



# SAFETY DATA SHEET

Revision date 06-Dec-2021

Version 1.02

Page 1 / 13

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

### 1.1. Product identifier

**Product Name** Palonosetron Injection (Hospira, Inc.)  
**Product Code(s)** PZ03572  
**Trade Name:** Palonosetron 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

**E-mail address** pfizer-MSDS@pfizer.com

### 1.4. Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

## 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** Non-hazardous 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 Palonosetron Injection (Hospira, Inc.)  
Revision date 06-Dec-2021

Page 2 / 13  
Version 1.02

**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	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Palonosetron hydrochloride (CAS #: 135729-62-3)	<1.0		Not Listed	Acute Tox. 4 (H302)	Not Listed	No data available	No data available
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5	Skin Corr. 1A (H314)	Eye Irrit. 2 :: 0.5%≤C<2% Skin Corr. 1A :: C≥5% Skin Corr. 1B :: 2%≤C<5% Skin Irrit. 2 :: 0.5%≤C<2%	No data available	No data available
+ Hydrochloric Acid (CAS #: 7647-01-0)	**	-	231-595-7	Acute Tox. 3 (H331) Skin Corr. 1A (H314) Press. Gas	Eye Irrit. 2 :: 10%≤C<25% Skin Corr. 1B :: C≥25% Skin Irrit. 2 :: 10%≤C<25% STOT SE 3 :: C≥10%	No data available	No data available

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified as hazardous	Not Listed	No data available	No data available
Sodium Citrate (CAS #: 6132-04-3)	*		612-118-5	Not classified as hazardous	Not Listed	No data available	No data available
Disodium EDTA (dihydrate) (CAS #: 6381-92-6)	*	-	Not Listed	Not classified as hazardous	Not Listed	No data available	No data available
Citric acid monohydrate	*	-	Not Listed	Skin Irrit. 2 (H315)	Not Listed	No data available	No data available

# SAFETY DATA SHEET

Product Name Palonosetron Injection (Hospira, Inc.)  
Revision date 06-Dec-2021

Page 3 / 13  
Version 1.02

(CAS #: 5949-29-1)				Eye Irrit. 2 (H319) STOT SE 3 (H335)			
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**Full text of H- and EUH-phrases: see section 16**

## Acute Toxicity Estimate

No information available

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available
+ Hydrochloric Acid 7647-01-0	238	5010	No data available	No data available	563.3022

## Additional information

\* Proprietary

\*\* to adjust pH

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

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

# SAFETY DATA SHEET

Product Name Palonosetron Injection (Hospira, Inc.)  
Revision date 06-Dec-2021

Page 4 / 13  
Version 1.02

## 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**

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

# SAFETY DATA SHEET

Product Name Palonosetron Injection (Hospira, Inc.)  
Revision date 06-Dec-2021

Page 5 / 13  
Version 1.02

## Exposure Limits

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

### Sodium hydroxide

ACGIH OEL (Ceiling)	2 mg/m <sup>3</sup>
ACGIH TLV	Ceiling: 2 mg/m <sup>3</sup>
Austria	2 mg/m <sup>3</sup> STEL 4 mg/m <sup>3</sup>
Bulgaria	2.0 mg/m <sup>3</sup>
Czech Republic	1 mg/m <sup>3</sup> Ceiling: 2 mg/m <sup>3</sup>
Denmark	Ceiling: 2 mg/m <sup>3</sup>
Estonia	1 mg/m <sup>3</sup> STEL: 2 mg/m <sup>3</sup>
Finland	Ceiling: 2 mg/m <sup>3</sup>
France	2 mg/m <sup>3</sup>
Hungary	1 mg/m <sup>3</sup> STEL: 2 mg/m <sup>3</sup>
Ireland	STEL: 2 mg/m <sup>3</sup>
Ceiling Limit Value	2 mg/m <sup>3</sup>
Latvia	0.5 mg/m <sup>3</sup>
Poland	STEL: 1 mg/m <sup>3</sup> 0.5 mg/m <sup>3</sup>
Romania	1 mg/m <sup>3</sup> STEL: 3 mg/m <sup>3</sup>
Slovakia	2 mg/m <sup>3</sup>
Spain	STEL: 2 mg/m <sup>3</sup>
Switzerland	2 mg/m <sup>3</sup> STEL: 2 mg/m <sup>3</sup>
OSHA PEL	2 mg/m <sup>3</sup> (vacated) Ceiling: 2 mg/m <sup>3</sup>
United Kingdom	STEL: 2 mg/m <sup>3</sup>

### + Hydrochloric Acid

ACGIH OEL (Ceiling)	2 ppm
ACGIH TLV	Ceiling: 2 ppm
Austria	5 ppm 8 mg/m <sup>3</sup> STEL 10 ppm STEL 15 mg/m <sup>3</sup>
Bulgaria	STEL: 10 ppm STEL: 15.0 mg/m <sup>3</sup> 5 ppm 8.0 mg/m <sup>3</sup>
Czech Republic	8 mg/m <sup>3</sup> Ceiling: 15 mg/m <sup>3</sup>
Denmark	Ceiling: 5 ppm Ceiling: 8 mg/m <sup>3</sup>
Estonia	5 ppm 8 mg/m <sup>3</sup> STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>
European Union	TWA: 5 ppm TWA: 8 mg/m <sup>3</sup> STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>
Finland	STEL: 5 ppm STEL: 7.6 mg/m <sup>3</sup>
Germany	2 ppm 3.0 mg/m <sup>3</sup>

# SAFETY DATA SHEET

Product Name Palonosetron Injection (Hospira, Inc.)  
Revision date 06-Dec-2021

Page 6 / 13  
Version 1.02

---

	Ceiling / Peak: 4 ppm
	Ceiling / Peak: 6 mg/m <sup>3</sup>
Germany	2 ppm
	3 mg/m <sup>3</sup>
Hungary	8 mg/m <sup>3</sup>
	STEL: 16 mg/m <sup>3</sup>
Ireland	8 mg/m <sup>3</sup>
	5 ppm
	STEL: 10 ppm
	STEL: 15 mg/m <sup>3</sup>
Italy	5 ppm
	8 mg/m <sup>3</sup>
	STEL: 10 ppm
	STEL: 15 mg/m <sup>3</sup>
Ceiling Limit Value	2 ppm
	3.0 mg/m <sup>3</sup>
Latvia	5 ppm
	8 mg/m <sup>3</sup>
	STEL: 10 ppm
	STEL: 15 mg/m <sup>3</sup>
Netherlands	8 mg/m <sup>3</sup>
	STEL: 15 mg/m <sup>3</sup>
Poland	STEL: 10 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>
Romania	5 ppm
	8 mg/m <sup>3</sup>
	STEL: 10 ppm
	STEL: 15 mg/m <sup>3</sup>
Russia	MAC: 5 mg/m <sup>3</sup>
Slovakia	5 ppm
	8.0 mg/m <sup>3</sup>
Spain	5 ppm
	7.6 mg/m <sup>3</sup>
	STEL: 10 ppm
	STEL: 15 mg/m <sup>3</sup>
Switzerland	2 ppm
	3 mg/m <sup>3</sup>
	STEL: 4 ppm
	STEL: 6 mg/m <sup>3</sup>
U.S. - OSHA - Final PELs - Ceiling Limits	5 ppm
	7 mg/m <sup>3</sup>
OSHA PEL	(vacated) Ceiling: 5 ppm
	(vacated) Ceiling: 7 mg/m <sup>3</sup>
	Ceiling: 5 ppm
	Ceiling: 7 mg/m <sup>3</sup>
United Kingdom	TWA: 1 ppm
	TWA: 2 mg/m <sup>3</sup>
	STEL: 5 ppm
	STEL: 8 mg/m <sup>3</sup>

## Pfizer Occupational Exposure Band (OEB) Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

## Palonosetron hydrochloride

Pfizer Occupational Exposure Band (OEB):

OEB 3 (control exposure to the range of 10ug/m<sup>3</sup> to < 100ug/m<sup>3</sup>)

# SAFETY DATA SHEET

Product Name Palonosetron Injection (Hospira, Inc.)  
Revision date 06-Dec-2021

Page 7 / 13  
Version 1.02

## 8.2. Exposure controls

<b>Engineering controls</b>	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.
<b>Environmental exposure controls</b>	No information available.
<b>Personal protective equipment</b>	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.
<b>Eye/face protection</b>	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.).
<b>Hand protection</b>	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.).
<b>Skin and body protection</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).
<b>Respiratory protection</b>	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.).
<b>General hygiene considerations</b>	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

<b>Physical state</b>	Solution
<b>Color</b>	Colorless
<b>Odor</b>	No information available.
<b>Odor threshold</b>	No information available
<b>Molecular formula</b>	Mixture
<b>Molecular weight</b>	Mixture
<b>Property</b>	<b>Values</b>
<b>pH</b>	3.3 - 4.0
<b>Melting point / freezing point</b>	No data available
<b>Boiling point / boiling range</b>	
<b>Flash point</b>	No information available
<b>Evaporation rate</b>	No data available
<b>Flammability (solid, gas)</b>	No data available
<b>Flammability Limit in Air</b>	
<b>Upper flammability limit:</b>	No data available
<b>Lower flammability limit:</b>	No data available
<b>Vapor pressure</b>	No data available
<b>Vapor density</b>	No data available
<b>Relative density</b>	No data available

# SAFETY DATA SHEET

Product Name Palonosetron Injection (Hospira, Inc.)  
Revision date 06-Dec-2021

Page 8 / 13  
Version 1.02

<b>Water solubility</b>	No data available
<b>Solubility(ies)</b>	No data available
<b>Partition coefficient</b>	No data available
<b>Autoignition temperature</b>	No data available
<b>Decomposition temperature</b>	No data available
<b>Kinematic viscosity</b>	No data available
<b>Dynamic viscosity</b>	No data available
<b>Particle characteristics</b>	
<b>Particle Size</b>	No information available
<b>Particle Size Distribution</b>	No information available
<b>Explosive properties</b>	No information available

## **9.2. Other information**

No information available

### **9.2.1. Information with regard to physical hazard classes**

No information available

### **9.2.2. Other safety characteristics**

No information available

## **Section 10: STABILITY AND REACTIVITY**

### **10.1. Reactivity**

**Reactivity** No data available.

### **10.2. Chemical stability**

**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 hazard classes as defined in Regulation (EC) No 1272/2008**

#### **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 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 and constipation. May cause irregular heartbeat (cardiac arrhythmia), hypersensitivity reactions.

#### **Acute toxicity**

Based on available data, the classification criteria are not met.

#### **Serious eye damage/eye irritation**

Based on available data, the classification criteria are not met.

#### **Skin corrosion/irritation**

Based on available data, the classification criteria are not met.

#### **Respiratory or skin sensitization**

Based on available data, the classification criteria are not met.

#### **STOT - single exposure**

Based on available data, the classification criteria are not met.

# SAFETY DATA SHEET

Product Name Palonosetron Injection (Hospira, Inc.)  
Revision date 06-Dec-2021

Page 9 / 13  
Version 1.02

**STOT - repeated exposure** Based on available data, the classification criteria are not met.  
**Reproductive toxicity** Based on available data, the classification criteria are not met.  
**Germ cell mutagenicity** Based on available data, the classification criteria are not met.  
**Carcinogenicity** Based on available data, the classification criteria are not met.  
**Aspiration hazard** Based on available data, the classification criteria are not met.

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

### Palonosetron hydrochloride

Rat Oral LD50 500 mg/kg

### Sodium hydroxide

Mouse IP LD50 40 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg ( Rat )	-	-
Sodium hydroxide	= 325 mg/kg ( Rat )	= 1350 mg/kg ( Rabbit )	-
+ Hydrochloric Acid	238 - 277 mg/kg ( Rat )	> 5010 mg/kg ( Rabbit )	= 1.68 mg/L ( Rat ) 1 h

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

### Citric acid monohydrate

Eye Irritation Rabbit Moderate

Skin Irritation Rabbit Moderate

### + Hydrochloric Acid

Skin irritation Severe

Eye irritation Severe

### Sodium hydroxide

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Severe

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

### Palonosetron hydrochloride

Fertility Rat Oral 30 mg/kg/day NOAEL Fertility

Embryo / Fetal Development Rat Oral 18 mg/kg/day NOAEL Fetotoxicity

Reproductive & Fertility Rat Oral 60 mg/kg/day NOEL No effects at maximum dose

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

### Palonosetron hydrochloride

Bacterial Mutagenicity (Ames) *In Vitro* Not specified Negative

*In Vivo* Unscheduled DNA Synthesis Rat Hepatocyte Negative

*In Vivo* Micronucleus Mouse Negative

*In Vitro* Chromosome Aberration Chinese Hamster Ovary (CHO) cells Positive

### + Hydrochloric Acid

Bacterial Mutagenicity (Ames) *Salmonella* Negative

*In Vivo* Micronucleus Rat Negative

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

### Palonosetron hydrochloride

104 Week(s) Rat Oral 60 mg/kg/day NOAEL Not carcinogenic

**Carcinogenicity** See below

### + Hydrochloric Acid

IARC Group 3 (Not Classifiable)

## 11.2. Information on other hazards

### 11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

# SAFETY DATA SHEET

Product Name Palonosetron Injection (Hospira, Inc.)  
Revision date 06-Dec-2021

Page 10 / 13  
Version 1.02

## 11.2.2. Other information

**Other adverse effects** No information available.

## 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

### 12.2. Persistence and degradability

**Persistence and degradability** No information available.

### 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 hydroxide	The substance is not PBT / vPvB PBT assessment does not apply
Sodium Citrate	The substance is not PBT / vPvB PBT assessment does not apply
Disodium EDTA (dihydrate)	The substance is not PBT / vPvB
Citric acid monohydrate	The substance is not PBT / vPvB
+ Hydrochloric Acid	The substance is not PBT / vPvB PBT assessment does not apply

### 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

### 12.7. 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 wastewater and waste disposal measures to prevent occupational exposure

# SAFETY DATA SHEET

Product Name Palonosetron Injection (Hospira, Inc.)  
Revision date 06-Dec-2021

Page 11 / 13  
Version 1.02

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.

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

**UN number:** Not applicable  
**UN proper shipping name:** Not applicable  
**Transport hazard class(es):** Not applicable  
**Packing group:** Not applicable  
**Environmental Hazard(s):** Not applicable  
  
**Special precautions for user:** Not applicable

## Section 15: REGULATORY INFORMATION

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

Palonosetron hydrochloride

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

Water

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

Sodium hydroxide

**CERCLA/SARA Section 313 de minimus %** Not Listed  
**Hazardous Substances RQs** 1000 lb  
**California Proposition 65** Not Listed  
**TSCA** Present  
**EINECS** 215-185-5  
**AICS** Present  
**Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)** Schedule 5  
Schedule 6

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

Disodium EDTA (dihydrate)

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

Citric acid monohydrate

**CERCLA/SARA Section 313 de minimus %** Not Listed

# SAFETY DATA SHEET

Product Name Palonosetron Injection (Hospira, Inc.)  
Revision date 06-Dec-2021

Page 12 / 13  
Version 1.02

<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
<b>AICS</b>	Present
+ Hydrochloric Acid	
<b>CERCLA/SARA Section 313 de minimus %</b>	1.0 %
<b>Hazardous Substances RQs</b>	5000 lb
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-595-7
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 5 Schedule 6

## European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

## Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Sodium hydroxide - 1310-73-2	Use restricted. See item 75.	
+ Hydrochloric Acid - 7647-01-0	Use restricted. See item 75.	

## Persistent Organic Pollutants

Not applicable

## Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Chemical name	Lower-tier requirements (tons)	Upper-tier requirements (tons)
+ Hydrochloric Acid - 7647-01-0	25	250

Chemical name	EU - Biocides
+ Hydrochloric Acid - 7647-01-0	Product-type 2: Disinfectants and algacides not intended for direct application to humans or animals

## Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

## 15.2. Chemical safety assessment

**Chemical Safety Report** No information available

## Section 16: OTHER INFORMATION

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

### Full text of H-Statements referred to under section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage

# SAFETY DATA SHEET

Product Name Palonosetron Injection (Hospira, Inc.)  
Revision date 06-Dec-2021

Page 13 / 13  
Version 1.02

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

**Revision date** 06-Dec-2021

**Prepared By** Pfizer Global Environment, Health, and Safety

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