



SAFETY DATA SHEET

Revision date 18-Mar-2020

Version 2.04

Page 1 / 10

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Ondansetron Hydrochloride Injection (Hospira, Inc.)
Product Code(s) PZ03381
Trade Name: Ondansetron Injection
Chemical Family: Mixture

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical product for the treatment of nausea and vomiting (antiemetic)

1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887
E-mail address pfizer-MSDS@pfizer.com

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Not classified as hazardous

2.2. Label elements

Signal word Not classified

Hazard statements Not classified in accordance with international standards for workplace safety.

2.3. Other hazards

Other hazards An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

SAFETY DATA SHEET

Product Name Ondansetron Hydrochloride Injection (Hospira, Inc.)
Revision date 18-Mar-2020

Page 2 / 10
Version 2.04

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Hazardous

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
Ondansetron hydrochloride dihydrate	Not Listed	103639-04-9	0.2	Acute Tox. 3 (H301) Aquatic. Acute 1 (H400) Aquatic. Chronic 1 (H410)	
Methyl-p-hydroxybenzoate	202-785-7	99-76-3	>1	Aquatic Chronic 2 (H411)	
Propylparaben	202-307-7	94-13-3	> 1	Aquatic Chronic 3 (H412)	

NonHazardous

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
Water	231-791-2	7732-18-5	*	Not Listed	
SODIUM CHLORIDE	231-598-3	7647-14-5	*	Not Listed	
Citric acid monohydrate	Not Listed	5949-29-1	*	Not Listed	
Sodium Citrate	612-118-5	6132-04-3	*	Not Listed	

Full text of H- and EUH-phrases: see section 16

Additional information

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

SAFETY DATA SHEET

Product Name Ondansetron Hydrochloride Injection (Hospira, Inc.)
Revision date 18-Mar-2020

Page 3 / 10
Version 2.04

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.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

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

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products Formation of toxic gases is possible during heating or fire.

5.3. Advice for firefighters

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

SAFETY DATA SHEET

Product Name Ondansetron Hydrochloride Injection (Hospira, Inc.)
Revision date 18-Mar-2020

Page 4 / 10
Version 2.04

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical drug product.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

Refer to available public information for specific member state Occupational Exposure Limits.

Ondansetron hydrochloride dihydrate

Pfizer OEL TWA-8 Hr: 10 µg/m³

SODIUM CHLORIDE

Latvia

5 mg/m³

Russia

MAC: 5 mg/m³

Ondansetron hydrochloride dihydrate

Russia

MAC: 0.05 mg/m³

Skin

Methyl-p-hydroxybenzoate

Russia

MAC: 4 mg/m³

Propylparaben

Russia

MAC: 10 mg/m³

SODIUM CHLORIDE

Pfizer Occupational Exposure
Band (OEB):

OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

8.2. Exposure controls

Engineering controls

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental exposure controls

No information available.

Personal protective equipment

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Eye/face protection

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection

Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection

Impervious protective clothing is recommended if skin contact with drug product is possible

SAFETY DATA SHEET

Product Name Ondansetron Hydrochloride Injection (Hospira, Inc.)
Revision date 18-Mar-2020

Page 5 / 10
Version 2.04

and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.).

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Solution
Color	Colorless
Molecular formula (MF):	Mixture
Molecular weight	Mixture
Odor	No data available.
Odor threshold	No data available

<u>Property</u>	<u>Values</u>
pH	3.3 - 4.0
Melting point / freezing point	No data available
Boiling point / boiling range	No data available
Flash point	No data available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Explosive properties	No data available
Oxidizing properties	No data available

9.2. Other information

Liquid Density	No data available
Bulk density	No data available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

SAFETY DATA SHEET

Product Name Ondansetron Hydrochloride Injection (Hospira, Inc.)
Revision date 18-Mar-2020

Page 6 / 10
Version 2.04

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

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

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 therapeutic use include headache, flushing, and constipation. May cause irregular heartbeat (cardiac arrhythmia), hypersensitivity reactions.

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

SODIUM CHLORIDE

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m³

Rat Oral LD 50 3 g/kg

Mouse Oral LD 50 4 g/kg

Rabbit Dermal LD 50 > 10 g/kg

Ondansetron hydrochloride dihydrate

Rat Oral LD50 95 mg/kg

Rat Para-periosteal LD50 20201 ug/kg

Dog Oral LD50 > 45 mg/kg

Methyl-p-hydroxybenzoate

Mouse Oral LD50 >8 g/kg

Rat Oral LD 50 2100 mg/kg

Propylparaben

Mouse Oral LD 50 6332 mg/kg

Mouse Sub-tenon injection (eye) LD 50 200 mg/kg

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
SODIUM CHLORIDE	= 3 g/kg (Rat)	> 10 g/kg (Rabbit)	> 42 g/m ³ (Rat) 1 h
Methyl-p-hydroxybenzoate	= 2100 mg/kg (Rat)	-	-

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)

SODIUM CHLORIDE

SAFETY DATA SHEET

Product Name Ondansetron Hydrochloride Injection (Hospira, Inc.)
Revision date 18-Mar-2020

Page 7 / 10
Version 2.04

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild
Methyl-p-hydroxybenzoate
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Slight
Skin Sensitization Guinea Pig Negative

Citric acid monohydrate
Eye Irritation Rabbit Mild
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 NOEL Central Nervous System, Liver
12 Month(s) Dog No route specified 12 mg/kg/day NOEL Central Nervous System, Liver

Methyl-p-hydroxybenzoate

28 Day(s) Rat Oral 250 mg/kg/day NOEL Gastrointestinal System, Spleen, Thymus

Propylparaben

3 Week(s) Rat Oral 27.1 g/kg LOEL Endocrine system
4 Week(s) Rat Oral 347.2 mg/kg LOEL Male reproductive system

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

Ondansetron hydrochloride dihydrate

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

Methyl-p-hydroxybenzoate

Embryo / Fetal Development Rabbit Oral 300 mg/kg/day NOEL Maternal toxicity, Developmental toxicity

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 Bone marrow Mouse Negative

Methyl-p-hydroxybenzoate

In Vivo Dominant Lethal Assay Rat Negative

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

Ondansetron hydrochloride dihydrate

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

Carcinogenicity None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Section 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:

12.1. Toxicity

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

Ondansetron hydrochloride dihydrate

Selenastrum capricornutum (Green Alga) IC-50 72 hours 0.87 mg/l
Daphnia magna (Water Flea) EC50 48 days 28 mg/L
Oncorhynchus mykiss (Rainbow Trout) EC50 96 hours 6.5 mg/l

SAFETY DATA SHEET

Product Name Ondansetron Hydrochloride Injection (Hospira, Inc.)
Revision date 18-Mar-2020

Page 8 / 10
Version 2.04

Activated sludge IC50 3 Hours > 1000 mg/L
Ceriodaphnia dubia (Daphnids) NOEC 8 days 0.32 mg/l

Methyl-p-hydroxybenzoate

Oryzias latipes (Japanese Rice Fish) OECD LC50 96 hours 59.5 mg/l
Daphnia magna (Water Flea) ISO EC50 48 hours 11.2 mg/L

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

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

12.2. Persistence and degradability

Persistence and degradability

Methyl-p-hydroxybenzoate

OECD Activated sludge Ultimate (CO2 Evolution) 89 % After 28 Day(s) Ready

12.3. Bioaccumulative potential

Bioaccumulation

No information available.

12.4. Mobility in soil

Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

No information available.

Chemical Name	PBT and vPvB assessment
SODIUM CHLORIDE	The substance is not PBT / vPvB PBT assessment does not apply
Methyl-p-hydroxybenzoate	The substance is not PBT / vPvB
Citric acid monohydrate	The substance is not PBT / vPvB
Sodium Citrate	The substance is not PBT / vPvB PBT assessment does not apply
Propylparaben	The substance is not PBT / vPvB

12.6. Other adverse effects

Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

SAFETY DATA SHEET

Product Name Ondansetron Hydrochloride Injection (Hospira, Inc.)
Revision date 18-Mar-2020

Page 9 / 10
Version 2.04

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

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-791-2
AICS	Present

SODIUM CHLORIDE

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-598-3
AICS	Present

Ondansetron hydrochloride dihydrate

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed

Methyl-p-hydroxybenzoate

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	202-785-7
AICS	Present

Citric acid monohydrate

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed
AICS	Present

Sodium Citrate

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5

Propylparaben

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	202-307-7
AICS	Present

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

SAFETY DATA SHEET

Product Name Ondansetron Hydrochloride Injection (Hospira, Inc.)
Revision date 18-Mar-2020

Page 10 / 10
Version 2.04

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

H301 - Toxic if swallowed H400 - Very toxic to aquatic life H410 - Very toxic to aquatic life with long lasting effects H411 - Toxic to aquatic life with long lasting effects H412 - Harmful to aquatic life with long lasting effects

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

Reason for revision Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 16 - Other Information.

Revision date 18-Mar-2020

Prepared By Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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