



Material Safety Data Sheet

MSDS Number: 1156476
Revision date: 05/21/2009
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1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

MSDS Number: 1156476
Product name: Ondansetron Injection, USP
Product Codes: NDC 10019-905-01, NDC 10019-906-03, NDC 10019-905-03, NDC 10019-906-04
Synonyms: None
Chemical Family: Antiemetic.
Product Type: Regulated Prescription Drug
Container Information: 2 or 20 ml vials
Product Use: Pharmaceutical.

Supplier:
BAXTER HEALTHCARE CORPORATION
DEERFIELD, ILLINOIS 60015
(800) 422-9837 or (847) 948-4770

Emergency telephone number: PROSAR: USA (888) 990-0996 OUTSIDE USA (615)917-6114
CHEMTREC: USA (800) 424-9300 OUTSIDE USA (743)741-6089

2. COMPOSITION/INFORMATION ON INGREDIENTS

Component	Weight %	UN Number:	Classification:
Ondansetron Hydrochloride 99614-01-4	0.2	None	None
Sodium Chloride 7647-14-5	<1	None	None
Citric Acid Monohydrate 5949-29-1	<0.1	None	None
Sodium Citrate, dihydrate 6132-04-3	<0.1	None	None
Propyl Paraben 94-13-3	0 - 0.05	None	None
Methyl Paraben 99-76-3	0 - 0.05	None	None
Water 7732-18-5	>98	None	None

3. HAZARDS IDENTIFICATION

Emergency overview: Avoid skin contact. Avoid eye contact. Irritation potential to skin, eyes, and mucous membranes. May cause allergic reaction.

Principle routes of exposure: Absorbed through skin. Ingestion. Eye contact.

Inhalation: Inhalation not likely under normal use conditions.

3. HAZARDS IDENTIFICATION

Ingestion:	Gastrointestinal effects (may include nausea/vomiting, abdominal pain, diarrhea, dry mouth, colic). Nervous system effects (headache, dizziness, light headedness). Cardiovascular effects (may include fluctuations in heart rate, changes in blood pressure, chest pain). Liver function effects (may include increased levels of SGOT, SGPT, serum LDH, jaundice). May cause allergic reaction.
Skin contact:	Avoid contact with skin. May cause irritation and/or allergic reactions.
Eye contact:	Irritating to eyes.

4. FIRST AID MEASURES

Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms appear.
Skin contact:	Wash contaminated skin with soap and water. Get medical attention if irritation develops.
Ingestion:	Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Seek medical attention.
Eye contact:	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention
Notes to physician:	See patient package insert in shipping carton for complete information.

5. FIRE FIGHTING MEASURES

Suitable extinguishing media:	Use foam or all purpose dry chemicals to extinguish.
Special protective equipment for firefighters:	Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.
Specific methods:	No information available
Flash point:	Not determined
Autoignition temperature:	Not available
Flammable limits in air-lower (%):	Not available
Flammable limits in air-upper (%):	Not available

6. ACCIDENTAL RELEASE MEASURES

Personal precautions:	Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).
Environmental precautions:	No information available.
Methods for cleaning up:	If emergency personnel are unavailable, contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.

7. HANDLING AND STORAGE

Handling:

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Technical measures/precautions: Avoid skin contact. Avoid eye contact. Wash thoroughly after handling.

Storage:

Technical measures/Storage conditions: Keep containers tightly closed in a cool, well-ventilated place. Store at room temperature between 20°C and 25°C (68°F and 77°F). Protect from light.

Incompatible products: No special restrictions on storage with other products.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

Component	OSHA- Time Weighted Average:	OSHA- Short Term Exposure Limit:	OSHA- Ceiling Limits	ACGIH- Time Weighted Average:	ACGIH- Short Term Exposure Limit:	ACGIH- Ceiling Limit Value:
Ondansetron Hydrochloride 99614-01-4	None	None	None	None	None	None
Sodium Chloride 7647-14-5	None	None	None	None	None	None
Citric Acid Monohydrate 5949-29-1	None	None	None	None	None	None
Sodium Citrate, dihydrate 6132-04-3	None	None	None	None	None	None
Propyl Paraben 94-13-3	None	None	None	None	None	None
Methyl Paraben 99-76-3	None	None	None	None	None	None
Water 7732-18-5	None	None	None	None	None	None

Engineering measures: No special containment is required. Good general ventilation should be sufficient to control airborne levels.

Personal protective equipment:

Respiratory protection: No personal respiratory protective equipment normally required.

Hand protection: Use chemical resistant, impervious gloves.

Skin and body protection: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.

Eye protection: Eye protection not required for normal final product use. Safety glasses with side-shields are recommended for laboratory and manufacturing use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid
Appearance: Aqueous solution
Color: Colorless
Odor: Not available.
pH: 3.3 - 4.0

9. PHYSICAL AND CHEMICAL PROPERTIES

Molecular weight:	Not applicable
Boiling point/range:	Not available.
Melting point/range:	Not available.
Density:	Not available.
Vapor pressure:	Not available.
Evaporation rate:	Not available.
Solubility:	Soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Viscosity:	Not available.
% Volatile by Volume:	Not available.

10. STABILITY AND REACTIVITY

Stability:	Stable under recommended storage conditions.
Polymerization:	Not applicable
Hazardous decomposition products:	Not available.
Materials to avoid:	Acids. Bases. Oxidizing agents.

11. TOXICOLOGICAL INFORMATION

Component	LD50s and LC50s
Ondansetron Hydrochloride 99614-01-4	None
Sodium Chloride 7647-14-5	Inhalation LC50 Rat >42 gm/m ³ /1H Oral LD50 Rat = 3 gm/kg Oral LD50 Mouse = 4 gm/kg Dermal LD50 Rabbit >10 gm/kg
Citric Acid Monohydrate 5949-29-1	None
Sodium Citrate, dihydrate 6132-04-3	None
Propyl Paraben 94-13-3	Oral LD50 Mouse = 6332 mg/kg
Methyl Paraben 99-76-3	Oral LD50 Mouse > 8 g/kg
Water 7732-18-5	Oral LD50 Rat: >50000 mg/kg

Acute toxicity: Gastrointestinal effects (may include nausea/vomiting, abdominal pain, diarrhea, dry mouth, colic). Nervous system effects (headache, dizziness, light headedness). Liver function effects (may include increased levels of SGOT, SGPT, serum LDH, jaundice). Cardiovascular effects (may include fluctuations in heart rate, changes in blood pressure, chest pain). May cause allergic reactions.

Chronic toxicity: No data is available on the product itself.

Carcinogenic effects: Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. Not carcinogenic at all dose levels evaluated based on animal data.

Mutagenic effects: Not mutagenic in a standard battery of genetic toxicological tests.

Reproductive toxicity: No impairment to fertility based on animal data. Not considered fetotoxic based on animal data.

FDA Pregnancy Category B

12. ECOLOGICAL INFORMATION

Environmental properties:

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Ecotoxicity - Microtox Data
Ondansetron Hydrochloride 99614-01-4	None.	None.	None.	None.
Sodium Chloride 7647-14-5	1000 mg/L EC50 48 h	12946mg/LLC50Lepomis macrochirus96h 7650mg/LLC50Pimephales promelas96h 9675mg/LLC50Lepomis macrochirus96h	None.	None.
Citric Acid Monohydrate 5949-29-1	120 mg/L EC50 72 h	1516mg/LLC50Lepomis macrochirus96h 440mg/LLC50Leuciscus idus96h	None.	14mg/LEC50Photobacterium phosphoreum15min
Sodium Citrate, dihydrate 6132-04-3	5600 mg/L EC50 48 h	18000mg/LLC50Poeilia reticulata96h	1800 - 3200 mg/L 96h	1800 - 3200mg/LEC50Pseudomonas fluorescens8h
Propyl Paraben 94-13-3	None.	None.	None.	None.
Methyl Paraben 99-76-3	None.	None.	None.	None.
Water 7732-18-5	None.	None.	None.	None.

Ecotoxicity effects: No data available

Bioaccumulation: No data available

13. DISPOSAL CONSIDERATIONS

Waste Classification: Not regulated.

Waste from residues / unused products: Waste disposal must be in accordance with appropriate Federal, State, and local regulations.

14. TRANSPORT INFORMATION

DOT:

DOT shipping name: None
UN Number: None
DOT Packing Group: None
DOT Hazard class: None

TDG (Canada):

TDG Proper shipping name: None
TDG UN/NA Number: None
TDG Packing Group: None
TDG Hazard class: None

ADR/RID:

ADR Official Transport Name: None
ADR Proper shipping name: None
ADR UN/NA number: None
ADR Hazard Class: None

ICAO / IATA:

IATA Proper shipping name: None
IATA UN NUMBER: None
IATA Primary Hazard: None
IATA Packing group: None
ICAO ERG Code: None

IMO / IMDG:

IMDG Proper Shipping Name: None
IMDG Hazard Class and Division: None
IMDG Packing Group: None
IMDG Subsidiary Risks: None

15. REGULATORY INFORMATION

U.S. Regulations:

TSCA Inventory List - OTHER REGULATIONS: The product is exempt from TSCA, it is FDA Regulated

Japanese Inventory (ENCS) This product does not comply with JPENCS

Component	Weight %	RCRA Status:	CERCLA Reportable Quantity:	CERCLA/SARA - 302 Ext. haz. substances:	Listed as Sara 313 title III:
Ondansetron Hydrochloride	0.2	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Chloride	<1	Not Listed	Not Listed	Not Listed	Not Listed
Citric Acid Monohydrate	<0.1	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Citrate, dihydrate	<0.1	Not Listed	Not Listed	Not Listed	Not Listed

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Product name: Ondansetron Injection, USP

15. REGULATORY INFORMATION

Propyl Paraben	0 - 0.05	Not Listed	Not Listed	Not Listed	Not Listed
Methyl Paraben	0 - 0.05	Not Listed	Not Listed	Not Listed	Not Listed
Water	>98	Not Listed	Not Listed	Not Listed	Not Listed

STATE REGULATIONS:

Component	California Prop 65:	Minnesota Right-To - Know:	Florida Right-to-Know Reporting List:	Rhode Island Right-to-Know List:	Massachusetts Right-to-Know List:	Pennsylvania Right-to-Know:	New Jersey Right-to-Know:
Ondansetron Hydrochloride	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Chloride	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Citric Acid Monohydrate	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Citrate, dihydrate	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Propyl Paraben	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Methyl Paraben	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Water	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

CANADIAN REGULATIONS:

Canada DSL Inventory List - This product does not comply with DSL

EU EINECS List - This product does not comply with EINECS

Risk Phrases:
Not determined

Safety Phrases:
Not Determined

16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s)?:
Additional product codes.

Additional information:
Not Available.

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End of safety data sheet: