



# MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.1

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## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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### Material Name: Ondansetron Hydrochloride Solution for Injection

**Trade Name:** Ondansetron Injection  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product for the treatment of nausea and vomiting (antiemetic)

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Ondansetron hydrochloride dihydrate	103639-04-9	Not listed	0.2
Citric acid, anhydrous	77-92-9	201-069-1	*

Ingredient	CAS Number	EU EINECS List	%
Sodium chloride	7647-14-5	231-598-3	*
Water for Injection	7732-18-5	231-791-2	*
Sodium citrate	68-04-2	200-675-3	*

**Additional Information:** \* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

**Appearance:** Colorless solution

**Statement of Hazard:** Non-hazardous in accordance with international standards for workplace safety.

### Additional Hazard Information:

**Short Term:** Active ingredient may be harmful if swallowed. May cause eye irritation (based on components) .

**Long Term:** May cause effects on central nervous system through prolonged or repeated exposure.

**Known Clinical Effects:** Adverse effects associated with the therapeutic use include headache, flushing, and constipation.

**EU Indication of danger:** Not classified

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**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

### 4. FIRST AID MEASURES

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Water, dry powder or foam extinguishers are recommended.

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**Fire / Explosion Hazards:** Not applicable

### 6. ACCIDENTAL RELEASE MEASURES

**Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Measures for Environmental Protections:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

**General Handling:** No special handling requirements for normal use of this material. Use appropriate personal protective equipment. Use appropriate ventilation.

**Storage Conditions:** Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

**Storage Temperature:** Store as directed by product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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The purpose of the Occupational Exposure Band (OEB) is to separate substances into different hazard categories and provide an exposure control and containment strategy for the compound as detailed in this section. The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to alteration when new information becomes available.

### Ondansetron hydrochloride dihydrate

**Pfizer Occupational Exposure Band (OEB):** OEB3 (control exposure to the range of >10ug/m<sup>3</sup> to < 100ug/m<sup>3</sup>)

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

### Personal Protective Equipment:

**Hands:** Wear impervious gloves if skin contact is possible.  
**Eyes:** Safety glasses or goggles  
**Skin:** Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.  
**Respiratory protection:** If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

## 9. PHYSICAL AND CHEMICAL PROPERTIES:

<b>Physical State:</b>	Solution	<b>Color:</b>	Colorless
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>pH:</b>	3.3 - 4.0		

## 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.  
**Conditions to Avoid:** Not determined  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers.

## 11. TOXICOLOGICAL INFORMATION

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.

### Acute Toxicity: (Species, Route, End Point, Dose)

#### Ondansetron hydrochloride dihydrate

Rat Oral LD50 95 mg/kg  
Rat Intravenous LD50 20201 ug/kg  
Dog Oral LD50 > 45 mg/kg

#### Citric acid, anhydrous

Rat Oral LD50 3000 mg/kg

#### Sodium chloride

Rat Oral LD50 3000 mg/kg

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Mouse Oral LD 50 4000 mg/kg

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

### Irritation / Sensitization: (Study Type, Species, Severity)

#### **Citric acid, anhydrous**

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Mild

#### **Sodium chloride**

Eye Irritation Rabbit Moderate  
Skin Irritation Rabbit Mild

### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

#### **Ondansetron hydrochloride dihydrate**

7 Week(s) Rat Oral 160 mg/kg/day Maximally Tolerated Dose  
18 Month(s) Rat No route specified 1 mg/kg/day NOAEL Central Nervous System, Liver  
12 Month(s) Dog No route specified 12 mg/kg/day NOAEL Central Nervous System, Liver

#### **Sodium chloride**

10 Day(s) Rat Oral 12500 mg/kg LOAEL Kidney, Ureter, Bladder

### Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

#### **Ondansetron hydrochloride dihydrate**

Reproductive & Fertility Rat Oral 15 mg/kg/day NOAEL Negative  
Fertility and Embryonic Development Rat Intravenous 4 mg/kg/day NOAEL No effects at maximum dose  
Fertility and Embryonic Development Rabbit Intravenous 4 mg/kg/day NOAEL No effects at maximum dose

### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

#### **Ondansetron hydrochloride dihydrate**

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative  
*In Vitro* Chromosome Aberration Human Lymphocytes Negative  
*In Vivo* Chromosome Aberration Mouse Bone Marrow Negative

### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

#### **Ondansetron hydrochloride dihydrate**

2 Year(s) Rat Oral 10 mg/kg/day NOAEL Not carcinogenic  
2 Year(s) Mouse Oral 30 mg/kg/day NOAEL Not carcinogenic

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

## 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided. See aquatic toxicity data for individual components below:

### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

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### Ondansetron hydrochloride dihydrate

Algae EC50 72 Hours 0.87 mg/L

Daphnia EC50 48 Hours 28 mg/L

Rainbow Trout EC50 96 Hours 6.5 mg/L

Activated sludge IC50 3 Hours > 1000 mg/L

**Aquatic Toxicity Comments:** A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

### 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** Dispose of waste in accordance with all applicable laws and regulations.

### 14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### 15. REGULATORY INFORMATION

**EU Indication of danger:** Not classified

#### OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

#### Canada - WHMIS: Classifications

#### WHMIS hazard class:

None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

#### Sodium chloride

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

EU EINECS List

231-598-3

#### Citric acid, anhydrous

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Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	201-069-1

### Water for Injection

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

### Sodium citrate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-675-3

## 16. OTHER INFORMATION

### Reasons for Revision:

Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity.

### Prepared by:

Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety

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**End of Safety Data Sheet**