SAFETY DATA SHEET

Product Name: Ondansetron Injection, USP, 2 mg/mL

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

<table>
<thead>
<tr>
<th>Manufacturer Names And Addresses</th>
<th>Hospira, Inc.</th>
<th>Hospira Australia Pty Ltd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Addresses</td>
<td>275 North Field Drive</td>
<td>1 Lexia Place</td>
</tr>
<tr>
<td></td>
<td>Lake Forest, Illinois 60045</td>
<td>Mulgrave VIC 3170</td>
</tr>
<tr>
<td></td>
<td>USA</td>
<td>AUSTRALIA</td>
</tr>
</tbody>
</table>

Emergency Telephone
CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418

Product Name: Ondansetron Injection, USP, 2 mg/mL

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(S) IDENTIFICATION

Emergency Overview: Ondansetron Injection, USP, 2 mg/mL 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, this material should be considered a potent drug, possibly irritating to skin, and possibly irritating to the eyes and respiratory tract. Possible target organs include the nervous system and liver.

U.S. OSHA GHS Classification

<table>
<thead>
<tr>
<th>Physical Hazards</th>
<th>Hazard Class</th>
<th>Hazard Category</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<table>
<thead>
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<th>Health Hazards</th>
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<table>
<thead>
<tr>
<th>Label Element(s)</th>
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</thead>
<tbody>
<tr>
<td>Pictogram</td>
</tr>
<tr>
<td>Signal Word</td>
</tr>
<tr>
<td>Hazard Statement(s)</td>
</tr>
</tbody>
</table>

Precautionary Statement(s)

Prevention: Do not breathe vapor or spray.
Wash hands thoroughly after handling.

Response: Get medical attention if you feel unwell.

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.
Product Name: Ondansetron Injection, USP, 2 mg/mL

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Chemical Formula</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ondansetron Hydrochloride Dihydrate</td>
<td>C_{18}H_{19}N_{3}O \cdot HCl \cdot 2H_{2}O</td>
</tr>
</tbody>
</table>

<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 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.

### 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 such as carbon dioxide, dry chemical extinguishing powder or foam.

**Special Fire Fighting Procedures**
No special provisions required beyond normal firefighting 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 control 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/PERSOXAL PROTECTION

Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>OSHA-PEL</th>
<th>ACGIH-TLV</th>
<th>AIHA WEEL</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: Not</td>
<td>8-hr TWA: Not</td>
</tr>
<tr>
<td></td>
<td>Established</td>
<td>Established</td>
<td>Established</td>
<td>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.

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>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance/Physical State</td>
<td>Clear, colorless aqueous solution</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>NA</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>Flash Point</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 (Air =1)</td>
<td>NA</td>
</tr>
<tr>
<td>Relative Density</td>
<td>NA</td>
</tr>
<tr>
<td>Solubility</td>
<td>Soluble in water</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>
<tr>
<td>Viscosity</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
Strong oxidizers.

Hazardous Decomposition
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 active ingredient 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>

LD50: Dosage that produces 50% mortality.

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 anticipated from normal handling of this product. 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.

Aspiration Hazard: None anticipated from normal handling of this product.

Dermal Irritation/Corrosion: None anticipated from normal handling of this product. However, repeated or prolonged contact of this product with skin may produce irritation and/or a rash.

Ocular Irritation/Corrosion: None anticipated from normal handling of this product. However, inadvertent contact of this product with the eyes or mucus membranes may produce irritation.

Dermal or Respiratory Sensitization: None anticipated from normal handling of this product. In clinical use, hypersensitivity reactions, including anaphylaxis and bronchospasm, have been reported in patients who have exhibited hypersensitivity to other selective 5-HT3 receptor antagonists. Ondansetron hydrochloride was negative in a sensitization study in guinea pigs.

Reproductive Effects: None anticipated from normal handling of this product. 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.
11. TOXICOLOGICAL INFORMATION: continued

**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.

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

**Specific Target Organ Toxicity**
- **Single Exposure**: NA
- **Repeat Exposure**: Based on clinical use, possible target organs include the nervous system and liver.

12. ECOLOGICAL INFORMATION

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

*Activated Sludge Respiration -
IC50 > 1000 mg/L, 3 hours, activated sludge

*Algal -
IC50 = 0.87 mg/L, 72 Hours, Selenastrum capricornutum (green algae); measured
NOEL: 0.31 mg/L, 72 Hours, Static test

*Daphnia -
EC50 = 28 mg/L, 48 Hours, Daphnia pulex, Static test
NOEL = 16 mg/L, 48 Hours, Daphnia pulex, Static test

*Fish –
Adult Oncorhyncus mykiss, rainbow trout
EC50 = 6.5 mg/L, 96 Hours, Static test
NOEL = 2.6 mg/L, 96 Hours, Measured

**Persistence/ Biodegradability**
Not determined for product. Information of ondansetron hydrochloride is provided below.

*Hydrolysis: Ondansetron has been reported to be chemically stable in water with a half-life (neutral pH) of > 1 year.

*Photolysis: Ondansetron is reported to be likely to undergo photodegradation,

**Biodegradation** - Ondansetron is reported as not readily biodegradable.

- **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.

*It is reported that the active pharmaceutical ingredient is considered likely to adsorb to sludge and/or 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.
Product Name: Ondansetron Injection, USP, 2 mg/mL

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

<table>
<thead>
<tr>
<th>ADR/ADG/ DOT STATUS</th>
<th>Proper Shipping Name</th>
<th>Hazard Class</th>
<th>UN Number</th>
<th>Packing Group</th>
<th>Reportable Quantity</th>
</tr>
</thead>
<tbody>
<tr>
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<table>
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<th>Reportable Quantity</th>
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<tbody>
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<thead>
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<th>IMDG STATUS</th>
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<tbody>
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</table>

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

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<tbody>
<tr>
<td>Exempt</td>
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GHS/CLP Classification*

<table>
<thead>
<tr>
<th>Hazard Class</th>
<th>Hazard Category</th>
<th>Pictogram</th>
<th>Signal Word</th>
<th>Hazard Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

*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.

Prevention
Do not breathe vapor or spray
Wash hands thoroughly after handling
Collect spillage. Avoid release into the environment

Response
Get medical attention if you feel unwell.

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.
Product Name: Ondansetron Injection, USP, 2 mg/mL

15. REGULATORY INFORMATION: continued

<table>
<thead>
<tr>
<th>EU Classification*</th>
<th>*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.</th>
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<tbody>
<tr>
<td>Classification(s)</td>
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</tr>
<tr>
<td>Symbol</td>
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</tr>
<tr>
<td>Indication of Danger</td>
<td>NA</td>
</tr>
<tr>
<td>Risk Phrases</td>
<td>NA</td>
</tr>
<tr>
<td>Safety Phrases</td>
<td>S23: Do not breathe vapor/spray S24: Avoid contact with the skin S25: Avoid contact with eyes S37/39: Wear suitable gloves and eye/face protection S61: Avoid release into the environment</td>
</tr>
</tbody>
</table>

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
STOT-SE: Specific Target Organ Toxicity – Single Exposure
STOT-RE: Specific Target Organ Toxicity – Repeated Exposure
TSCA: Toxic Substance Control Act
TWA: 8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
Date Prepared: October 19, 2012
Date Revised: June 02, 2014

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