

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME
ONDANSETRON HYDROCHLORIDE, USP (Dihydrate)
PRODUCT CODE
2415
SUPPLIER
MEDISCA Inc.

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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

USES

Antiemetic

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.

AUSTRALIA-ONLY HAZARDS

Not Applicable.

PRECAUTIONARY STATEMENT(S)
Prevention

Wash thoroughly after handling.

Do not eat, drink or smoke when using this product.

Wear eye and face protection protection.

In case of inadequate ventilation wear respiratory protection.

Do not breathe dust/fume/gas/mist/ vapors/spray.

Avoid release to the environment.

Response

IF SWALLOWED: Immediately call a poison center or medical professional; Rinse mouth.
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. 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 call a poison center or medical professional.
 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.

HMIS 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	C ₁₈ H ₁₉ N ₃ O·HCl·2H ₂ O		
CAS NUMBER	103639-04-9		
ALTERNATE CAS NUMBER	Not applicable		
MOLECULAR WEIGHT	365.859		
COMPOSITION	CHEMICAL NAME	CAS NUMBER	% BY WEIGHT

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

Chemical family: 5-HT₃ antagonist.
 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
SYMPTOMS AND EFFECTS	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.

EXTINGUISHING MEDIA
Small fire: dry chemical, CO₂ or water spray. **Large fire:** dry chemical, CO₂, 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.

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.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight, in a dry and well-ventilated area, away from incompatible materials. Store in accordance with local regulations. Eliminate all ignition sources. Separate from oxidizing materials. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination.

Preserve in tight, light-resistant containers. Store at 25°, excursions permitted between 15° and 30°C.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

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

	TWA	Ceiling	STEL	REL	IDLH	Remarks
OSHA PEL	N/L	N/L	-	-	-	-
ACGIH TLV	N/L	N/L	N/L	-	-	-
NIOSH	N/L	N/L	N/L	N/L	N/L	-
AIHA WEEL	N/L	N/L	N/L	-	-	-
Safe Work Australia HSIS	N/L	N/L	N/L	-	-	-
HSE	N/L	N/L	N/L	-	-	-

N/L = Not Listed

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.

SPECIFIC ENGINEERING CONTROLS

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

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 combustible at high temperature				
ODOR THRESHOLD	Not available	pH	4.6 - 4.7 (10% suspension)	MELTING POINT	(217 - 218)°C, (422.6-424.4)°F
BOILING POINT	Not available	FREEZING POINT	(217 - 218)°C, (422.6-424.4)°F	FLASH POINT	Not available
SPECIFIC GRAVITY	Not available	EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available
UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available	LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available	VAPOR PRESSURE	Not available
VAPOR DENSITY (AIR = 1)	Not available	RELATIVE DENSITY (WATER = 1)	Not available	log P (OCTANOL-WATER)	0.8 (20°C, pH 7)
AUTO-IGNITION TEMPERATURE	Not available	DECOMPOSITION TEMPERATURE	Not available	VISCOSITY	Not available

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established
STABILITY	Stable under recommended storage conditions
MATERIALS TO AVOID	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: LD50: (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 OR SKIN 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.

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.

CARCINOGENICITY

OSHA ONDANSETRON HYDROCHLORIDE (Dihydrate) is not listed.

NTP ONDANSETRON HYDROCHLORIDE (Dihydrate) is not listed.

IARC ONDANSETRON HYDROCHLORIDE (Dihydrate) is not evaluated.

California Proposition 65 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

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

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

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

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

Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms related to the physical, chemical, and toxicological characteristics: Headache. Dizziness.

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

Delayed and immediate effects of exposure: Hypotension.

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

TOXICITY	EC50: 48 Hr: Daphnia magna: (mg/L): 28 LC50: 96 Hr: Fish: (mg/L): 6.5 IC50: 72 Hr: Algae: (mg/L): 0.87
PERSISTENCE AND DEGRADABILITY	Biodegradation: Minimally 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

WASTE DISPOSAL	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.
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SECTION 14: TRANSPORT INFORMATION

UNITED STATES & CANADA

UN PROPER SHIPPING NAME	TOXIC SOLID, ORGANIC, N.O.S.
UN NUMBER	2811
CLASS	6.1
PACKING GROUP	III

AUSTRALIA

UN PROPER SHIPPING NAME	TOXIC SOLID, ORGANIC, N.O.S.
UN NUMBER	2811
CLASS	6.1
PACKING GROUP	III
HAZCHEM	2X

ENVIRONMENTAL HAZARDS	Not available
SPECIAL SHIPPING INFORMATION	Not applicable

SECTION 15: REGULATORY INFORMATION

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355 Appendix A	EPA 40 CFR Part 355 Appendix B	Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
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 Regulation	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors
ONDANSETRON HYDROCHLORIDE (Dihydrate) 103639-04-9	Not Listed	Listed as Schedule 4	Not Listed

SECTION 16: OTHER INFORMATION**REFERENCES**

Available upon request

ABBREVIATIONS AND ACRONYMS

CAS – Chemical Abstract Service; **GHS** – Global Harmonized System; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **TWA** – Time Weighted Average; **HSIS** – Hazardous Substances Information System; **STEL** – Short Term Exposure Limit; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **LD50** – Lethal Dose, 50%; **IARC** – International Agency for Research on Cancer; **NTP** – National Toxicology Program; **WHMIS** – Workplace Hazardous Materials Information System; **SARA** – Superfund Amendments and Reauthorization Act; **EPA** – Environmental Protection Agency; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **HMIS** – Hazardous Materials Information System; **NIOSH** – National Institute for Occupational Safety and Health; **MSHA** – Mine Safety and Health Administration; **ACGIH** – American Conference of Governmental Industrial Hygienists; **IDHL** – Immediately Dangerous to Health or Life; **TLV** – Threshold Limit Value; **HSE** – Health and Safety Executive; **REL** – Recommended Exposure Limit

LAST REVISION

02/2016

SUPERSEDES

09/2013

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.