# ONDANSETRON INJECTION USP 2mg/mL, 2 mL (SINGLE DOSE)

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations
Revision Date: 10/03/2016 Date of Issue: 10/03/2016 Version: 1.0

## SECTION 1: IDENTIFICATION

### 1.1. Product Identifier

**Product Form:** Mixture

**Product Name:** ONDANSETRON INJECTION USP 2mg/mL, 2 mL (SINGLE DOSE)

### 1.2. Intended Use of the Product

**Use of the Substance/Mixture:** Pharmaceutical. For professional use only.

### 1.3. Name, Address, and Telephone of the Responsible Party

**Company**

Accord Healthcare, Inc.
1009 Slater Road
Suite 210-B
Durham, NC 27703
USA
Telephone: 1-919-941-7880
Fax- 1-919-941-7881
www.accord-healthcare.com

### 1.4. Emergency Telephone Number

**Emergency Number** : 1-800-424-9300 Call CHEMTREC Day or Night

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the Substance or Mixture

**GHS-US Classification**

Not classified

### 2.2. Label Elements

**GHS-US Labeling**

No labeling applicable

### 2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

### 2.4. Unknown Acute Toxicity (GHS-US)

No data available

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substance

Not applicable

### 3.2. Mixture

| Name | Product Identifier | % | GHS-US classification |
|---|---|---|---|
| Water | (CAS No) 7732-18-5 | 98.8 | Not classified |
| Sodium chloride | (CAS No) 7647-14-5 | 0.9 | Not classified |
| Ondansetron hydrochloride dihydrate | (CAS No) 103639-04-9 | 0.225 | Acute Tox. 3 (Oral), H301<br>Eye Dam. 1, H318<br>Aquatic Acute 1, H400<br>Aquatic Chronic 1, H410 |
| Citric acid monohydrate | (CAS No) 5949-29-1 | 0.05 | Eye Irrit. 2A, H319 |
| Trisodium citrate | (CAS No) 68-04-2 | 0.025 | Comb. Dust |

Full text of H-phrases: see section 16

## SECTION 4: FIRST AID MEASURES

### 4.1. Description of First-aid Measures

**First-aid Measures General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

**First-aid Measures After Inhalation:** When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

**First-aid Measures After Skin Contact:** Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

**First-aid Measures After Eye Contact:** Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

**First-aid Measures After Ingestion:** Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

### 4.2. Most Important Symptoms and Effects Both Acute and Delayed

**Symptoms/Injuries:** Not expected to present a significant hazard under anticipated conditions of normal use. Please refer to the package insert for more detailed information.

**Symptoms/Injuries After Inhalation:** Prolonged exposure may cause irritation.

**Symptoms/Injuries After Skin Contact:** Prolonged exposure may cause skin irritation.

**Symptoms/Injuries After Eye Contact:** May cause slight irritation to eyes.

**Symptoms/Injuries After Ingestion:** Ingestion may cause adverse effects.

**Chronic Symptoms:** None known.

### 4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

## SECTION 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing Media

**Suitable Extinguishing Media:** Use extinguishing media appropriate for surrounding fire.

**Unsuitable Extinguishing Media:** Do not use a heavy water stream. Use of heavy stream of water may spread fire.

### 5.2. Special Hazards Arising From the Substance or Mixture

**Fire Hazard:** Not flammable.

**Explosion Hazard:** Product is not explosive.

**Reactivity:** Hazardous reactions will not occur under normal conditions.

### 5.3. Advice for Firefighters

**Precautionary Measures Fire:** Exercise caution when fighting any chemical fire.

**Firefighting Instructions:** Use water spray or fog for cooling exposed containers.

**Protection During Firefighting:** Do not enter fire area without proper protective equipment, including respiratory protection.

**Hazardous Combustion Products:** Carbon oxides (CO, $CO_2$). Oxides of sodium. Chloride compounds. Toxic fumes.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

**General Measures:** Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray).

#### 6.1.1. For Non-Emergency Personnel

**Protective Equipment:** Use appropriate personal protection equipment (PPE).

**Emergency Procedures:** Evacuate unnecessary personnel.

#### 6.1.2. For Emergency Personnel

**Protective Equipment:** Equip cleanup crew with proper protection.

**Emergency Procedures:** Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

### 6.2. Environmental Precautions

Prevent entry to sewers and public waters.

### 6.3. Methods and Materials for Containment and Cleaning Up

**For Containment:** Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

**Methods for Cleaning Up:** Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

### 6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for Safe Handling

**Precautions for Safe Handling:** Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray.

**Hygiene Measures:** Handle in accordance with good industrial hygiene and safety procedures.

### 7.2. Conditions for Safe Storage, Including Any Incompatibilities

**Technical Measures:** Comply with applicable regulations.

**Storage Conditions:** Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

**Incompatible Products:** Strong acids, strong bases, strong oxidizers.

### 7.3. Specific End Use(s)

Pharmaceutical. For professional use only.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

### 8.2. Exposure Controls

**Appropriate Engineering Controls** : Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

**Personal Protective Equipment** : Gloves. Protective clothing. Protective goggles.

**Materials for Protective Clothing** : Chemically resistant materials and fabrics.

**Hand Protection** : Wear protective gloves.

**Eye Protection** : Chemical safety goggles.

**Skin and Body Protection** : Wear suitable protective clothing.

**Respiratory Protection** : If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

**Other Information** : When using, do not eat, drink or smoke.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on Basic Physical and Chemical Properties

| | |
|---|---|
| **Physical State** | : Liquid |
| **Appearance** | : No data available |
| **Odor** | : No data available |
| **Odor Threshold** | : No data available |
| **pH** | : No data available |
| **Evaporation Rate** | : No data available |
| **Melting Point** | : No data available |
| **Freezing Point** | : No data available |
| **Boiling Point** | : No data available |
| **Flash Point** | : No data available |
| **Auto-ignition Temperature** | : No data available |
| **Decomposition Temperature** | : No data available |
| **Flammability (solid, gas)** | : No data available |
| **Vapor Pressure** | : No data available |
| **Relative Vapor Density at 20°C** | : No data available |
| **Relative Density** | : No data available |
| **Solubility** | : No data available |
| **Partition Coefficient: N-Octanol/Water** | : No data available |
| **Viscosity** | : No data available |

### 9.2. Other Information

No additional information available

## SECTION 10: STABILITY AND REACTIVITY

**10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.

**10.2. Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).

**10.3. Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.

**10.4. Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials.

**10.5. Incompatible Materials:** Strong acids, strong bases, strong oxidizers.

**10.6. Hazardous Decomposition Products:** Under normal conditions of storage and use, hazardous decomposition products will not be produced.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on Toxicological Effects

**Acute Toxicity:** Not classified

| **Ondansetron hydrochloride dihydrate (103639-04-9)** | |
|---|---|
| **ATE (Oral)** | 100.00 mg/kg body weight |

| **Sodium chloride (7647-14-5)** | |
|---|---|
| **LD50 Oral Rat** | 3 g/kg |
| **LC50 Inhalation Rat** | > 42 g/m³ (Exposure time: 1 h) |

| **Trisodium citrate (68-04-2)** | |
|---|---|
| **LD50 Oral Rat** | 5.4 g/kg |
| **LD50 Dermal Rat** | > 2000 mg/kg |

| **Citric acid monohydrate (5949-29-1)** | |
|---|---|
| **LD50 Oral Rat** | 5790 mg/kg |

**Skin Corrosion/Irritation:** Not classified

**Serious Eye Damage/Irritation:** Not classified

**Respiratory or Skin Sensitization:** Not classified

**Germ Cell Mutagenicity:** Not classified

**Carcinogenicity:** Not classified

**Reproductive Toxicity:** Not classified

**Specific Target Organ Toxicity (Single Exposure):** Not classified

**Specific Target Organ Toxicity (Repeated Exposure):** Not classified

**Aspiration Hazard:** Not classified

**Symptoms/Injuries After Inhalation:** Prolonged exposure may cause irritation.

**Symptoms/Injuries After Skin Contact:** Prolonged exposure may cause skin irritation.

**Symptoms/Injuries After Eye Contact:** May cause slight irritation to eyes.

**Symptoms/Injuries After Ingestion:** Ingestion may cause adverse effects.

**Chronic Symptoms:** None known.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

**Ecology - General** : Not classified.

| **Sodium chloride (7647-14-5)** | |
|---|---|
| **LC50 Fish 1** | 5560 (5560 - 6080) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through]) |
| **EC50 Daphnia 1** | 1000 mg/l (Exposure time: 48 h - Species: Daphnia magna) |
| **LC50 Fish 2** | 12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static]) |
| **EC50 Daphnia 2** | 340.7 (340.7 - 469.2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static]) |

| **Trisodium citrate (68-04-2)** | |
|---|---|
| **LC50 Fish 1** | 18000 (18000 - 32000) mg/l (Exposure time: 96 h - Species: Poecilia reticulata) |
| **EC50 Daphnia 1** | 5600 (5600 - 10000) mg/l (Exposure time: 48 h - Species: Daphnia magna) |
| **EC50 Other Aquatic Organisms 1** | 18000 (18000 - 32000) mg/l (Exposure time: 96 h - Species: Chlorella vulgaris) |

### 12.2. Persistence and Degradability

| **ONDANSETRON INJECTION USP 2mg/mL, 2 mL (SINGLE DOSE)** | |
|---|---|
| **Persistence and Degradability** | Not established. |

### 12.3. Bioaccumulative Potential

| **ONDANSETRON INJECTION USP 2mg/mL, 2 mL (SINGLE DOSE)** | |
|---|---|
| **Bioaccumulative Potential** | Not established. |

| **Sodium chloride (7647-14-5)** | |
|---|---|
| **BCF Fish 1** | (no bioaccumulation) |

### 12.4. Mobility in Soil
No additional information available

### 12.5. Other Adverse Effects

**Other Information** : Avoid release to the environment.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste Treatment Methods

**Waste Disposal Recommendations:** Dispose of contents/container in accordance with local, regional, national, and international regulations.

**Additional Information:** Container may remain hazardous when empty. Continue to observe all precautions. Contaminated sharps should be handled with care and discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a syringe disposal program. In hospital and workplace settings, contaminated sharps are to be handled in accordance with all applicable regulations.

**Ecology - Waste Materials:** Avoid release to the environment.

## SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

### 14.1. In Accordance with DOT
Not regulated for transport

### 14.2. In Accordance with IMDG
Not regulated for transport

### 14.3. In Accordance with IATA
Not regulated for transport

## SECTION 15: REGULATORY INFORMATION

### 15.1. US Federal Regulations

| **Sodium chloride (7647-14-5)** |
|---|
| Listed on the United States TSCA (Toxic Substances Control Act) inventory |

| **Trisodium citrate (68-04-2)** |
|---|
| Listed on the United States TSCA (Toxic Substances Control Act) inventory |

| **Water (7732-18-5)** |
|---|
| Listed on the United States TSCA (Toxic Substances Control Act) inventory |

### 15.2. US State Regulations
Neither this product nor its chemical components appear on any US state lists.

## SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

**Revision Date** : 10/03/2016

**Other Information** : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

**GHS Full Text Phrases:**

| | |
|---|---|
| Acute Tox. 3 (Oral) | Acute toxicity (oral) Category 3 |
| Aquatic Acute 1 | Hazardous to the aquatic environment - Acute Hazard Category 1 |
| Aquatic Chronic 1 | Hazardous to the aquatic environment - Chronic Hazard Category 1 |
| Comb. Dust | Combustible Dust |
| Eye Dam. 1 | Serious eye damage/eye irritation Category 1 |
| Eye Irrit. 2A | Serious eye damage/eye irritation Category 2A |
| H301 | Toxic if swallowed |
| H318 | Causes serious eye damage |
| H319 | Causes serious eye irritation |
| H400 | Very toxic to aquatic life |
| H410 | Very toxic to aquatic life with long lasting effects |

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*

SDS US (GHS HazCom)