MATERIAL SAFETY DATA SHEET

Version No: MSDS/Onda-AUS/DP-003 **Effective Date:** 03rd April 2020

ONDANSETRON INJECTION 4 MG/2 ML AND 8 MG/4 ML

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Name: Ondansetron Injection 4 mg/2 mL and 8 mg/4 mL

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against	
Intended Use:	Pharmaceutical product for the treatment of nausea and vomiting (antiemetic)
Details of the Supplier of the Safety Data Sheet	
Manufacturer: Intas Pharmaceuticals Ltd. Plot No. 457, 458 Village-Matoda, Bavla Road, Ta. Sanand, Dist. Ahmedabad-382 210, Gujarat, India	**Sponsor:** Accord Healthcare Pty Ltd Level 24, 570 Bourke Street, Melbourne, VIC, 3000, Australia

SECTION 2 – COMPOSITION, INFORMATION ON INGREDIENTS

Active Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Ondansetron Hydrochloride Dihydrate.	103639-04-9	Not Listed	Acute Tox. 3 (H301) Aquatic. Acute 1 (H400) Aquatic. Chronic 1 (H410)	0.2

Inactive Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
sodium citrate dihydrate	6132-04-3	Not Listed	Not Listed	*
citric acid monohydrate	5949-29-1	Not Listed	Not Listed	*
hydrochloric acid and	7647-01-0	231-595-7	Press. Gas Skin Corr.1A (H314) Acute Tox.3 (H331)	**
sodium hydroxide	1310-73-2	215-185-5		**
water for injection	7732-18-5	231-791-2	Not Listed	*

Additional Information: * Proprietary ** to adjust pH

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

SECTION 3 - HAZARDS IDENTIFICATION

Classification of the Substance or Mixture:

GHS – Classification: Not classified as hazardous

Label Elements:

Signal Word: Not Classified

Hazard Statements: Non-hazardous in accordance with international standards for workplace safety.

Other Hazards: An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

SECTION 4 - FIRST AID MEASURES

Description of First Aid Measures:

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed:

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 3 – Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed:

Notes to Physician: None

SECTION 5 - FIRE FIGHTING MEASURES

Extinguishing Media: Water, dry powder or foam extinguishers are recommended.

Special Hazards Arising from the Substance or Mixture:

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters: During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure

Environmental Precautions: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up:

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

SECTION 7 - HANDLING AND STORAGE

Precautions for Safe Handling: Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities:

Storage Conditions: Store as directed by product packaging

Specific end use(s): Pharmaceutical drug product

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters:

Ondansetron hydrochloride dehydrate:
Occupational Exposure Band (OEB): OEB 3 (control exposure to the range of 10µg/m^3 to < 100µg/m^3)

Refer to available public information for specific member state Occupational Exposure Limits.
The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Sodium chloride

Latvia OEL - TWA	:	5 mg/m^3
Lithuania OEL - TWA	:	5 mg/m^3

Hydrochloric Acid

ACGIH Ceiling Threshold Limit	:	2 ppm
Australia PEAK	:	5 ppm 7.5 mg/m^3
Austria OEL – MAKs	:	5 ppm 8 mg/m^3
Belgium OEL - TWA	:	5 ppm 8 mg/m^3
Bulgaria OEL - TWA	:	5 ppm 8.0 mg/m^3
Cyprus OEL - TWA	:	5 ppm 8 mg/m^3
Czech Republic OEL - TWA	:	8 mg/m^3
Estonia OEL - TWA	:	5 ppm 8 mg/m^3
Germany - TRGS 900 - TWAs	:	2 ppm 3 mg/m^3
Germany (DFG) - MAK	:	2 ppm 3.0 mg/m^3
Greece OEL - TWA	:	5 ppm

		7 mg/m^3
Hungary OEL - TWA	:	8 mg/m^3
Ireland OEL - TWAs	:	5 ppm 8 mg/m^3
Italy OEL - TWA	:	5 ppm 8 mg/m^3
Japan - OELs - Ceilings	:	2 ppm 3.0 mg/m^3
Latvia OEL – TWA	:	5 ppm 8 mg/m^3
Lithuania OEL - TWA	:	5 ppm 8 mg/m^3
Luxembourg OEL - TWA	:	5 ppm 8 mg/m^3
Malta OEL - TWA	:	5 ppm 8 mg/m^3
Netherlands OEL - TWA	:	8 mg/m^3
Poland OEL - TWA	:	5 mg/m^3
Portugal OEL - TWA	:	5 ppm 8 mg/m^3
Romania OEL - TWA	:	5 ppm 8 mg/m^3
Slovakia OEL - TWA	:	5 ppm 8.0 mg/m^3
Slovenia OEL - TWA	:	5 ppm 8 mg/m^3
Spain OEL – TWA	:	5 ppm 7.6 mg/m^3
Switzerland OEL –TWAs	:	2 ppm 3.0 mg/m^3
Vietnam OEL - TWAs	:	5 mg/m^3

Sodium hydroxide

ACGIH Ceiling Threshold Limit	:	2 mg/m^3
Australia PEAK	:	2 mg/m^3
Austria OEL – MAKs	:	2 mg/m^3
Bulgaria OEL – TWA	:	2.0 mg/m^3
Czech Republic OEL – TWA	:	1 mg/m^3
Estonia OEL – TWA	:	1 mg/m^3
France OEL – TWA	:	2 mg/m^3
Greece OEL – TWA	:	2 mg/m^3
Hungary OEL – TWA	:	2 mg/m^3
Japan - OELs – Ceilings	:	2 mg/m^3
Latvia OEL – TWA	:	0.5 mg/m^3
OSHA - Final PELS - TWAs	:	2 mg/m^3
Poland OEL – TWA	:	0.5 mg/m^3
Slovakia OEL – TWA	:	2 mg/m^3

Slovenia OEL – TWA : 2 mg/m^3
Sweden OEL - TWAs : 1 mg/m^3

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands: Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solution
Color:	Colorless
Odor:	No data available.
Odor Threshold:	No data available.
Molecular Formula:	Mixture
Molecular Weight:	Mixture
Solvent Solubility:	No data available
Water Solubility:	No data available
pH:	3.3 - 4.0
Melting/Freezing Point (°C):	No data available

Boiling Point (°C): No data available
Partition Coefficient: (Method, pH, Endpoint, Value)
Water for Injection: No data available
Citric acid monohydrate: No data available
Sodium citrate, dehydrate: No data available
Ondansetron hydrochloride dehydrate: No data available
Decomposition Temperature (°C): No data available
Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available
Flammablity:
Autoignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
Flash Point (Liquid) (°C): No data available
Upper Explosive Limits (Liquid) (% by Vol.): No data available
Lower Explosive Limits (Liquid) (% by Vol.): No data available

SECTION 10 - STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products: No data available

SECTION 11 - TOXICOLOGY INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients
Short Term: Active ingredient may be harmful if swallowed. May cause eye irritation (based on components)
Long Term: May cause effects on central nervous system through prolonged or repeated exposure
Known Clinical Effects: Adverse effects associated with therapeutic use include headache, flushing, and constipation.

May cause irregular heartbeat (cardiac arrhythmia), hypersensitivity reactions

Acute Toxicity:

Ondansetron hydrochloride dehydrate:

Species:	Route	End Point	Dose
Rat	Oral	LD50	95 mg/kg
Rat	Para-periosteal	LD50	20201µg/kg
Dog	Oral	LD50	> 45mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Sodium hydroxide:

Species	Route	End Point	Dose
Mouse	IP	LD50	40 mg/kg

Sodium chloride:

Species	Route	End Point	Dose
Rat	Oral	LD50	3000 mg/kg
Mouse	Oral	LD50	4000 mg/kg

Irritation / Sensitization:

Sodium hydroxide

Study Type	Species	Severity
Eye Irritation	Rabbit	Severe
Skin Irritation	Rabbit	Severe

Sodium chloride:

Study Type	Species	Severity
Eye Irritation	Rabbit	Moderate
Skin Irritation	Rabbit	Mild

Hydrochloric Acid:

Study Type	Species	Severity
Skin	Irritation	Severe
Eye	Irritation	Severe

Citric acid monohydrate:

Study Type	Species	Severity
Eye Irritation	Rabbit	Mild
Skin Irritation	Rabbit	Mild

Repeated Dose Toxicity:

Ondansetron hydrochloride dihydrate					
Duration	**Species**	**Route**	**Dose**	**End Point**	**Target Organ**
7 Week(s)	Rat	Oral	Maximally Tolerated Dose		
18 Week(s)	Rat	No route specified	1 mg/kg/day	NOAEL	Central Nervous System, Liver
12 Week(s)	Dog	No route specified	12 mg/kg/day	NOAEL	Central Nervous System, Liver

Reproduction & Development Toxicity:

Ondansetron hydrochloride dihydrate					
Duration	**Species**	**Route**	**Dose**	**End Point**	**Effect (s)**
Reproductive & Fertility	Rat	Oral	15 mg/kg/day	NOAEL	Negative
Fertility and Embryonic Development	Rat	Intravenous	4 mg/kg/day	NOAEL	No effects at maximum dose
Fertility and Embryonic Development	Rabbit	Intravenous	4 mg/kg/day	NOAEL	No effects at maximum dose

Genetic Toxicity:

Ondansetron hydrochloride dihydrate		
Study Type	**Cell Type/Organism**	**Severity**
Bacterial Mutagenicity (Ames)	*Salmonella* , *E. coli*	Negative
In Vitro Chromosome Aberration	Human Lymphocytes	Negative
In Vitro Chromosome Aberration	Mouse Bone Marrow	Negative

Carcinogenicity:

Ondansetron hydrochloride dehydrate:

Duration	**Species**	**Route**	**Dose**	**End Point**	**Effect (s)**
2 Year(s)	Rat	Oral	10 mg/kg/day	NOAEL	Not carcinogenic
2 Year(s)	Mouse	Oral	30 mg/kg/day	NOAEL	Not carcinogenic

Carcinogen Status:

Hydrochloric Acid
IARC: Group 3 (Not Classifiable)

SECTION 12 - ENVIRONMENTAL IMPACT INFORMATION

Environmental Overview: The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided. See aquatic toxicity data for individual components below:

Toxicity:
Aquatic Toxicity:

Ondansetron hydrochloride dihydrate				
Species	**Method**	**End Point**	**Duration**	**Result**
Selenastrum capricornutum	Green Alga	IC-50	72 Hours	0.87 mg/L
Daphnia magna	Water Flea	EC50	48 Hours	28 mg/L
Oncorhynchus mykiss	Rainbow Trout	EC50	96 Hours	6.5 mg/L
Activated sludge		IC-50	3 Hours	> 1000 mg/L
Ceriodaphnia dubia	Daphnids	NOEC	8 Days	0.32 mg/L

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

SECTION 13 - DISPOSAL INFORMATION

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

SECTION 14 - TRANSPORTATION INFORMATION

The following refers to all modes of transportation unless specified below:
Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations

SECTION 15 - REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Ondansetron hydrochloride dehydrate:

CERCLA/SARA 313 Emission reporting	**:**	Not Listed
California Proposition 65	**:**	Not Listed
EU EINECS/ELINCS List	**:**	Not Listed

Citric acid monohydrate:

CERCLA/SARA 313 Emission reporting	**:**	Not Listed
California Proposition 65	**:**	Not Listed
Australia (AICS)	**:**	Present
EU EINECS/ELINCS List	**:**	Not Listed

Sodium citrate, dihydrate:

CERCLA/SARA 313 Emission reporting	**:**	Not Listed
California Proposition 65	**:**	Not Listed
Australia (AICS)	**:**	Present
EU EINECS/ELINCS List	**:**	Not Listed

Water for Injection:

CERCLA/SARA 313 Emission reporting	**:**	Not Listed
California Proposition 65	**:**	Not Listed
Inventory - United States TSCA - Sect. 8(b)	**:**	Present
Australia (AICS)	**:**	Present
REACH - Annex IV - Exemptions from the obligations of Register	**:**	Present
EU EINECS/ELINCS List	**:**	231-791-2

Sodium chloride:

CERCLA/SARA 313 Emission reporting	**:**	Not Listed
California Proposition 65	**:**	Not Listed
Inventory - United States TSCA - Sect. 8(b)	**:**	Present
Australia (AICS):	**:**	Present
EU EINECS/ELINCS List	**:**	231-598-3

Hydrochloric Acid:

CERCLA/SARA 313 Emission reporting	**:**	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	**:**	5000 lb 2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	**:**	500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	**:**	5000 lb
California Proposition 65	**:**	Not Listed
Inventory - United States TSCA - Sect. 8(b)	**:**	Present

Australia (AICS):	**:**	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	**:**	Schedule 5 Schedule 6
EU EINECS/ELINCS List	**:**	231-595-7

Sodium hydroxide:

CERCLA/SARA Hazardous Substances and their Reportable Quantities	:	1000 lb 454 kg
Inventory - United States TSCA - Sect. 8(b)	:	Present
Australia (AICS)	:	Present
Standard for the Uniform Scheduling for Drugs and Poisons	:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	:	215-185-5

SECTION 16 - OTHER DATA

Text of CLP/GHS Classification abbreviations mentioned in Section 2

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life
Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

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