



**MATERIAL SAFETY DATA SHEET**

**1. CHEMICAL PRODUCT AND COMPANY INFORMATION**

<b>Manufacturer Name And Address</b>	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045
<b>Emergency Telephone Hospira, Inc.</b>	CHEMTREC: 800-424-9300 224 212-2055
<b>Product Names</b>	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.
<b>Synonyms</b>	1,2,3,9-Tetrahydro-90methyl-3-[(2-methyl-1H-imidazol-1-yl)methyl]-4H-carbazol-4-one hydrochloride

**2. COMPOSITION/INFORMATION ON INGREDIENTS**

<b>Ingredient Name</b>	Ondansetron Hydrochloride Dihydrate
<b>Chemical Formula</b>	C18H19N3O * HCL * 2H2O

<b>Component</b>	<b>Approximate Percent by Weight</b>	<b>CAS Number</b>	<b>RTECS Number</b>
Ondansetron Hydrochloride Dihydrate	<0.20%	103639-04-9	FE6375500

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**

<b>Emergency Overview</b>	Caution – Potent pharmaceutical agent. Health effects information is based on hazards of components.
<b>Occupational Exposure Potential</b>	Handling this product in its final form presents minimal risk from occupational exposure.
<b>Signs and Symptoms</b>	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.
<b>Medical Conditions Aggravated by Exposure</b>	Hypersensitivity to material and impaired liver function.

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**4. FIRST AID MEASURES**

<b>Eye Contact</b>	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.
<b>Skin Contact</b>	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.
<b>Inhalation</b>	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.
<b>Ingestion</b>	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**5. FIRE FIGHTING MEASURES**

<b>Flammability</b>	Non-Flammable
<b>Fire &amp; Explosion Hazard</b>	Not expected for the product.
<b>Extinguishing Media</b>	Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.
<b>Special Fire Fighting Procedures</b>	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**

<b>Spill Cleanup and Disposal</b>	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.
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**7. HANDLING AND STORAGE**

<b>Handling</b>	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.
<b>Storage</b>	No special storage required for hazard control. Refer to the product insert for product storage information.
<b>Special Precautions</b>	None

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### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Exposure Guidelines

Component	Exposure limits		
	OSHA-PEL	ACGIH-TLV	Hospira EEL
Ondansetron Hydrochloride	N/E	N/E	0.02 mg/m <sup>3</sup>

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.

<b>Respiratory Protection</b>	None, physical form suggests that risk of inhalation exposure is negligible.
<b>Skin Protection</b>	If contact with unprotected skin is likely, glove use is prudent practice.
<b>Eye Protection</b>	Eye protection is not required during expected product use conditions but may be warranted if eye contact is likely.
<b>Engineering Controls</b>	Engineering controls are not needed during normal product use conditions.

### 9. PHYSICAL/CHEMICAL PROPERTIES

<b>Appearance/Physical State</b>	Clear, Colorless Liquid
<b>Odor</b>	Odorless
<b>Boiling Point</b>	N/E
<b>Melting Point</b>	177 – 179 °C
<b>Vapor Pressure</b>	N/E
<b>Vapor Density (Air =1)</b>	N/E
<b>Evaporation Rate</b>	N/E
<b>Specific Gravity</b>	0.39 g/cm <sup>3</sup> (poured bulk density), 0.59 g/cm <sup>3</sup> (tapped bulk density)
<b>Solubility</b>	4% in Water, Active Ingredient
<b>pH</b>	4.5 based upon a 1% aqueous solution

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**10. STABILITY AND REACTIVITY**

<b>Chemical Stability</b>	Stable
<b>Incompatibilities</b>	Strong Oxidizing Agents
<b>Hazardous Decomposition Products</b>	Toxic fumes of NO <sub>x</sub> and HCl
<b>Hazardous Polymerization</b>	No

**11. TOXICOLOGICAL INFORMATION:**

**Acute Toxicity – Oral:**

<b>Ingredient(s)</b>	<b>Test Type</b>	<b>Value</b>	<b>Units</b>	<b>Species</b>
Ondansetron Hydrochloride	LD <sub>50</sub>	95	mg/kg	Rat
Ondansetron Hydrochloride	LD <sub>50</sub>	45	mg/kg	Dog

LD50 is the dosage producing 50% mortality.

Product contains approximately 1% 2, 6-Diisopropylphenol.

<b>Mutagenicity</b>	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.
<b>Dermal Irritation</b>	Corrosive to skin.
<b>Ocular Irritation</b>	Severe eye irritant.
<b>Target Organ Effects</b>	Liver
<b>Carcinogenicity</b>	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.
<b>Sensitization</b>	Potential to produce respiratory sensitization.
<b>Genetic Toxicity</b>	Not expected to be genotoxic under occupational exposure conditions.
<b>Reproductive Effects</b>	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).
<b>Other Adverse Effects</b>	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.

LC<sub>50</sub>: 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 daphids.

EC<sub>50</sub>: 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 Oncorhynchus mykiss, rainbow trout.

EC<sub>50</sub>: 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

**Product Name: Ondansetron Injection, USP**

**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
EC <sub>50</sub>	Effect Concentration affecting 50% of tested individuals
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LC <sub>50</sub>	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.
LD <sub>50</sub>	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

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