Section 1 - Identification

(a) Product Identifier: Ondansetron Injection, USP (40 mg/20 mL)

(b) Product Code: 70860-777

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

(c) Product Use: Pharmaceutical, Injectable

Product Type: Regulated Prescription Drug

Container Information: Vial

(d) Distributor: Athenex Pharmaceutical Division, 10 N. Martingale Road, Suite 230, Schaumburg, IL 60173, 847-886-9515

(e) Emergency Telephone: 855-273-0154

Section 2 - Hazards Identification

(a) Classification:

NFPA Rating	
Health Hazard	1
Fire Hazard	0
Reactivity Hazard	0

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	**(c) Description of Hazards:**
Signal Word:	- Not Available
Hazard Statements: - Non-hazardous in accordance with international standards for workplace safety	

(d) Unknown Acute Toxicity N/A

Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
(±) 1, 2, 3, 9-tetrahydro-9-methyl-3-[(2-methyl-1H-imidazol-1-yl)methyl]-4H-carbazol-4-one, monohydrochloride, dihydrate	Ondansetron Hydrochloride Dihydrate	2.5 mg	103639-04-9	N/A
Sodium Chloride	Sodium Chloride	8.3 mg	7647-14-5	N/A
2-hydroxypropane-1,2,3-tricarboxylic acid	Citric Acid Monohydrate	0.5 mg	5949-29-1	N/A
Trisodium 2-hydroxypropane-1,2,3-tricarboxylate	Sodium Citrate Dihydrate	0.25 mg	6132-04-3	N/A
Methyl 4-hydroxybenzoate	Methylparaben*	1.2 mg	99-76-3	N/A
Propyl 4-hydroxybenzoate	Propylparaben*	0.15 mg	94-13-3	N/A
Water	Water for Injection	q.s. to 1.0 mL	7732-18-5	N/A

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

(a) 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.

(b) Hazardous Combustion Products: Toxic, corrosive, or flammable thermal decomposition products are expected when the product is exposed to fire.

(c) Special Protective Equipment / Precautions: 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.

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.

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

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Ondansetron	OSHA ACGIH ----- GSK	PEL TLV STEL OEL	NE NE NE 30 mcg/m3 (8 hr TWA)
Sodium Chloride	OSHA ACGIH -----	PEL TLV STEL	NE NE NE
Sodium Citrate Dihydrate	OSHA ACGIH -----	PEL TLV STEL	NE NE NE
Methylparaben	OSHA ACGIH -----	PEL TLV STEL	NE NE NE
Propylparaben	OSHA ACGIH -----	PEL TLV STEL	NE NE NE
Water for Injection	OSHA ACGIH -----	PEL TLV STEL	NE NE NE

(b) Engineering Controls

Ventilation: Handle product in a well ventilated area.

(c) Individual Protection Measures

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.
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.

Section 9 - Physical and Chemical Properties

(a)	**Appearance**	Clear, colorless solution
(b)	**Odor**	No Odor
(c)	**Odor Threshold**	None
(d)	**pH**	3.3 – 4.0
(e)	**Melting Point:**	Not Applicable
(f)	**Initial Boiling Point:**	Approx to water
(g)	**Flash Point**	Not applicable
(h)	**Evaporation Rate:**	Approx to water
(i)	**Flammability**	Non-flammable
(j)	**Upper Lower Flammability or Explosion Limits**	Not applicable
(k)	**Vapor Pressure:**	Approx to water
(l)	**Vapor Density:**	Approx to water
(m)	**Relative Density**	Approx to water
(n)	**Solubility(ies)**	Soluble in water
(o)	**Partition Coefficient: n-octanol/water**	Not available

(p)	**Auto-ignition Temperature**	Not available
(q)	**Decomposition Temperature**	Not available
(r)	**Viscosity**	Not available

Section 10 - Stability and Reactivity

(a)	**Reactivity**	Not Reactive
(b)	**Chemical Stability**	Stable
(c)	**Possibility of Hazardous Reactions**	Hazardous polymerization will not occur.
(d)	**Conditions to Avoid**	None identified.
(e)	**Incompatible Materials**	Oxidizing agents. See product packaging and the Physicians' Desk Reference (PDR) for Drug Interactions.
(f)	**Hazardous Decomposition Products**	Decomposition products of this compound may include potentially hazardous byproduct of carbon monoxide and carbon dioxide.

Section 11 - Toxicological Information

(a)	**Likely Routes of Exposure**	Inhalation, eye/skin contact, or ingestion.
(b)	**Symptoms related to the physical, chemical and toxicological characteristics**	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, musclemen pain, drowsiness, sedation, malaise, fatigue, shivers, injection site react ion, 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.

(c)	**Delayed and immediate effects and also chronic effects from short and long term exposure**	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.

(d) Acute Toxicity

Component	Type	Route	Species	Dosage
Ondansetron	LD_{50}	Oral	Mouse	10 mg/kg
Ondansetron	LD_{50}	IV	Mouse	2500 mg/kg
Ondansetron	LD_{50}	Intraperitoneal	Mouse	5 kg mg/kg
Ondansetron	LD_{50}	IV	Rat	20 mg/kg
Ondansetron	LD_{50}	Oral	Rat	95 mg/kg
Ondansetron	LD_{50}	Oral	Dog	>45 mg/kg
Ondansetron	LD_{50}	IV	Dog	>15 mg/kg

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

(e) Hazardous Chemical Listings

NTP: Not Listed IARC: Not Listed OSHA: Not Listed

Section 12 - Ecological Information

(a)	**Ecotoxicity**	This material contains an active pharmaceutical ingredient that is very toxic to algae. LC50: 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. EC50: 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. EC50: 6.5 mg/l, 96 Hours, Static Test NOEL: 2.6 mg/l, 96 Hours, Measured IC50 - other microorganisms - > 1,000 mg/l - 3 h
(b)	**Persistence and degradability**	Not readily biodegradable.
(c)	**Bioaccumulative potential**	Not established
(d)	**Mobility in soil**	Not established
(e)	**Other Adverse Effects**	Not established

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

(a)	**UN Number**	Not available
(b)	**UN Proper Shipping Name**	Not available
(c)	**Transport Hazard Class(es)**	Not available
(d)	**Packing Group**	Not available
(e)	**Environmental Hazards**	Not available
(f)	**Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)**	Not available
(g)	**Special Precautions**	Not available

DOT: Not regulated
ICAO/IATA: Not regulated
IMDG: Not regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Athenex Pharmaceutical Division 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
Prop 65 (Calif.) – Not on this list
RCRA – Not on this list
Other – Based on this product's us, the requirements of the OSHA Bloodborne Pathogen Standard (29 CFR 1910.130) are applicable.

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 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:

Athenex Pharmaceutical Division
10 N. Martingale Road, Suite 230
Schaumburg, IL 60173
847-886-9515

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

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
SDS	Safety Data Sheet
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)

Signature Manifest

Document Number: SDS002 **Revision:** 01

Title: Ondansetron Injection, USP (40 mg/20 mL)

All dates and times are in Eastern Standard Time.

SDS002

Change Request

Name/Signature	Title	Date	Meaning/Reason
Michael Scribner (MSCRIBNER)	CORPORATE QA MANAGER	24 Jan 2017, 03:34:26 PM	Approved

Dept Approval

Name/Signature	Title	Date	Meaning/Reason
Tom Moutvic (TMOUTVIC)	VP of Regulatory Affairs	25 Jan 2017, 01:53:39 PM	Approved

Final QA Approval/Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Sheila Moran (SMORAN)	VP of Quality Assurance	25 Jan 2017, 02:09:22 PM	Approved