MATERIAL SAFETY DATA SHEET

Product Name: ONDANSETRON - ondansetron hydrochloride injection, solution

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Names And Addresses
Hospira, Inc.  Hospira Australia Pty Ltd
275 North Field Drive  1 Lexia Place
Lake Forest, Illinois 60045  Mulgrave VIC 3170
USA    AUSTRALIA

Emergency Telephone #’s
CHEMTREC: North America: 800-424-9300; International: 1-703-527-3887
Australia: (02) 8014 4880
Hospira, Inc., Non-Emergency 224-212-2055
Product Name ONDANSETRON - 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. HAZARD INFORMATION

Emergency Overview
ONDANSETRON - ondansetron hydrochloride injection, solution contains 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.

Occupational Exposure
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
During occupational use, this material should be considered potentially irritating to the skin, and possibly severely irritating to the eyes and respiratory tract. In the workplace, 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.

Medical Conditions
Pre-existing hypersensitivity to ondansetron hydrochloride or other components in this product.

Carcinogen Lists:
IARC: Not listed  NTP: Not listed  OSHA: Not listed

3. 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>0.2</td>
<td>103639-04-9</td>
<td>FE6375500</td>
</tr>
</tbody>
</table>

Non-hazardous ingredients include water. Hazardous ingredients present at less than 1% include sodium chloride, sodium citrate and citric acid.
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**
Non-flammable

**Fire & Explosion Hazard**
None.

**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 USP controlled room temperature storage recommendations noted on the product case label, the primary container label, or the product insert.

**Special Precautions**
Protect from freezing, light and extreme heat.
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>8 hr TWA: Not</td>
<td>8 hr TWA: Not</td>
<td>8 hr TWA: 20 mcg/m3</td>
</tr>
<tr>
<td></td>
<td>Established</td>
<td>Established</td>
<td>STEL: Not Established</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.
AIHA WEEL: Workplace Environmental Exposure Level
EEL: Employee Exposure Limit.
TWA: 8 hour Time Weighted Average.
STEL: 15-minute Short Term Exposure Limit.

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 (N99 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

Appearance/Physical State: Clear, colorless aqueous solution
Odor: Odorless
Odor Threshold: Not determined
pH: pH 3.3-4.0
Melting point/Freezing point: NA
Initial Boiling Point/Boiling Point Range: NA
Evaporation Rate: NA
Flammability (solid, gas): NA
Upper/Lower Flammability or Explosive Limits: NA
Vapor Pressure: NA
Vapor Density (Air =1): NA
Evaporation Rate: NA
9. PHYSICAL/CHEMICAL PROPERTIES: continued

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, nitrogen oxides (NOx), and hydrogen chloride.

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>Ondansetron Hydrochloride Dihydrate</td>
<td>100</td>
<td>LD50</td>
<td>Oral</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>Ondansetron Hydrochloride Dihydrate</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>&gt; 15</td>
<td>mg/kg</td>
<td>Dog</td>
</tr>
</tbody>
</table>

LD50: Dosage that produces 50% mortality.
## 11. TOXICOLOGICAL INFORMATION: continued

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aspiration Hazard</strong></td>
<td>None anticipated from normal handling of this product.</td>
</tr>
<tr>
<td><strong>Dermal Irritation/Corrosion</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Ocular Irritation/Corrosion</strong></td>
<td>None anticipated from normal handling of this product. Aqueous solutions of the active ingredient, ondansetron hydrochloride, are reported to be severely irritating to the eyes. Inadvertent contact of this product with eyes or mucus membranes may produce irritation.</td>
</tr>
<tr>
<td><strong>Dermal or Respiratory Sensitization</strong></td>
<td>None anticipated from normal handling of this product. The active ingredient, ondansetron hydrochloride, was negative in a sensitization study in guinea pigs. In clinical use, pruritus, urticaria, other skin rashes, wheal and flare over the vein with intravenous injection, and diaphoresis have been reported with narcotic analgesics.</td>
</tr>
<tr>
<td><strong>Reproductive Effects</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Mutagenicity</strong></td>
<td>Ondansetron was not mutagenic in a standard battery of tests for mutagenicity.</td>
</tr>
<tr>
<td><strong>Carcinogenicity</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Target Organ Effects</strong></td>
<td>Based on clinical use, possible target organs include the central nervous system and liver.</td>
</tr>
</tbody>
</table>

## 12. ECOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aquatic Toxicity</strong></td>
<td>Not determined for product. Information of ondansetron hydrochloride is provided below.</td>
</tr>
<tr>
<td><em>Activated Sludge Respiration</em></td>
<td>This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms.</td>
</tr>
<tr>
<td></td>
<td>IC50: &gt; 1000 mg/l, 3 hours, activated sludge</td>
</tr>
<tr>
<td><em>Algal</em></td>
<td>This material contains an active pharmaceutical ingredient that is very toxic to algae.</td>
</tr>
<tr>
<td></td>
<td>IC50: 0.87 mg/l, 72 Hours, Selenastrum capricornutum (green algae); measured NOEL: 0.31 mg/l, 72 Hours, Static test</td>
</tr>
<tr>
<td><em>Daphnia</em></td>
<td>This material contains an active pharmaceutical ingredient that is harmful to daphnia.</td>
</tr>
<tr>
<td></td>
<td>EC50: 28 mg/l, 48 Hours, Daphnia pulex, Static test NOEL: 16 mg/l, 48 Hours, Daphnia pulex, Static test</td>
</tr>
<tr>
<td><em>Fish</em></td>
<td>This material contains an active pharmaceutical ingredient that is toxic to fish.</td>
</tr>
<tr>
<td></td>
<td>Adult Oncorhyncus mykiss, rainbow trout EC50: 6.5 mg/l, 96 Hours, Static test NOEL: 2.6 mg/l, 96 Hours, Measured</td>
</tr>
</tbody>
</table>

*GlaxoSmithKline MSDS*
12. ECOLOGICAL INFORMATION: continued

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 %, 28 days, Semi-continuous activated sludge (SCAS), activated sludge.

Aerobic - Soil
Percent Degradation: 20.3 to 99.9 %, 64 days.

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 sludges and other biomass.

*GlaxoSmithKline MSDS
1. LC50: Concentration in water that produces 50% mortality in fish or Daphnia
2. EC50: Concentration in water that produces 50% inhibition of growth in algae or inhibition of respiration in activated sludge.

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

DOT STATUS: Not regulated
Proper Shipping Name: NA
Hazard Class: NA
UN Number: NA
Packing Group: NA
Reportable Quantity: NA

ICAO/IATA STATUS: Not regulated
Proper Shipping Name: NA
Hazard Class: NA
UN Number: NA
Packing Group: NA
Reportable Quantity: NA

IMDG STATUS: Not regulated
Proper Shipping Name: NA
Hazard Class: NA
UN Number: NA
Packing Group: NA
Reportable Quantity: NA

Notes: DOT - US Department of Transportation Regulations
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>TSCA Status</td>
<td>Exempt.</td>
</tr>
<tr>
<td>CERCLA Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>SARA 302 Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>SARA 304 Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>SARA 313 Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>RCRA Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>PROP 65 (Calif.)</td>
<td>Not listed</td>
</tr>
</tbody>
</table>


U.S. OSHA Classification       Possible Irritant  
                              Target Organ Toxin

GHS Classification*           *Where medicinal products are not exempt, the recommended GHS workplace classification is as follows:

<table>
<thead>
<tr>
<th>Hazard Class</th>
<th>Acute Oral Toxicity</th>
<th>Eye Irritation</th>
<th>Target Organ Toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard Category</td>
<td>Unclassified</td>
<td>2B</td>
<td>2</td>
</tr>
<tr>
<td>Symbol</td>
<td>NA</td>
<td>NA</td>
<td></td>
</tr>
</tbody>
</table>

| Signal Word     | NA                  | Warning        | Warning               |
| Hazard Statement| NA                  | Causes eye irritation | May cause damage to the central nervous system and liver through prolonged or repeated exposure. |

Prevention: Do not breathe vapor or spray.

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.
**15. REGULATORY INFORMATION:** continued

**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.

**Classification(s):**

<table>
<thead>
<tr>
<th>Toxic</th>
<th>Irritant</th>
</tr>
</thead>
</table>

**Symbol:**

![Skull and Crossbones]

**Indication of Danger:**

<table>
<thead>
<tr>
<th>T</th>
<th>Xi</th>
</tr>
</thead>
</table>

**Risk Phrases:**

- R25 – Toxic if swallowed
- R36/37 - Irritating to eyes and respiratory system.

**Safety Phrases:**

- S24: Avoid contact with the skin
- S25: Avoid contact with eyes
- S37/39 Wear suitable gloves and eye/face protection.

**16. OTHER INFORMATION**

**Notes:**

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH TLV</td>
<td>American Conference of Governmental Industrial Hygienists – Threshold Limit Value</td>
</tr>
<tr>
<td>CAS</td>
<td>Chemical Abstracts Service Number</td>
</tr>
<tr>
<td>CERCLA</td>
<td>US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act</td>
</tr>
<tr>
<td>DOT</td>
<td>US Department of Transportation Regulations</td>
</tr>
<tr>
<td>EEL</td>
<td>Employee Exposure Limit</td>
</tr>
<tr>
<td>IATA</td>
<td>International Air Transport Association</td>
</tr>
<tr>
<td>LD50</td>
<td>Dosage producing 50% mortality</td>
</tr>
<tr>
<td>NA</td>
<td>Not applicable/Not available</td>
</tr>
<tr>
<td>NE</td>
<td>Not established</td>
</tr>
<tr>
<td>NIOSH</td>
<td>National Institute for Occupational Safety and Health</td>
</tr>
<tr>
<td>OSHA PEL</td>
<td>US Occupational Safety and Health Administration – Permissible Exposure Limit</td>
</tr>
<tr>
<td>Prop 65</td>
<td>California Proposition 65</td>
</tr>
<tr>
<td>RCRA</td>
<td>US EPA, Resource Conservation and Recovery Act</td>
</tr>
<tr>
<td>RTECS</td>
<td>Registry of Toxic Effects of Chemical Substances</td>
</tr>
<tr>
<td>SARA</td>
<td>Superfund Amendments and Reauthorization Act</td>
</tr>
<tr>
<td>STEL</td>
<td>15-minute Short Term Exposure Limit</td>
</tr>
<tr>
<td>TSCA</td>
<td>Toxic Substance Control Act</td>
</tr>
<tr>
<td>TWA</td>
<td>8-hour Time Weighted Average</td>
</tr>
</tbody>
</table>

**MSDS Coordinator:** Global Occupational Toxicology

**Date Prepared:** 10/30/2006

**Date Revised:** November 6, 2009

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