


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	ONDANSETRON HYDROCHLORIDE, USP (Dihydrate)
PRODUCT CODE	2415
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
RECOMMENDED USES	Pharmaceutical Manufacturing
RESTRICTIONS ON USE	Not applicable

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Acute Toxicity - Oral (Category 3) Eye Damage (Category 1) Sensitization - Respiratory (Category 1) Specific Target Organ Toxicity - Repeated Exposure (Category 1) - (cardiovascular system, liver, nervous system) Acute Aquatic Toxicity (Category 1)
PICTOGRAM	
SIGNAL WORD	Danger
HAZARD STATEMENT(S)	Toxic if swallowed. Causes serious eye damage. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Causes damage to organs through prolonged or repeated exposure (cardiovascular system, liver, nervous system). Very toxic to aquatic life.
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Not Applicable.

PRECAUTIONARY STATEMENT(S)
Prevention

Wash hands thoroughly after handling. Do not touch eyes.
Do not eat, drink or smoke when using this product.
Wear eye and face protection.
In case of inadequate ventilation wear respiratory protection.
Avoid breathing dust/fume/gas/mist/ vapors/spray.
Avoid release to the environment.

Response

IF SWALLOWED: Immediately call a poison center. Get emergency medical help immediately. Rinse mouth.
IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do.
Continue rinsing. Get medical help; Immediately call a poison center or medical professional.
IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms, get medical help immediately call a poison center or medical professional
Get medical help if you feel unwell.
IF EXPOSED OR CONCERNED: Get medical advice/attention.
COLLECT SPILLAGE

Storage

Store locked up.

Disposal

Dispose of contents and/or container in accordance with local regulations.

HMS CLASSIFICATION
Health Hazard

3

Flammability

0

Reactivity

0

Personal Protection

G

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS
CHEMICAL NAME

4H-Carbazol-4-one, 1,2,3,9-tetrahydro-9-methyl-3-(2-methyl-1H-imidazol-1-yl)methyl-, monohydrochloride, (±)-, dihydrate

BOTANICAL NAME

Not applicable

SYNONYM

Not applicable

CHEMICAL FORMULA

C₁₈H₁₉N₃O·HCl·2H₂O

CHEMICAL FAMILY

5-HT₃ antagonist

CAS NUMBER

103639-04-9

ALTERNATE CAS NUMBER

Not applicable

MOLECULAR WEIGHT

365.859

COMPOSITION

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
ONDANSETRON HYDROCHLORIDE (Dihydrate)	103639-04-9	600-465-5	100

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

NOTES

Ondansetron is a 5-HT₃ antagonist (5-HT₃-receptor antagonist) with antiemetic activity.

SECTION 4: FIRST-AID MEASURES
IN CASE OF EYE CONTACT

Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

IN CASE OF SKIN CONTACT	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
IF SWALLOWED	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
IF INHALED	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician
MEDICAL ATTENTION AND SPECIAL TREATMENT	Get emergency medical help.
SYMPTOMS CAUSED BY EXPOSURE	Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL	Not applicable
FLAMMABLE PROPERTIES	May be combustible at high temperature
HAZARDOUS COMBUSTION PRODUCTS	Under fire conditions, hazardous fumes will be present.
SUITABLE & UNSUITABLE EXTINGUISHING MEDIA	Small fire: dry chemical, CO ₂ or water spray. Large fire: dry chemical, CO ₂ , alcohol resistant foam or water spray. Do not get water inside containers.
PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS	Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.
METHODS & MATERIAL FOR CONTAINMENT	On land, sweep or shovel into suitable containers. Minimize generation of dust.
CLEANUP PROCEDURE	Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.
REFERENCE TO OTHER SECTIONS	See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING	Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.
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CONDITIONS FOR SAFE STORAGE

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture.

Store at 25°. Short term excursions, temperature excursions as experienced during shipping and warehousing, between 15° and 30°C are acceptable

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: ONDANSETRON HYDROCHLORIDE (Dihydrate) CAS #: 103639-04-9

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

NOTES

USP TWA: 30 micrograms/m³

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE

Solid

DESCRIPTION

White to off-white powder.

SOLUBILITY	Sparingly soluble in water and in alcohol; soluble in methanol; slightly soluble in isopropyl alcohol and in dichloromethane; very slightly soluble in acetone, in chloroform and in ethyl acetate.				
ODOR	Not available.				
FLAMMABILITY	May be combustibile at high temperature				
AUTO-IGNITION TEMPERATURE	Not available	BOILING POINT	Not available	DECOMPOSITION TEMPERATURE	Not available
EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available	FLASH POINT	Not available
log P (OCTANOL-WATER)	0.8 (20°C, pH 7)	LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available	MELTING/FREEZING POINT	(217 - 218)°C, (422.6-424.4)°F
PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	pH	4.6 - 4.7 (10% suspension)
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	Not available	UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available
VAPOR DENSITY (AIR = 1)	Not available	VAPOR PRESSURE	Not available	VISCOSITY	Not available

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established
CHEMICAL STABILITY	Stable under recommended storage conditions
INCOMPATIBLE MATERIALS	Strong oxidants
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur
HAZARDOUS POLYMERIZATION	Will not occur
POSSIBILITY OF HAZARDOUS REACTION	Not established
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): 95 Dermal: Rabbit: LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available
SKIN CORROSION/IRRITATION	Due to lack of data the classification is not possible.

**SERIOUS EYE DAMAGE/EYE
IRRITATION**

Causes serious eye damage.
Irritancy test (species not specified): Eye: Irritant: Severe.
Corrosive. Causes burns. Burning sensation. Pain.

RESPIRATORY SENSITIZATION

Anaphylactoid reactions have been reported in patients given ondansetron injections. The FDA stated in October 1993 that it had received 24 reports of such reactions, mostly occurring after the first ondansetron dose of the second or third chemotherapy cycle, and characterised by urticaria, angioedema, hypotension, bronchospasm, and dyspnoea. Similar effects have been reported in a patient with no prior exposure to ondansetron.

Cross sensitivity: Persons sensitive to granisetron or dolasetron may be sensitive to this material also. It was recommended that another 5-HT₃ antagonist should not be given as a replacement to patients who developed a hypersensitivity reaction to a drug of this class.

SKIN SENSITIZATION

Due to lack of data, the classification is not possible.

GERM CELL MUTAGENICITY

Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.

Mutagenicity:

Bacteria fluctuation test: Negative.

In vitro Ames bacteria test: Negative (with or without activation).

In vivo mouse micronucleus test: Negative.

Modified in vitro Ames bacteria test: Negative (with or without activation)

Yeast gene conversion assay: Negative.

Suspected mutagen: KNN Mutagenicity model in VEGA (Q)SAR platform predicts that the chemical is Mutagen (moderate reliability); SARPY Mutagenicity model in VEGA (Q)SAR platform predicts that the chemical is Mutagen (moderate reliability)

CARCINOGENICITY

OSHA ONDANSETRON HYDROCHLORIDE (Dihydrate) is not listed.

NTP ONDANSETRON HYDROCHLORIDE (Dihydrate) is not listed.

IARC ONDANSETRON HYDROCHLORIDE (Dihydrate) is not evaluated.

California Proposition This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

**ADDITIONAL CARCINOGENICITY
INFORMATION**

Carcinogenicity study (oral): Rat: 10 mg/kg/day: 2 years: Not carcinogenic.

Carcinogenicity study (oral): Mouse: 30 mg/kg/day: 2 years: Not carcinogenic.

REPRODUCTIVE TOXICITY

Based on available data, the classification criteria are not met.

Reproductivity study: Rat: 15 mg/kg/day: No harm to fetus.

Reproductivity study: Rabbit: 30 mg/kg/day: No harm to fetus.

**SPECIFIC TARGET ORGAN
TOXICITY - SINGLE EXPOSURE**

Due to lack of data the classification is not possible.

**SPECIFIC TARGET ORGAN
TOXICITY - REPEATED
EXPOSURE**

Causes damage to organs through prolonged or repeated exposure (cardiovascular system, liver, nervous system).

ASPIRATION HAZARDS

Due to lack of data the classification is not possible.

SIGNS AND SYMPTOMS OF EXPOSURE
ROUTES OF EXPOSURE:

Oral, Dermal, Inhalation, Eye contact

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

Not available

DELAYED HEALTH EFFECT FROM EXPOSURE:

Hypotension

Symptoms related to the physical, chemical, and toxicological characteristics:

Headache. Dizziness. Restlessness. Fatigue. Flushing. Fever. Vision loss. Diarrhea. Constipation.

Cross sensitivity: Persons sensitive to granisetron or dolasetron may be sensitive to this material also.

Medical conditions aggravated by exposure: Impaired liver function

POTENTIAL HEALTH EFFECTS
Inhalation

May be harmful if inhaled. May cause respiratory tract irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Ingestion

Toxic if swallowed.

Skin

May be harmful if absorbed through skin. May cause skin irritation.

Eyes

Causes serious eye damage.

SECTION 12: ECOLOGICAL INFORMATION
ECOTOXICITY

EC50: 48 Hr: Daphnia Pulex: (mg/L): 28

LC50: 96 Hr: Fish: (mg/L): 6.5

EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): 0.87

PERSISTENCE AND DEGRADABILITY

Biodegradation: Minimally biodegradable.

Suspected persistent in the environment: The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable

BIOACCUMULATIVE POTENTIAL

Log Pow: 0.8 (20°C, pH 7)

MOBILITY IN SOIL

Not available

OTHER ADVERSE EFFECTS

Not available

This product is not intended to be released into the environment

SECTION 13: DISPOSAL CONSIDERATIONS
DISPOSAL METHODS

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION
UN PROPER SHIPPING NAME

TOXIC SOLID, ORGANIC, N.O.S.

UN NUMBER

2811

CLASS

6.1

PACKING GROUP

III

AUSTRALIA
HAZCHEM

2X

EU
**TRANSPORT IN BULK ACCORDING
TO ANNEX II OF MARPOL 73/78
AND THE IBC CODE**

Not listed

ENVIRONMENTAL HAZARDS

Not available

**SPECIAL SHIPPING
INFORMATION**

Not applicable

SECTION 15: REGULATORY INFORMATION
UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR	EPA 40 CFR Part 355		Pennsylvania	Right-to-know		California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts	
ONDANSETRON HYDROCHLORIDE (Dihydrate) 103639-04-9	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
ONDANSETRON HYDROCHLORIDE (Dihydrate) 103639-04-9	N/L	Listed as Schedule 4*	N/L	Listed*	N/L	N/L

N/L = Not Listed

EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
ONDANSETRON HYDROCHLORIDE (Dihydrate) 103639-04-9	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

**SUBJECT TO INTERNATIONAL
AGREEMENT**

Not applicable

NOTES

*Listed as the base

SECTION 16: OTHER INFORMATION
REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

LAST REVISION

07/2023

SUPERSEDES

09/2020

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.