this product. Aqueous solutions of the active ingredient, ondansetron hydrochloride, are reported to be a severely irritating to the eyes. Inadvertent contact of this product with eyes or mucus membranes may produce irritation.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product. The active ingredient, ondansetron hydrochloride, was negative in a sensitization study in guinea pigs.
Product Name: Ondansetron Hydrochloride Injection, Solution

pigs. However, in the workplace, possible effects of overexposure may include: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing).

Reproductive Effects

Oral administration of ondansetron at dosages up to 15 mg/kg per day did not affect fertility or general reproductive performance of male and female rats. Reproduction studies in pregnant rats and rabbits using intravenous dosages up to 4 mg/kg per day have revealed no evidence of impaired fertility or harm to the fetus due to ondansetron.

Mutagenicity

Ondansetron was not mutagenic in a standard battery of tests for mutagenicity.

Carcinogenicity

Carcinogenic effects were not seen in 2-year studies in rats and mice with oral ondansetron dosages up to 10 and 30 mg/kg per day, respectively.

Target Organ Effects

Based on clinical use, possible target organs include the central nervous system and liver.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity

Not determined for product. Information of ondansetron hydrochloride is provided below.

*Activated Sludge Respiration - This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms. IC50: > 1000 mg/l, 3 hours, activated sludge

*Algal - This material contains an active pharmaceutical ingredient that is very toxic to algae. IC50: 0.87 mg/l, 72 Hours, Selenastrum capricornutum (green algae); measured NOEL: 0.31 mg/l, 72 Hours, , Static test

*Daphnia - This material contains an active pharmaceutical ingredient that is harmful to daphnia. EC50: 28 mg/l, 48 Hours, Daphnia pulex, Static test NOEL: 16 mg/l, 48 Hours, Daphnia pulex, Static test

*Fish – 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

*GlaxoSmithKline MSDS

Persistence/Biodegradability

Not determined for product. Information of ondansetron hydrochloride is provided below.

*Hydrolysis: Ondansetron has been shown to be chemically stable in water with a half-life (neutral pH) of > 1 year. Hydrolysis is unlikely to be a significant depletion mechanism.

*Photolysis: Ondansetron is likely to undergo photodegradation,

*Biodegradation - Ondansetron is not readily biodegradable (as defined by 1993 OECD Testing Guidelines). Aerobic - Inherent Percent Degradation: 18.9
**Product Name: Ondansetron Hydrochloride Injection, Solution**

%, 28 days, Semi-continuous activated sludge (SCAS), activated sludge. Aerobic - Soil Percent Degradation: 20.3 to 99.9 %, 64 days.

*GlaxoSmithKline MSDS

**Bioaccumulation**
Not determined for product.

**Mobility in Soil**
Not determined for product. Information of ondansetron hydrochloride is provided below. This material contains an active pharmaceutical ingredient that is likely to adsorb to sludge and/or other biomass.

### 13. DISPOSAL CONSIDERATIONS

**Waste Disposal**
All waste materials must be properly characterized. 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>Ondansetron Hydrochloride</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

**RCRA Status**
Not Listed

**U.S. OSHA Classification**
Target Organ Toxin

**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

**Hazard Category**
Not Applicable

**Signal Word**
Not Applicable

**Symbol**
Not Applicable
Product Name: Ondansetron Hydrochloride Injection, Solution

Prevention

P260 - Do not breathe dust/fume/gas/mist/vapors/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 Ondansetron Hydrochloride Dihydrate.

Classification(s): Not Applicable

Symbol: Not Applicable

Indication of Danger: Not Applicable

Risk Phrases: Not Applicable

Safety Phrases:

S23 - Do not breathe vapor.
S24/25 - Avoid contact with skin and 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
CAS Chemical Abstracts Service Number
CERCLA US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT US Department of Transportation Regulations
EEL Employee Exposure Limit
IATA International Air Transport Association
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
TSCA Toxic Substance Control Act
TWA 8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
Date Prepared: 10/28/2011
Obsolete Date: 11/06/2009
Product Name: Ondansetron Hydrochloride Injection, Solution

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