



Safety Data Sheet

Claris Lifesciences Inc.

SDS No. CLI/SDS/OND/01/00

ONDANSETRON INJECTION, USP

1. PRODUCT IDENTIFICATION

Common/Trade Name:	Ondansetron Injection, USP
How Supplied	Glass Vial
Strength	2 mg/mL
Chemical Class	Indoles
Chemical Name	(+) 1,2,3,9-tetrahydro-9-methyl-3- [(2-methyl-1H-imidazol-1- yl) methyl]-4H-carbazol-4-one, monohydrochloride, dihydrate
Formula	C ₁₈ H ₁₉ N ₃ O * HCl * 2H ₂ O
Product Type	Prescription Drug
Product Use	Pharmaceutical, Injectable
Distributor Name	CLARIS LIFESCIENCES INC.
Distributor Address	1445 US HIGHWAY 130, North Brunswick, NJ 08902
Manufacturer's Name	CLARIS INJECTABLES LIMITED
Address	CHACHARWADI-VASANA, AHMEDABAD - 382 213, INDIA.
Telephone Number For Information/ Medical Emergency	1-877-7CLARIS (1-877-725-2747)
Date Prepared	28 th , April 2016

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2. HAZARDOUS IDENTIFICATION

Emergency Overview

ONDANSETRON - ondansetron hydrochloride injection, is a solution containing ondansetron hydrochloride, a serotonin-blocking drug used intravenously or orally 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. In the workplace, ondansetron hydrochloride should be considered a potent drug, possibly irritating to skin, and possibly severely irritating to the eyes and respiratory tract. Possible target organs include the central nervous system and liver.

Occupational Exposure Potential

Information on the absorption of this compound via ingestion, inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact with solution.

Signs and Symptoms

In the workplace, this material should be considered potentially irritating to the skin, and possibly severely irritating to the eyes and respiratory tract. 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.

Medical Conditions Aggravated by Exposure

Pre-existing hypersensitivity to ondansetron hydrochloride or other components in this product.
Pre-existing central nervous system or liver ailments.

3. COMPOSITION INFORMATION

Component	Content mg/ml (Multi Dose)	Content mg/ml (Single Dose)	CAS
Ondansetron Hydrochloride Dihydrate Equivalent to Ondansetron	2.0	2.0	[103639-04-9]
Citric Acid Monohydrate	0.50	0.50	[5949-29-1]
Sodium Citrate Dihydrate	0.25	0.25	[6132-04-3]
Sodium Chloride	8.30	9.00	[7647-14-5]
Methyl Paraben	1.20	--	[99-76-3]
Propyl Paraben	0.15	--	[94-13-3]
Water for Injection	q.s.to 1.0 mL	q.s.to 1.0 mL	[7732-18-5]

q.s.: Quantity Sufficient



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4. FIRST-AID MEASURES

Eye contact

Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin contact

Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation

Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion

Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE-FIGHTING MEASURES:

Flammability

None anticipated for this aqueous product.

Fire & Explosion Hazard

None anticipated for this aqueous product.

Extinguishing media

As with any fire, use extinguishing media appropriate for primary cause of fire.

Special Fire Fighting Procedures

No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal

Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.



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7. HANDLING AND STORAGE

Handling

No special handling required for hazard control under conditions of normal product use.

Storage

No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions

No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION INFORMATION

Component	Exposure Limits				
	Type	mg/m ³	ppm	µg/m ³	Note
Ondansetron Hydrochloride Dihydrate	Not Applicable	N/A	N/A	N/A	None Established

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.

Skin protection

If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

Eye protection

Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls

Engineering controls are normally not needed during the normal use of this product.



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9.0 PHYSICAL AND CHEMICAL DATA

Appearance/Physical State	: Liquid
Color	: Clear and colorless
Odor	: NA
Odor Threshold	: NA
pH	: 3.3-4.0
Melting point/Freezing point	: NA
Initial Boiling Point/Boiling Point Range	: NA
Evaporation Rate	: NA
Flammability (solid, gas)	: NA
Upper/Lower Flammability or Explosive Limits	: NA
Vapor Pressure	: NA
Vapor Density	: NA
Specific Gravity	: NA
Solubility	: Soluble in water
Partition coefficient: n-octanol/water	: NA
Auto-ignition temperature	: NA
Decomposition temperature	: NA

10.0 STABILITY AND REACTIVITY

Reactivity	: Not determined.
Chemical Stability	: Stable under standard use and storage conditions.
Hazardous Reactions	: Not determined.
Conditions to avoid	: Not determined.
Incompatibilities	: Not determined.
Hazardous decomposition products	: Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and sulfur oxides (SOx).
Hazardous Polymerization	: Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Not determined for the product formulation. Information for the ingredients is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Ondansetron Hydrochloride Dihydrate	100	LD50	Oral	95 >45	mg/kg mg/kg	Rat Dog
Ondansetron Hydrochloride Dihydrate	100	LD50	Intravenous	20.1 >15	mg/kg mg/kg	Rat Dog



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Aspiration Hazard

None anticipated from normal handling of this product.

Dermal Irritation/Corrosion

None anticipated from normal handling of this product. Aqueous solutions of the active ingredient, ondansetron hydrochloride, are reported to be severely irritating/corrosive to the skin. Inadvertent contact of this product with skin may produce mild irritation.

Ocular Irritation/Corrosion

None anticipated from normal handling of this product. Aqueous solutions of the active ingredient, ondansetron hydrochloride, are reported to be a severely irritating to the eyes. Inadvertent contact of this product with eyes or mucus membranes may produce irritation.

Dermal or Respiratory Sensitization

None anticipated from normal handling of this product. The active ingredient, ondansetron hydrochloride, was negative in a sensitization study in guinea pigs. However, in the workplace, possible effects of overexposure may include: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing).

Reproductive 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.

Mutagenicity:

Ondansetron was not mutagenic in a standard battery of tests for mutagenicity.

Carcinogenicity:

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.

Target Organ Effects:

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

12. ECOLOGICAL INFORMATION

Aquatic Toxicity

Not determined for product. Information of ondansetron hydrochloride is provided below.

Activated Sludge Respiration - This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms.
IC50: > 1000 mg/l, 3 hours, activated sludge



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Algal - This material contains an active pharmaceutical ingredient that is very toxic to algae.
IC50: 0.87 mg/l, 72 Hours, Selenastrum capricornutum (green algae);
measured
NOEL: 0.31 mg/l, 72 Hours, Static test

Daphnia - This material contains an active pharmaceutical ingredient that is harmful to daphnia.
EC50: 28 mg/l, 48 Hours, Daphnia pulex, Static test
NOEL: 16 mg/l, 48 Hours, Daphnia pulex, Static test

Fish – This material contains an active pharmaceutical ingredient that is toxic to fish. Adult
Oncorhynchus mykiss, rainbow trout
EC50: 6.5 mg/l, 96 Hours, Static test
NOEL: 2.6 mg/l, 96 Hours, Measured

Persistence/Biodegradability

Not determined for product. Information of ondansetron hydrochloride is provided below.

Hydrolysis: Ondansetron has been shown to be chemically stable in water with a half-life (neutral pH) of > 1 year. Hydrolysis is unlikely to be a significant depletion mechanism.

Photolysis: Ondansetron is likely to undergo photodegradation,

Biodegradation - Ondansetron is not readily biodegradable (as defined by 1993 OECD Testing Guidelines). Aerobic - Inherent Percent Degradation: 18.9 %, 28 days, Semi-continuous activated sludge (SCAS), activated sludge. Aerobic - Soil Percent Degradation: 20.3 to 99.9 %, 64 days.

Bioaccumulation

Not determined for product

Mobility in Soil

Not determined for product. Information of ondansetron hydrochloride is provided below. This material contains an active pharmaceutical ingredient that is likely to adsorb to sludge and/or other biomass.

13. DISPOSAL CONSIDERATIONS

Waste Disposal

All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal

Dispose of container and unused contents in accordance with federal, state and local regulations.



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14. TRANSPORT INFORMATION

ADR/ADG/ DOT STATUS : Not regulated
IMDG STATUS : Not regulated
ICAO/IATA STATUS : Not regulated
Transport Comments : None

15. REGULATORY INFORMATION

USA Regulations

RCRA Status	Not Listed
U.S. OSHA Classification	Target Organ Toxin Possible Reproductive Toxin Possible Irritant
GHS Classification	*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:
Hazard Class	Not Applicable
Hazard Category	Not Applicable
Signal Word	Not Applicable
Symbol	Not Applicable
Prevention	P260 - Do not breathe dust/fume/gas/mist/vapors/spray.
Hazard Statement	Not Applicable
Response:	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling. Get medical attention if you feel unwell.

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Ondansetron Hydrochloride Dihydrate

Classification(s):	Not Applicable
Symbol:	Not Applicable
Indication of Danger:	Not Applicable
Risk Phrases:	Not Applicable
Safety Phrases:	S23 - Do not breathe vapor. S24 - Avoid contact with skin. S25 - Avoid contact with eyes. S37/39 - Wear suitable gloves and eye/face protection.



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16. OTHER INFORMATION

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD50	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

The above information is believed to be correct based on our present knowledge but does not purport to be complete. The product is for research use only and for trained personnel. The burden of safe use of this material rests entirely with the user.

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