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Section 1 - Chemical Product and Company

Distributor:

Sagent Pharmaceuticals, Inc.
1901 N. Roselle Rd, Suite 700
Schaumburg, IL 60195
847-908-1600

Emergency Telephone: 866-625-1618

Product Identifier: Ondansetron Injection, USP (32 mg/50 mL)
Product Code: NDC 25021-776-50
Common/Trade Name: Ondansetron in 5% Dextrose Injection
Chemical Name: (+) 1,2,3,9-tetrahydro-9-methyl-3-[(2-methyl-1H-imidazol-1-yl)methyl]-4H-carbazol-4-one, monohydrochloride, dihydrate
Chemical Family: Antiemetic
Product Use: Pharmaceutical, Injectable
Product Type: Regulated Prescription Drug
Container Information: Plastic Bag


Section 2 - Composition / Information on Ingredients

Ingredient	Weight %	OSHA PEL	ACGGIH TLV	Other Limits Recommended	CAS No.
Ondansetron Hcl Dihydrate	0.1	None	None	None	103639-04-9
Citric Acid Monohydrate	<0.1	None	None	None	5949-29-1
Sodium Citrate Dihydrate	<0.1	None	None	None	6132-04-3
Dextrose Monohydrate	5.0	None	None	None	5996-10-1
Water for Injection	>94.0	None	None	None	7732-18-5

Section 3 - Hazards Identification

EMERGENCY OVERVIEW: Avoid skin contact. Avoid eye contact. Irritation potential to skin, eyes, and mucous membranes. May cause allergic reaction.

Primary Physical and Health Hazards: Ondansetron is used for treating nausea and vomiting for patients undergoing chemotherapy. It affects the digestive system and may affect the central nervous system. Minimal health hazard is expected upon occupational exposure.

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Routes of Entry: Ondansetron injection may be absorbed via contact with skin or eyes; inhalation of aerosols or accidentally ingested. Under normal use with supervision of a physician, Ondansetron Injection presents little hazard.

Signs & Symptoms of Exposure: Acute signs and symptoms of exposure may include irritation to eyes, skin, and respiratory tract. May cause allergic reaction in sensitized individuals.

Chemical Listed as Carcinogen: **NTP:** None
IARC: None
OSHA: None

Medical Conditions Generally Aggravated by Exposure: Ondansetron is not recommended for use in patients who have exhibited hypersensitivity to other selective 5-HT₃ receptor antagonists.

Section 4 - First Aid Measures

Eye Exposure: Flush eyes with large volumes of water for 15 minutes or more. Seek treatment from physician.


Skin Exposure: Wash skin with cool, soapy water. Remove contaminated clothing.

Ingestion: If ingestion occurs, flush mouth with water and seek medical attention immediately. If person is conscious, induce vomiting; never induce vomiting on an unconscious person.

Injection: Under normal use with supervision of a physician, Ondansetron Injection presents little hazard.

Inhalation: If difficulty breathing, administer oxygen. See medical attention immediately. If necessary, provide artificial respiration. Overdose should be treated symptomatically.

Notes to Physician: See patient package insert in shipping carton for complete information.


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Section 5 - Fire Fighting Measures

Flash Point	Not Applicable
Autoignition Temperature:	Not Applicable
Flammable Limits in Air	Lower %: Not Applicable Upper %: Not Applicable
Flammable Limits:	Not Applicable
Extinguishing Media	Use water or multi-purpose ABC extinguisher.
Special Fire Fighting Procedures:	As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke. Product is not expected to present a fire hazard concern.
Unusual Fire/Explosion Hazards:	None.

Section 6 - Accidental Release Measures

Spill:	Absorb Ondansetron with absorbent materials and dispose according to local, state, and federal guidelines. Prevent contact with sewers and waterways. Wash area with soap and water. Wear personal protective equipment.
Release to Air:	If aerosolized, reduce exposures by ventilating area. Clean up immediately to prevent evaporation. Wear respiratory protection as necessary.
Release to Water:	Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

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Section 7 - Handling and Storage

- General Handling:** Keep this and all drugs out of the reach of children. Use normal precautions for storage of a drug. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.
- Waste Disposal Method:** Dispose of according to local, state, and federal guidelines. Incineration at a licensed facility is recommended.
- Storage Conditions:** Protect from light. Avoid excessive heat. Protect from freezing. Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature], excursions permitted to 40° for not more than 48 hours.

Section 8 - Exposure Controls / Personal Protection

Under normal use and handling conditions, no protective equipment is required. The following is recommended for a production setting.

- Respiratory Protection:** Under normal use, respiratory protection should not be required if adequate ventilation is available. A dust/mist respirator (N95) may be necessary if excessive aerosols are generated. For large spill emergencies, self-contained breathing apparatus (SCBA) may be required. Personnel wearing respirators should be fit tested and approved for respirator use under OSHA Respiratory Protection Standard, 29 CFR 1910.134.
- Eye Protection:** Safety glasses or goggles.
- Ventilation:** Handle product in a well ventilated area.
- Skin Protection:** Work uniform or lab coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suites) to avoid exposed skin surfaces.
- Other Protective Equipment:** Lab coat.
- Additional Exposure Precautions:** Wash hands following use. No eating, drinking or smoking when handling this product.

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Exposure Limits


<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Ondansetron	OSHA	PEL	NE
	ACGIH	TLV	NE
	----	STEL	NE

Section 9 - Physical and Chemical Properties

Physical State:	Liquid	Specific Gravity:	Approx to water
Appearance and Odor:	Clear, colorless solution, odorless	Evaporation Rate:	Approx to water
Boiling Point:	Approx to water	Solubility in Water:	Soluble
Vapor Pressure:	Approx to water	pH:	3.0 – 4.0
Vapor Density:	Approx to water	Molecular Weight	Not applicable

Section 10 - Stability and Reactivity

Stability:	Stable
Incompatibility (Materials to avoid):	Oxidizing agents. See product packaging and the Physicians' Desk Reference (PDR) for Drug Interactions.
Hazardous Decomposition:	Decomposition products of this compound may include potentially hazardous byproduct of carbon monoxide and carbon dioxide.
Hazardous Polymerization:	Will not occur.
Conditions to Avoid:	None identified.

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Section 11 - Toxicological Information

Signs & Symptoms of Exposure & Overexposure: Overexposure to this product may cause symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty in breathing); headache; constipation; flushing; abnormal nervous system sensations.

Acute Toxicity

Component	Type	Route	Species	Dosage
Ondansetron	LD _{LO}	Oral	Mouse	10 mg/kg
Ondansetron	LD _{LO}	IV	Mouse	2500 mg/kg
Ondansetron	LD _{LO}	Intraperitoneal	Mouse	5 kg mg/kg
Ondansetron	LD _{LO}	IV	Rat	20 mg/kg

Carcinogenicity: Negative for carcinogenicity in rats and mice administered oral doses of up to 10 and 30 mg/kg/day, respectively. NTP, IARC or OSHA does not list it as carcinogenic.

Mutagenicity: Negative in a battery of short-term screening tests for mutagenicity.

Reproductive Toxicity: Negative for fertility impairment in rats administered doses up to 15 and 30 mg/kg/day, respectively.


Section 12 - Ecological Information

Information is currently not available on the environmental impact of Ondansetron. Handle in a manner to prevent spills or releases to the environment.

Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations. Incineration at an approved, permitted facility is recommended.

Container Handling and Disposal: Dispose of container and unused contents in accordance with federal, state and local regulations.

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Section 14 - Transport Information

Regulatory Organizations:

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations


TSCA - *Not on this list*

CERCLA - *Not on this list*

SARA 302 - *Not on this list*

SARA 313 - *Not on this list*

Other – *Based on this product's use, the requirements of the OSHA Bloodborne Pathogen Standard (29 CFR 1910.130) are applicable.*


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Section 16 - Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. **THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE).** In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Sagent Pharmaceuticals, Inc.
 1901 N. Roselle Rd, Suite 700
 Schaumburg, IL 60195
 847-908-1600

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Glossary: This glossary contains definitions of general terms used in MSDSs. Not all of these Glossary Terms will apply to this MSDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)