SAFETY DATA SHEETS

This SDS packet was issued with item:

078934462

N/A

SAFETY DATA SHEET

1. Identification

Product identifier **Ondansetron Injection, USP - Multi Dose**

Other means of identification

Synonyms Ondansetron Hydrochloride Injection, Solution * Ondansetron Hydrochloride Dihydrate * (±) 1, 2, 3, 9-tetrahydro-9-methyl-3-[(2-methyl-1H-imidazol-1-yl)m
ethyl]-4H-carbazol-4-one, monohydrochloride, dihydrate

Recommended use Pharmaceutical product for the treatment of nausea and vomiting (antiemetic).

ONDANSETRON – ondansetron hydrochloride injection, is a solution containing ondansetron hydrochloride, a serotonin-blocking drug used intravenously 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.

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Distributor

Company name Accord Healthcare, Inc.

Address 1009 Slater Road Suite
210-B Durham, NC 27703, USA.

Telephone number 1-919-941-7880

Fax 1-919-941-7881

Contact Name Technical Representative

Website www.accord-healthcare.com

Emergency telephone number 1-800-424-9300 Call CHEMTREC Day or Nigh

Manufacturer

Company name Intas Pharmaceuticals Limited,

Address Plot No.: 457 – 458,
Village: Matoda, Taluka: Sanand,
Sarkhej - Bavla Highway,
District: Ahmedabad
Gujarat, India. 382 210

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Hazard symbol None.

Signal word None.

Hazard statement The mixture does not meet the criteria for classification.

Precautionary statement

Prevention Observe good industrial hygiene practices.

Response Wash hands after handling.

Storage Store away from incompatible materials.

Disposal Dispose of waste and residues in accordance with local authority requirements.

Hazard(s) not otherwise classified (HNOC) None known.

Supplemental information Finished Pharmaceutical products in their final packages are not subject to OSHA labeling requirements. Handling pharmaceutical products in workplace is subject to OSHA requirements for labeling.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
Citric acid monohydrate	5949-29-1	Proprietary
Methyl 4-hydroxybenzoate	99-76-3	Proprietary
Ondansetron hydrochloride dihydrate	103639-04-9	Proprietary
Propylparaben	94-13-3	Proprietary
Sodium chloride	7647-14-5	Proprietary
Sodium citrate	6132-04-3	Proprietary

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume. Active: Each vial contains 2 mg/ml, 20 ml Ondansetron hydrochloride dihydrate. Inactive: Each Ondansetron for Injection multiple dose contains as well Sodium Chloride, Sodium citrate, Citric Acid Monohydrate, Methyl Paraben, Propyl Paraben and water for injection.

4. First-aid measures

Inhalation Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

Skin contact Remove contaminated clothing. Wash off with soap and water. Get medical attention if irritation develops and persists.

Eye contact Hold eyelids apart and flush eyes with plenty of water for 15 minutes. Get medical attention if irritation develops and persists.

Ingestion Rinse mouth. Never give anything by mouth to a victim who is unconscious or is having convulsions. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Get medical advice/attention if you feel unwell.

Most important symptoms/effects, acute and delayed Direct contact with eyes may cause temporary irritation. May cause slight respiratory tract irritation. May cause skin irritation. 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.

Indication of immediate medical attention and special treatment needed Treat symptomatically.

General information Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media Water. Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical During fire, hazardous combustion products are released that may include: Carbon oxides (COx). Nitrogen Oxides (NOx).

Special protective equipment and precautions for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions Move containers from fire area if you can do so without risk.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Stop the flow of material, if this is without risk. Absorb the liquid with suitable material and clean affected area with soap and water. Clean surface thoroughly to remove residual contamination. Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Provide adequate ventilation. Avoid breathing mist or vapor. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Wear appropriate personal protective equipment. Wash thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment

Eye/face protection	Wear safety glasses with side shields (or goggles).
Skin protection	
Hand protection	Nitrile. Latex gloves.
Other	Wear appropriate chemical resistant clothing. Use of an impervious apron is recommended.
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.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance	Clear liquid.
Physical state	Liquid.
Form	Liquid.
Color	Colorless.
Odor	Odorless.
Odor threshold	Not available.
pH	3 - 4
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.

Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation	May cause slight respiratory tract irritation.
Skin contact	May cause skin irritation.
Eye contact	Direct contact with eyes may cause temporary irritation. Ondansetron hydrochloride dihydrate (CAS 103639-04-9) Risk of serious damage to eyes.
Ingestion	May be harmful if swallowed.
Symptoms related to the physical, chemical and toxicological characteristics	Direct contact with eyes may cause temporary irritation. May cause slight respiratory tract irritation. May cause skin irritation. 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.

Information on toxicological effects

Acute toxicity May be harmful if swallowed.

Components	Species	Test Results
Ondansetron hydrochloride dihydrate (CAS 103639-04-9)		
Acute		
Oral		
LD50	Rat	94.9 - 150 mg/kg
Sodium chloride (CAS 7647-14-5)		
Acute		
Dermal		
LD50	Rabbit	> 10000 mg/kg

Components	Species	Test Results
Inhalation		
LC50	Rat	> 42 mg/l, 1 Hours
Oral		
LD50	Rat	3550 mg/kg

Skin corrosion/irritation May cause skin irritation.

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Eye Contact

Ondansetron hydrochloride dihydrate (CAS 103639-04-9) Risk of serious damage to eyes.

Respiratory or skin sensitization

Respiratory sensitization May cause inhalation hypersensitivity (occupational asthma) in sensitive individuals.

Skin sensitization May cause allergic skin disorders in sensitive individuals.

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. 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.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

NTP Report on Carcinogens

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects. 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.

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Not classified.

Aspiration hazard Not available.

Chronic effects Based on clinical use, possible target organs include the nervous system and liver.

Further information Adverse effects associated with therapeutic use include headache, flushing, and constipation.

12. Ecological information

Ecotoxicity This material has not been tested for environmental effects.

Components		Species	Test Results
Ondansetron hydrochloride dihydrate (CAS 103639-04-9)			
Aquatic			
Algae	IC50	Algae	0.87 mg/l, 72 h
Crustacea	EC50	Daphnia	28 mg/l, 48 h
Fish	LC50	Fish	6.5 mg/l, 96 h

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

Ondansetron hydrochloride dihydrate (CAS 103639-04-9)	0.8
Propylparaben (CAS 94-13-3)	3.04

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not established.

15. Regulatory information

US federal regulations	This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. This product is exempt from the TSCA Inventory. It is regulated by the FDA. This product is exempt from SARA 311/312 reporting requirements when used as a food, food additive, color additive, drug or cosmetic under 40CFR370.13(a)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - No Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical	No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)	Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

16. Other information, including date of preparation or last revision

Issue date	10-September-2015
Revision date	-
Version #	01
NFPA ratings	
Disclaimer	Accord Healthcare, Inc. cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.