SAFETY DATA SHEET

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

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Names And Addresses	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA	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 - 61-290372994; UK - 44-870-8200418	
Hospira, Inc., Non-Emergency	224 212-2000	
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

Physical Hazards	**Hazard Class**	**Hazard Category**
	Not Classified	Not Classified

Health Hazards	**Hazard Class**	**Hazard Category**
	Not Classified	Not Classified

Label Element(s)

Pictogram	NA
Signal Word	NA
Hazard Statement(s)	NA
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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name Ondansetron Hydrochloride Dihydrate
Chemical Formula $C_{18}H_{19}N_3O \bullet \cdot HCl \cdot \bullet 2H_2O$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Ondansetron Hydrochloride Dihydrate	0.2	103639-04-9	FE6375500

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/PERSONAL PROTECTION

Exposure Guidelines

	Exposure Limits			
Component	**OSHA-PEL**	**ACGIH-TLV**	**AIHA WEEL**	**Hospira EEL**
Ondansetron Hydrochloride	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established

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

Appearance/Physical State	Clear, colorless aqueous solution
Odor	Odorless
Odor Threshold	NA
pH	3.3 to 4.0
Melting point/Freezing Point	NA
Initial Boiling Point/Boiling Point Range	NA
Flash Point	NA
Evaporation Rate	NA
Flammability (solid, gas)	NA
Upper/Lower Flammability or Explosive Limits	NA
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Relative Density	NA
Solubility	Soluble in water
Partition Coefficient: n-octanol/water	NA
Auto-ignition Temperature	NA
Decomposition Temperature	NA
Viscosity	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 active ingredient is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Ondansetron Hydrochloride Dihydrate	100	LD50	Oral	95 >45	mg/kg mg/kg	Rat Dog
Ondansetron Hydrochloride Dihydrate	100	LD50	Intravenous	20.1 >15	mg/kg mg/kg	Rat Dog

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

Specific Target Organ Toxicity – 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.

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

ADR/ADG/ 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

US TSCA Status	Exempt
US CERCLA Status	Not listed
US SARA 302 Status	Not listed
US SARA 313 Status	Not listed
US RCRA Status	Not listed
US 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

GHS/CLP 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	Hazard Category	Pictogram	Signal Word	Hazard Statement
NA	NA	NA	NA	NA

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.

15. REGULATORY INFORMATION: continued

EU Classification*	*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.
Classification(s)	NA
Symbol	NA
Indication of Danger	NA
Risk Phrases	NA
Safety Phrases	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

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
LD_{50}	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
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