	<b>Sagent Pharmaceuticals, Inc.</b>				
	<b>Ondansetron Injection, USP</b>			<b>Material Safety Data Sheet (MSDS)</b>	
	Issue Date: <b>MAY 09 2012</b>	MSDS No.: <b>MSDS 011</b>	Version No.: <b>2.0</b>	Form Number: <b>R-SOP-009-F001</b>	Page: <b>1 of 10</b>

### 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 (2 mL, 20 mL)  
**Product Code:** NDC 25021-777  
 NDC 25021-782  
**Common/Trade Name:** Ondansetron Injection, USP  
**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:** Vial

### Section 2 - Composition / Information on Ingredients

Ingredient	Amount	CAS No.
Ondansetron Hydrochloride	2 mg/mL	103639-04-9
Sodium Chloride	9.0 mg	7647-14-5
Citric Acid Monohydrate	0.5 mg	5949-29-1
Sodium Citrate Dihydrate	0.25 mg	6132-04-3
Methylparaben*	1.2 mg/mL	99-76-3
Propylparaben*	0.15 mg/mL	94-13-3
Water for Injection	QS	7732-18-5

\*Product code 25021-777 is preservative-free and does not contain these ingredients.

	<b>Sagent Pharmaceuticals, Inc.</b>				
	<b>Ondansetron Injection, USP</b>			<b>Material Safety Data Sheet (MSDS)</b>	
	Issue Date: <b>MAY 09 2012</b>	MSDS No.: <b>MSDS 011</b>	Version No.: <b>2.0</b>	Form Number: <b>R-SOP-009-F001</b>	Page: <b>2 of 10</b>

### Section 3 - Hazards Identification

**EMERGENCY OVERVIEW:** Material is clear solution. Avoid contact with eyes, skin and clothing. Do not taste or swallow. Wash thoroughly after handling

**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.


**Routes of Entry:** Inhalation, eye/skin contact, or ingestion.

**Signs & Symptoms of Exposure:** This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Possible adverse reactions include: diarrhea, headache, fever, constipation, dizziness, muscle pain, drowsiness, sedation, malaise, fatigue, shivers, injection site reaction, urinary retention, pain, chest pain, anxiety, dysuria, hypotension, fever, cold sensation, pruritus, and paresthesia. Flushing, rare cases of hypersensitivity reactions including anaphylaxis, bronchospasm, cardiopulmonary arrest, hypotension, laryngeal edema, laryngospasm, shock, shortness of breath, and stridor have also been reported.

Local reactions such as pain, redness, and burning at the site of injection have been reported. Dystonic reactions including oculogyric crisis, urticaria, hiccups, transient dizziness, and transient blurred vision have also been reported. Transient blindness which resolved within a few minutes or up to 48 hrs was also reported.

Occupational exposure has not been fully investigated. 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, and central nervous system activity.

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

	<b>Sagent Pharmaceuticals, Inc.</b>				
	<b>Ondansetron Injection, USP</b>			<b>Material Safety Data Sheet (MSDS)</b>	
	Issue Date: <b>MAY 09 2012</b>	MSDS No.: <b>MSDS 011</b>	Version No.: <b>2.0</b>	Form Number: <b>R-SOP-009-F001</b>	Page: <b>3 of 10</b>

**Medical Conditions Generally Aggravated by Exposure:** Minor irritation might occur following direct contact with eyes. Adverse effects might occur in the central nervous system following overexposure.

#### 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:** Remove contaminated clothing immediately. Wash skin with cool, soapy water for at least 15 minutes. Seek medical attention if skin reaction occurs, which may be immediate or delayed.

**Ingestion:** Do not induce vomiting. Flush mouth out with water. If subject is fully conscious, give plenty of water to drink. Seek medical attention.

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

**Inhalation:** Physical form suggests that risk of inhalation exposure is negligible.

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

#### 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. Carbon dioxide extinguishers may be ineffective. If possible, contain and collect firefighting water for later disposal.

**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.

	<b>Sagent Pharmaceuticals, Inc.</b>			
	<b>Ondansetron Injection, USP</b>		<b>Material Safety Data Sheet (MSDS)</b>	
	Issue Date: <b>MAY 09 2012</b>	MSDS No.: <b>MSDS 011</b>	Version No.: <b>2.0</b>	Form Number: <b>R-SOP-009-F001</b>

**Unusual Fire/Explosion Hazards:** Toxic, corrosive, or flammable thermal decomposition products are expected when the product is exposed to fire.

### Section 6 - Accidental Release Measures


- Spill:** Wear recommended personal protective equipment consistent with the degree of hazard. Spread an inert absorbent on the spill and place in a suitable, properly labeled container for recovery or disposal. No specific decontamination or detoxification procedures have been identified with this product. Prevent entry into waterways, sewers, surface drainage systems, and poorly ventilated areas.
- 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.

### Section 7 - Handling and Storage

- General Handling:** No special handling requirements for the normal use of this substance. Normal room ventilation is expected to be adequate for routine handling of this product.
- Waste Disposal Method:** Dispose of according to local, state, and federal guidelines. Incineration at a licensed facility is recommended.
- Storage Conditions:** Protect from light. Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

### 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.

	<b>Sagent Pharmaceuticals, Inc.</b>				
	<b>Ondansetron Injection, USP</b>			<b>Material Safety Data Sheet (MSDS)</b>	
	Issue Date: <b>MAY 09 2012</b>	MSDS No.: <b>MSDS 011</b>	Version No.: <b>2.0</b>	Form Number: <b>R-SOP-009-F001</b>	Page: <b>5 of 10</b>

**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.

### Exposure Limits

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Ondansetron	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE
	GSK	OEL	30 mcg/m <sup>3</sup> (8 hr TWA)
Sodium Chloride	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE
Sodium Citrate Dihydrate	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE

	<b>Sagent Pharmaceuticals, Inc.</b>				
	<b>Ondansetron Injection, USP</b>			<b>Material Safety Data Sheet (MSDS)</b>	
	Issue Date: <b>MAY 09 2012</b>	MSDS No.: <b>MSDS 011</b>	Version No.: <b>2.0</b>	Form Number: <b>R-SOP-009-F001</b>	Page: <b>6 of 10</b>


Methylparaben	OSHA ACGIH -----	PEL TLV STEL	NE NE NE
Propylparaben	OSHA ACGIH -----	PEL TLV STEL	NE NE NE
<u>Compound</u> Water for Injection	OSHA ACGIH -----	PEL TLV STEL	NE NE NE

### Section 9 - Physical and Chemical Properties

<b>Physical State:</b>	Liquid	<b>Specific Gravity:</b>	Approx to water
<b>Appearance and Odor:</b>	Clear, colorless solution	<b>Evaporation Rate:</b>	Approx to water
<b>Boiling Point:</b>	Approx to water	<b>Solubility in Water:</b>	Soluble
<b>Vapor Pressure:</b>	Approx to water	<b>pH:</b>	3.3 – 4.0
<b>Vapor Density:</b>	Approx to water	<b>Molecular Weight</b>	365.86

### Section 10 - Stability and Reactivity

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

	<b>Sagent Pharmaceuticals, Inc.</b>				
	<b>Ondansetron Injection, USP</b>			<b>Material Safety Data Sheet (MSDS)</b>	
	Issue Date: <b>MAY 09 2012</b>	MSDS No.: <b>MSDS 011</b>	Version No.: <b>2.0</b>	Form Number: <b>R-SOP-009-F001</b>	Page: <b>7 of 10</b>

## Section 11 - Toxicological Information

### Signs & Symptoms of Exposure & Overexposure:

This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Possible adverse reactions include: diarrhea, headache, fever, constipation, dizziness, muscle pain, drowsiness, sedation, malaise, fatigue, shivers, injection site reaction, urinary retention, pain, chest pain, anxiety, dysuria, hypotension, fever, cold sensation, pruritus, and paresthesia. Flushing, rare cases of hypersensitivity reactions including anaphylaxis, bronchospasm, cardiopulmonary arrest, hypotension, laryngeal edema, laryngospasm, shock, shortness of breath, and stridor have also been reported.


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Occupational exposure has not been fully investigated. 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, and central nervous system activity.

### Acute Toxicity

Component	Type	Route	Species	Dosage
Ondansetron	LD <sub>50</sub>	Oral	Mouse	10 mg/kg
Ondansetron	LD <sub>50</sub>	IV	Mouse	2500 mg/kg
Ondansetron	LD <sub>50</sub>	Intraperitoneal	Mouse	5 kg mg/kg
Ondansetron	LD <sub>50</sub>	IV	Rat	20 mg/kg

**Reproductive Effects:** Not expected to produce adverse effects on fertility or development under occupational exposure conditions.

	<b>Sagent Pharmaceuticals, Inc.</b>				
	<b>Ondansetron Injection, USP</b>			<b>Material Safety Data Sheet (MSDS)</b>	
	Issue Date: <b>MAY 09 2012</b>	MSDS No.: <b>MSDS 011</b>	Version No.: <b>2.0</b>	Form Number: <b>R-SOP-009-F001</b>	Page: <b>8 of 10</b>

### 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.

### 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.*

	<b>Sagent Pharmaceuticals, Inc.</b>				
	<b>Ondansetron Injection, USP</b>			<b>Material Safety Data Sheet (MSDS)</b>	
	Issue Date: <b>MAY 09 2012</b>	MSDS No.: <b>MSDS 011</b>	Version No.: <b>2.0</b>	Form Number: <b>R-SOP-009-F001</b>	Page: <b>9 of 10</b>

**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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	<b>Ondansetron Injection, USP</b>			<b>Material Safety Data Sheet (MSDS)</b>	
	Issue Date: <b>MAY 09 2012</b>	MSDS No.: <b>MSDS 011</b>	Version No.: <b>2.0</b>	Form Number: <b>R-SOP-009-F001</b>	Page: <b>10 of 10</b>

**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)