SAFETY DATA SHEETS

This SDS packet was issued with item:

078555749

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078555756 078911794

Ondansetron Injection, USP

Safety Data Sheet

Section 1: Identification

Common/Trade Name: Ondansetron Injection, USP, 2 mg/mL, 2 mL, Single-dose Vial and Ondansetron Injection, USP, 2 mg/mL, 20 mL, Multidose Vial

Manufacturer's Name: Wockhardt Limited, Mumbai, India.

Emergency Telephone Number: +91-22-2653 4444

Section 2: Hazard(s) Identification

EMERGENCY OVERVIEW:

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

Symptoms of Overexposure by Route of Exposure: This material is intended for intravenous use under the supervision of physicians.

Inhalation: Inhalation of significant amounts of the product is not anticipated to occur because of the small size of individual containers.

Contact with Skin or Eyes: Contact may cause mild irritation. Effects may include stinging, watering, and redness of the eyes and redness and a burning sensation on the skin.

Ingestion: Ingestion is not an anticipated route of occupational exposure. However, the active ingredient, Ondansetron Hydrochloride, is not toxic if ingested. Symptoms similar to those identified under injection may occur.

Injection: Local redness and pain are the primary symptoms of accidental injection in an occupational setting. Medical personnel are not anticipated to experience over-exposures to the therapeutic doses of this product. However, effects including hypersensitivity (such as skin rash, hives, itching and breathing difficulties), headache, constipation, flushing and abnormal nervous system sensations may occur. See package insert for other adverse reactions associated with therapeutic doses of this product.

Health Effects or Risks From Exposure **(An explanation in lay terms):**

Acute: The primary health effects anticipated in an occupational setting include irritation of eyes and skin as well as redness and local swelling after accidental injection. In case of over-exposure by injection, effects such as hypersensitivity (such as skin rash, hives, itching and breathing difficulties), headache, constipation, and flushing may occur.

Target Organs: No target organ effects expected.

Other Comments: Rare cases of hypersensitivity reactions, sometimes severe have been reported. Some reactions were accompanied by cardiopulmonary arrest, hypotension, shock, and breathing difficulties.

Pre-Existing Medical Conditions: None known.

Section 3: Composition/Information on Ingredients

Chemical Name	CAS#	SDV Conc. %w/w	MDV Conc. %w/w	ACGIH		OSHA	
				TLV	STEL	TLV	PEL
Ondansetron (as Ondansetron Hydrochloride Dihydrate)	103639-04-9	0.25	0.25	NE	NE	NE	NE
Sodium chloride	7647-14-5	0.900	0.830	NE	NE	NE	NE
Citric acid monohydrate	5949-29-1	0.050	0.050	NE	NE	NE	NE
Sodium citrate dihydrate	6132-04-3	0.025	0.025	NE	NE	NE	NE
Methyl paraben	99-76-3	Not applicable	0.120	NE	NE	NE	NE
Propyl paraben	94-13-3	Not applicable	0.015	NE	NE	NE	NE
Water for Injection	----	98.775	98.71	NE	NE	NE	NE

Section 4: First-Aid Measures

Skin Exposure: Remove contaminated shoes and clothing and cleanse affected area(s) thoroughly by washing with mild soap and water. If irritation or redness develops and persists, seek medical attention.

Eye Exposure: If irritation or redness develops, move victim away from exposure and into fresh air. Flush eyes with clean water and seek medical attention.

Inhalation: If respiratory symptoms develop, move victim away from source of exposure and into fresh air. If symptoms persist, seek medical attention. If victim is not breathing, clear airway and immediately begin artificial respiration. If breathing difficulties develop, oxygen should be administered by qualified personnel. Seek immediate medical attention.

Ingestion: If swallowed, seek emergency medical attention. If victim is drowsy or unconscious and vomiting, place on the left side with the head down and DO NOT give anything by mouth. If not vomiting and professional advice is not available, DO NOT induce vomiting. If possible, do not leave victim unattended and observe closely for adequacy of breathing.

Section 5: Fire-Fighting Measures

Flash Point: Non-flammable

Autoignition Temperature: Not applicable

Flammable Limits (in air by volume, %): Lower: Not applicable Upper: Not applicable

Fire Extinguishing Equipment: Use extinguishing agent suitable for type of surrounding fire.

Water Spray: OK Carbon Dioxide: OK Halon: OK Foam: OK Dry Chemical: OK Other: Any "ABC" Class

Unusual Fire and Explosion Hazards: No unusual fire or explosion hazards are expected.

Explosion Sensitivity to Mechanical Impact: Not sensitive.	Explosion Sensitivity to Static Discharge: Not sensitive.

Special Fire Fighting Procedures: For fires beyond the incipient stage, emergency responders in the immediate hazard area should wear bunker gear. When the potential chemical hazard is unknown, in enclosed or confined spaces, or when explicitly required by DOT, a self-contained breathing apparatus should be worn. In addition, wear other appropriate protective equipment as conditions warrant (see Section 8). Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Move undamaged containers from immediate hazard area if it can be done with minimal risk. Cool equipment exposed to fire with water, if it can be done with minimal risk.

NFPA HAZARD CLASS:
Health: 1 (Slight)
Flammability: 0 (Least)
Reactivity: 0 (Least)

Section 6: Accidental Release Measures

Spill and Leak Response:

For small releases of this product, wear latex or nitrile gloves and safety glasses. Absorb spilled liquid and rinse area thoroughly with soap and water.

For large or uncontrolled releases, stay away from spill. Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Wear appropriate protective equipment including respiratory protection as conditions warrant (see Section 8). Prevent spilled material from entering sewers, storm drains, other unauthorized treatment drainage systems, and natural waterways. Dike far ahead of spill for later recovery or disposal. Spilled material may be absorbed into an appropriate absorbent material. Notify appropriate federal, state, and local agencies. Immediate cleanup of any spill is recommended.

Section 7: Handling and Storage

Work and Hygiene Practices: As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling.

Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Precautions should be taken during the following activities:

- Withdrawal of needles from drug vials.
- Drug transfers using syringes and needles or filter straws.
- Expulsion of air from drug-filled syringes.

Storage and Handling Practices: Employees must be trained to properly use the product. Ensure vials are properly labeled. Store only in approved containers. Keep away from sources of ignition and any incompatible materials or conditions (see Section 10).

Protective Practices During Maintenance of Contaminated Equipment: When cleaning non-disposable equipment, wear latex or nitrile gloves (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. All needles, syringes, vials and other disposable items contaminated with this product should be disposed of properly.

Section 8: Exposure Controls/Personal Protection

Ventilation and Engineering Controls: Use with adequate ventilation. Follow standard medical product handling procedures.
Respiratory Protection: Not normally required for routine, medical administration of this product. A NIOSH certified air-purifying respirator with a type 95 filter may be used under conditions where airborne concentrations are expected to be excessive. Protection provided by air purifying respirators is limited (see manufacturer's respirator selection guide). Use a positive pressure air supplied respirator if there is potential for uncontrolled release, exposure levels are not known, or any other circumstances where air-purifying respirators may not provide adequate protection. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions warrant a respirator's use.
Eye Protection: Approved eye protection to safeguard against potential eye contact, irritation or injury is recommended. Depending on conditions of use, a face shield may be necessary.
Hand Protection: Use latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before and after using gloves.
Body Protection: o special body protection required for routine, medical administration of this product. Wear lab coat, gown, or smock, as appropriate for procedure.

Product Preparation Instructions for Medical Personnel: Follow standard procedure for handling pharmaceutical materials and recommendations presented on the Package Insert.

Section 9: Physical and Chemical Properties

Appearance & Physical Form Aqueous solution.

pH of Aqueous Solutions 3.3 to 4.0 pH

Section 10: Stability and Reactivity

Stability: Stable under normal conditions of storage and handling.

Materials With Which Substance is Incompatible: This product is generally compatible with other common materials in a medical facility.

Hazardous Polymerization: Will not occur.

Hazardous Combustion Products: Oxides of carbon.

Section 11: Toxicological Information

Toxicity Data: The following information is for Ondansetron Hydrochloride, the active ingredient
Oral LD50(rat) = 95 mg/kg Oral LD50(dog) > 45 mg/kg IV LD50(rat) = 20201 ug/kg
IV LD50(dog) > 15 mg/kg
Chronic Toxicity: No studies identified for Ondansetron Hydrochloride.
Carcinogenicity: Negative for carcinogenicity in rats and mice administered oral doses of up to 10 and 30

mg/kg/day, respectively. It is not listed as carcinogenic by NTP, IARC or OSHA.
Irritancy of Product: This product is not expected to be irritating to contaminated skin, eyes and other tissues.
Sensitization to the Product: A non-sensitizer to the skin.
Reproductive Toxicity Information: Listed below is information concerning the effects of Ondansetron Hydrochloride on human and animal reproductive systems. This material is classified as a Pregnancy Category B:

- Mutagenicity: Negative in a battery of short-term screening tests for mutagenicity.
- Embryotoxicity/Teratogenicity: No evidence of teratogenic effects in pregnant rats and rabbits given intravenous doses up to 4 mg/kg/day.
- Reproductive Toxicity: Negative for fertility impairment in rats administered doses up to 15 and 30 mg/kg/day, respectively.

ACGIH Biological Exposure Indices: Currently there are no Biological Exposure Indices (BEIs) associated with the components of this product.

Section 12: Ecological Information* (non-mandatory)

All work practices must be aimed at eliminating environmental contamination

Environmental Stability: This product will be relatively stable under ambient environmental conditions
Effect of Materials on Plants or Animals: No specific information is available on the effect of Ondansetron Hydrochloride on plants or animals in the environment. Due to the small product size and dilute concentration of the components, this product is not anticipated to cause adverse effects.

Effect of Chemicals on Aquatic Life: No specific information is available on the effect of Ondansetron Hydrochloride on plants or animals in the aquatic environment. Due to the small product size and dilute concentration of the components, this product is not anticipated to cause adverse effects.

Section 13: Disposal Considerations* (non-mandatory)

Preparing Wastes for Disposal: This material, if discarded as produced, is not a RCRA "listed" or "characteristic" hazardous waste. Use resulting in chemical or physical change or contamination may subject it to regulation as a hazardous waste. Along with properly characterizing all waste materials consult state and local regulations regarding the proper disposal of this material.

Section 14: Transport Information* (non-mandatory)

This Materials is not Hazardous as Defined by 49 CFR 172.101 by the U. S. Department of Transportation
Proper Shipping Name: Not applicable
Hazard Class Number and Description: Not applicable
UN Identification Number: Not applicable
Packing Group: Not applicable
DOT Label(s) Required: Not applicable
North American Emergency Response Guidebook Number (1996): Not applicable.
MARINE POLLUTANT: No component of this product is listed as a Marine Pollutant (49 CFR 172.101, Appendix B)
Transport Canada Transportation of Dangerous Goods Regulations: Not applicable

Section 15: Regulatory Information* (non-mandatory)

Not Available

Section 16: Other Information

Date of Preparation: 27th July, 2015

*Note: Since other Agencies regulate this information, OSHA will not be enforcing Sections 12 through 15(29 CFR 1910.1200(g)(2)).