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

Component	Approximate Percent by Weight	CAS Number	RTECS Number
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

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

	Exposure limits		
Component	**OSHA-PEL**	**ACGIH-TLV**	**Hospira EEL**
Ondansetron Hydrochloride	N/E	N/E	0.02 mg/m^3

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

Appearance/Physical State Clear, Colorless Liquid

Odor Odorless

Boiling Point N/E

Melting Point 177 – 179 °C

Vapor Pressure N/E

Vapor Density (Air =1) N/E

Evaporation Rate N/E

Specific Gravity 0.39 g/cm^3 (poured bulk density), 0.59 g/cm^3 (tapped bulk density)

Solubility 4% in Water, Active Ingredient

pH 4.5 based upon a 1% aqueous solution

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:

Ingredient(s)	Test Type	Value	Units	Species
Ondansetron Hydrochloride	LD_{50}	95	mg/kg	Rat
Ondansetron Hydrochloride	LD_{50}	45	mg/kg	Dog

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.

12. ECOLOGICAL INFORMATION:

Aquatic Toxicity

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

LC_{50}: 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_{50}: 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.

EC_{50}: 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
EC_{50}	Effect Concentration affecting 50% of tested individuals
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LC_{50}	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_{50}	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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