

## MATERIAL SAFETY DATA SHEET

Date Printed: FEB 2009

### ONDANSETRON FOR INJECTION

#### SECTION 1. PRODUCT AND COMPANY INFORMATION

Product Name: Ondansetron Hydrochloride for Injection  
Supplier: West-Ward Pharmaceuticals  
401 Industrial Way West  
Eatontown, NJ 07724  
Phone (732 542 1191)  
Fax (732 720 6220)  
  
Technical Phone: (800 631 2174)

#### SECTION 2. COMPOSITION/INFORMATION ON INGREDIENTS

| CAS No.     | Description                   | % in final Product |
|-------------|-------------------------------|--------------------|
| 103639-04-9 | Ondansetron HCl               | 0.2                |
| 7647-14-5   | Sodium Chloride               | 0.9                |
| 6132-04-3   | Sodium Citrate Dihydrate, USP | 0.02               |
| 5949-29-1   | Citric Acid Monohydrate       | 0.05               |
| 7732-18-5   | Water for Injection           | 98.83              |

Category: Anti-emetic

#### SECTION 3. HAZARDS IDENTIFICATION, EMERGENCY OVERVIEW

Route of Entry: Inhalation, eye/skin contact, or ingestion

Potential Health Effects

| Route        | ShortTerm Exposure | Long Term Exposure |
|--------------|--------------------|--------------------|
| Inhalation   | Irritation         | Hypersensitivity   |
| Skin Contact | Irritation         | Hypersensitivity   |
| Eye Contact  | Irritation         | Hypersensitivity   |
| Ingestion    | Constipation       | Hypersensitivity   |

Ondansetron is not recommended for use in patients who have exhibited hypersensitivity to other selective 5-HT<sub>3</sub> receptor antagonists.

Chemical List as

Carcinogen:

NTP: No

IARC: No

OSHA: No

BVL Hazard Category: 3 BVL Occupational Exposure limit (OEL): 20 µg/m<sup>3</sup>

**Note:** Ondansetron Hydrochloride may be classified as hazardous according to the OSHA Hazard Communication Standard per US OSHA Standard ( 29 CFR part 1910.1200).

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#### SECTION 4. FIRST AID MEASURES

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- Eyes: Immediately flush eyes with water for at least 15 minutes. Seek medical attention.
- Skin: Remove from source of exposure, wash affected area with soap and water, seek medical attention if reaction occurs, this maybe immediate.
- Inhalation: Physical form suggests that risk of inhalation exposure is negligible.
- Ingestion: If ingestion occurs, flush mouth with water and seek medical attention immediately. Never induce vomiting , if person is fully conscious, give plenty of water to drink. Seek medical attention.

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#### SECTION 5. FIRE AND EXPLOSION DATA

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##### **Fire and explosion Data**

- Closed Cup Flash Point: N/A
- Open Cup Flash Point N/A
- Fire Point: N/A
- Autoignition: N/A
- Lower Explosion Limit: N/A
- General Hazard: Not expected to support combustion.
- Fire Fighting Instructions: Evacuate personnel to safe area. Water spray, dry chemical, or foam carbon dioxide may be ineffective. If possible contain and collect water used.
- Fire Fighting Equipment: Firefighters should wear protective clothing and self-contained breathing equipment for fires involving large amounts of product.
- Hazardous Combustion Products: Thermal decomposition may yield toxic, corrosive, or flammable products.

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#### SECTION 6. ACCIDENTAL RELEASE MEASURES

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- Clean Up: Wear recommended personal protective equipment. Use an inert absorbent material to clean affected area, and place in a properly labelled container for recovery or disposal. Prevent entry into waterways, sewers, drainage systems and poorly ventilated areas. No specific decontamination or detoxification procedures have been identified for this product.  
Dispose of materials according to the applicable federal, state and/ or local regulations.

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#### SECTION 7. HANDLING AND STORAGE

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- General Handling: When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with product.
- Storage Conditions: Store between 2° - 25°C (36° - 77°F). Protect from light and excessive heat.

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## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: N/A

### **Personal Protective Equipment**

Eye protection: Not required during normal use and handling.

Hand protection: Not required during normal use and handling.

Respiratory Protection: A dust/ mist respirator (N95 may be needed).

Skin Protection: Not required during normal use and handling.

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## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical Form/ Appearance: Clear colourless Solution

Boiling Point/ Boiling Range: Approximate to Water.

Melting Point/ Melting Range: Approximate to Water.

Freezing Point: Approximate to Water.

Vapor Pressure: Approximate to Water.

Relative Vapor Density: Approximate to Water.

Percent Volatiles: N/A

pH: 3.3-4.0

Molecular Weight: 365.86

Solvent Solubility: Sparingly soluble in water

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## SECTION 10. STABILITY AND REACTIVITY DATA.

Stability: Stable under most conditions

Conditions to Avoid: Oxidizing agents.

Hazardous Polymerization: N/A

Hazardous Decomposition or Byproducts: Thermal decomposition may yield hazardous carbon  
Oxide fumes.

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## SECTION 11. TOXICOLOGICAL INFORMATION

Acute Toxicity:

| Compound                  | Type | Route | Species | Dosage     |
|---------------------------|------|-------|---------|------------|
| Ondansetron Hydrochloride | LD50 | IV    | Rat     | 20 mg/kg   |
|                           | LD50 | IV    | Mouse   | 2500 mg/kg |
|                           | LD50 | IP    | Mouse   | > 5 mg/kg  |
|                           | LD50 | Oral  | Mouse   | 10 mg/kg   |

Other: Additional reproductive health data is available from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS)

Reproductive Effects: Not expected to produce adverse effects on fertility or development under occupational exposure conditions.

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#### SECTION 12. ECOLOGICAL INFORMATION

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Information is currently not available on the environmental impact of Ondansetron. Handle in a manner to prevent spills or releases to the environment.

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#### SECTION 13. DISPOSAL CONSIDERATIONS

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Dispose of by incineration at an approved /permitted incinerator. Review local, state, and federal regulations for your regulatory area.

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#### SECTION 14. TRANSPORT INFORMATION

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**UN/NA Number:** N/A

**US DOT Hazard Class:** N/A

**Proper Shipping Name:** N/A

**Shipping Label:** N/A

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#### SECTION 15. REGULATORY INFORMATION

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**U.S. Regulatory Information:** not regulated.

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#### SECTION 16. OTHER INFORMATION

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