



SDS Title: Palonosetron Hydrochloride Injection Safety Data Sheet	SDS Number: SDS-000070	Page Number: Page 1 of 14
Function: Regulatory Affairs	Effective Date: September 09, 2022	Version number: 1.0

Section 1. Identification

GHS product identifier : Palonosetron Hydrochloride Injection

Other means of identification : Not available.

Product type : Liquid.

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

Product use : Pharmaceuticals. (For intended use only.)
Observe technical data sheet/instructions for use.
Specific Treatments: Treatment of the nausea and vomiting associated with cancer chemotherapy.

Area of application : Professional applications.

Supplier's details : Meitheal Pharmaceuticals, Inc.
8700 W. Bryn Mawr, Suite 600S
Chicago, IL 60631

Telephone: 224-443-4617
www.meithealpharma.com

e-mail address of person responsible for this SDS : info@meithealpharma.com

Emergency telephone number (with hours of operation) : 844-824-8426 (Monday - Friday, 08:00 - 18:00 CST)

Section 2. Hazards identification

OSHA/HCS status : While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

Classification of the substance or mixture : Not classified.

GHS label elements

Signal word : No signal word.

Hazard statements : No known significant effects or critical hazards.

Precautionary statements

Prevention : Not applicable.

Response : Not applicable.

Storage : Not applicable.

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Section 2. Hazards identification

- Disposal** : Not applicable.
- Hazards not otherwise classified** : None known.

Section 3. Composition/information on ingredients

- Substance/mixture** : Mixture
- Other means of identification** : Not available.

Ingredient name	Other names	%	CAS number
water	Water	≥90	7732-18-5
mannitol	-	≤5	87-78-5
1,2,3-Propanetricarboxylic acid, 2-hydroxy-, sodium salt, hydrate (1:3:2)	Sodium citrate	≤1	6132-04-3
1,2,3-Propanetricarboxylic acid, 2-hydroxy-, hydrate (1:1)	Citric acid hydrous	≤0.3	5949-29-1
Hydrochloric acid	-	≤0.1	7647-01-0
sodium hydroxide	-	≤0.1	1310-73-2
nitrogen	Nitrogen	≤0.1	7727-37-9
disodium dihydrogen ethylenediaminetetraacetate	Edetate Disodium	≤0.1	139-33-3
Palonosetron Hydrochloride	-	≤0.1	149653-99-6

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.

Section 4. First aid measures

Description of necessary first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.
- Skin contact** : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
- Ingestion** : Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Potential acute health effects

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Section 4. First aid measures

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

Over-exposure signs/symptoms

- Eye contact** : No specific data.
- Inhalation** : No specific data.
- Skin contact** : No specific data.
- Ingestion** : No specific data.

Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
- Specific treatments** : No specific treatment.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : Do not use water jet.

Specific hazards arising from the chemical : In a fire or if heated, a pressure increase will occur and the container may burst.

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide

- Special protective actions for fire-fighters** : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

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Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Put on appropriate personal protective equipment.
- For emergency responders** : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

- Environmental precautions** : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

- Small spill** : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.
- Large spill** : Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8).
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

- Conditions for safe storage, including any incompatibilities** : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

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Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
water	None.
mannitol	None.
1,2,3-Propanetricarboxylic acid, 2-hydroxy-, sodium salt, hydrate (1:3:2)	None.
1,2,3-Propanetricarboxylic acid, 2-hydroxy-, hydrate (1:1)	None.
Hydrochloric acid	None. ACGIH TLV (United States, 1/2022). C: 2 ppm NIOSH REL (United States, 10/2020). CEIL: 5 ppm CEIL: 7 mg/m ³ OSHA PEL (United States, 5/2018). CEIL: 5 ppm CEIL: 7 mg/m ³
sodium hydroxide	ACGIH TLV (United States, 1/2022). C: 2 mg/m ³ NIOSH REL (United States, 10/2020). CEIL: 2 mg/m ³ OSHA PEL (United States, 5/2018). TWA: 2 mg/m ³ 8 hours.
nitrogen	ACGIH TLV (United States, 1/2022). Oxygen Depletion [Asphyxiant].
disodium dihydrogen ethylenediaminetetraacetate	None.
Palonosetron Hydrochloride	None.

Appropriate engineering controls

: Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Environmental exposure controls

: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

Hygiene measures

: Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection

: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection

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Section 8. Exposure controls/personal protection

- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

Appearance

- Physical state** : Liquid. [Clear solution.]
- Color** : Colorless.
- Odor** : Not available.
- Odor threshold** : Not available.
- pH** : 4.5 to 5.5
- Melting point** : Not available.
- Boiling point, initial boiling point, and boiling range** : Not available.
- Flash point** : Not available.
- Evaporation rate** : Not available.
- Flammability** : Not available.
- Lower and upper explosion limit/flammability limit** : Not available.

Vapor pressure :

Ingredient name	Vapor Pressure at 20° C			Vapor pressure at 50° C		
	mm Hg	kPa	Method	mm Hg	kPa	Method
water	23.8	3.2		92.258	12.3	

- Relative vapor density** : Not available.
- Relative density** : Not available.
- Density** : 1.0015 to 1.0174 g/cm³ [25°C (77°F)]

Solubility(ies) :

Media	Result
cold water	Easily soluble
hot water	Easily soluble

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Section 9. Physical and chemical properties

Miscible with water	: Yes.
Partition coefficient: n-octanol/water	: Not applicable.
Auto-ignition temperature	: Not available.
Decomposition temperature	: Not available.
SADT	: Not available.
Viscosity	: Not available.
Flow time (ISO 2431)	: Not available.
Particle characteristics	
Median particle size	: Not applicable.
Other information	
Physical/chemical properties comments	: No additional information.

Section 10. Stability and reactivity

Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
Chemical stability	: The product is stable.
Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur. Under normal conditions of storage and use, hazardous polymerization will not occur.
Conditions to avoid	: No specific data.
Incompatible materials	: No specific data.
Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
disodium dihydrogen ethylenediaminetetraacetate	LD50 Oral	Rat	2 g/kg	-

Irritation/Corrosion

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Section 11. Toxicological information

Product/ingredient name	Result	Species	Score	Exposure	Observation
1,2,3-Propanetricarboxylic acid, 2-hydroxy-, hydrate (1:1)	Eyes - Mild irritant	Rabbit	-	0.5 minutes 5 mg	-
Hydrochloric acid	Eyes - Mild irritant	Rabbit	-	0.5 minutes 5 mg	-
sodium hydroxide	Eyes - Mild irritant	Rabbit	-	400 ug	-
	Eyes - Severe irritant	Rabbit	-	1 %	-
	Eyes - Severe irritant	Rabbit	-	0.5 minutes 1 mg	-
	Eyes - Severe irritant	Rabbit	-	24 hours 50 ug	-
	Skin - Severe irritant	Rabbit	-	24 hours 500 mg	-

Sensitization

Not available.

Mutagenicity

Conclusion/Summary : Not available.

Carcinogenicity

Conclusion/Summary : Not available.

Classification

Product/ingredient name	OSHA	IARC	NTP
Hydrochloric acid	-	3	-

Reproductive toxicity

Conclusion/Summary : Not available.

Teratogenicity

Conclusion/Summary : Not available.

Specific target organ toxicity (single exposure)

Name	Category	Route of exposure	Target organs
Hydrochloric acid	Category 3	-	Respiratory tract irritation
sodium hydroxide	Category 3	-	Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

Name	Category	Route of exposure	Target organs
disodium dihydrogen ethylenediaminetetraacetate	Category 2	inhalation	respiratory tract

Aspiration hazard

Not available.

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Section 11. Toxicological information

Information on the likely routes of exposure : Not available.

Potential acute health effects

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No specific data.

Inhalation : No specific data.

Skin contact : No specific data.

Ingestion : No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Long term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Potential chronic health effects

General : No known significant effects or critical hazards.

Carcinogenicity : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

Reproductive toxicity : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapors) (mg/l)	Inhalation (dusts and mists) (mg/l)
disodium dihydrogen ethylenediaminetetraacetate	2000	N/A	N/A	N/A	1.5

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Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
Hydrochloric acid	Acute LC50 240000 µg/l Marine water	Crustaceans - Carcinus maenas - Adult	48 hours
sodium hydroxide	Acute LC50 282 ppm Fresh water Acute EC50 40.38 mg/l Fresh water	Fish - Gambusia affinis - Adult Crustaceans - Ceriodaphnia dubia - Neonate	96 hours 48 hours
disodium dihydrogen ethylenediaminetetraacetate	Acute LC50 125 ppm Fresh water Chronic NOEC 25 mg/l	Fish - Gambusia affinis - Adult Daphnia	96 hours 21 days

Conclusion/Summary : Not available.

Persistence and degradability

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
1,2,3-Propanetricarboxylic acid, 2-hydroxy-, sodium salt, hydrate (1:3:2)	-	-	Readily
1,2,3-Propanetricarboxylic acid, 2-hydroxy-, hydrate (1:1)	-	-	Readily
disodium dihydrogen ethylenediaminetetraacetate	-	-	Not readily

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
water	-1.38	-	low
1,2,3-Propanetricarboxylic acid, 2-hydroxy-, hydrate (1:1)	-1.72	-	low
nitrogen	0.67	-	low
disodium dihydrogen ethylenediaminetetraacetate	-4.3	1.8	low

Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

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Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	No.	No.	No.

Additional information

Special precautions for user : **Transport within user’s premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to IMO instruments : Not available.

Section 15. Regulatory information

U.S. Federal regulations : **TSCA 8(a) CDR Exempt/Partial exemption:** Not determined
United States inventory (TSCA 8b): Not determined.
Clean Water Act (CWA) 311: Hydrochloric acid; sodium hydroxide

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Listed

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Section 15. Regulatory information

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

Name	%	EHS	SARA 302 TPQ		SARA 304 RQ	
			(lbs)	(gallons)	(lbs)	(gallons)
Hydrochloric acid	≤0.1	Yes	500	50.6	5000	506.5

SARA 304 RQ : 5555555.6 lbs / 2522222.2 kg [660063 gal / 2498610.4 L]

SARA 311/312

Classification : Not applicable.

Composition/information on ingredients

Name	%	Classification
1,2,3-Propanetricarboxylic acid, 2-hydroxy-, sodium salt, hydrate (1:3:2)	≤1	COMBUSTIBLE DUSTS
1,2,3-Propanetricarboxylic acid, 2-hydroxy-, hydrate (1:1)	≤0.3	EYE IRRITATION - Category 2A
Hydrochloric acid	≤0.1	SKIN CORROSION - Category 1B SERIOUS EYE DAMAGE - Category 1 SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3 HNOC - Corrosive to digestive tract
sodium hydroxide	≤0.1	CORROSIVE TO METALS - Category 1 SKIN CORROSION - Category 1A SERIOUS EYE DAMAGE - Category 1 SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3 HNOC - Corrosive to digestive tract [severe]
nitrogen	≤0.1	GASES UNDER PRESSURE - Compressed gas SIMPLE ASPHYXIANTS
disodium dihydrogen ethylenediaminetetraacetate	≤0.1	ACUTE TOXICITY (oral) - Category 4 ACUTE TOXICITY (inhalation) - Category 4 SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2

SARA 313



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Section 15. Regulatory information

Not applicable.

State regulations

Massachusetts : None of the components are listed.

New York : None of the components are listed.

New Jersey : None of the components are listed.

Pennsylvania : None of the components are listed.

California Prop. 65

This product does not require a Safe Harbor warning under California Prop. 65.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Section 16. Other information

Hazardous Material Information System (U.S.A.)

Health	/	0
Flammability		0
Physical hazards		0

Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings and the associated label are not required on SDSs or products leaving a facility under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered trademark and service mark of the American Coatings Association, Inc.

The customer is responsible for determining the PPE code for this material. For more information on HMIS® Personal Protective Equipment (PPE) codes, consult the HMIS® Implementation Manual.

National Fire Protection Association (U.S.A.)

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Section 16. Other information



Procedure used to derive the classification

Classification	Justification
Not classified.	

History

- Date of issue/Date of revision** : 09/09/2022
- Date of previous issue** : No previous validation
- Version** : 1.0
- Prepared by** : Sphera Solutions
- Key to abbreviations** :
 - ATE = Acute Toxicity Estimate
 - AMP = Acceptable maximum peak above the acceptable ceiling concentration for an 8-hr shift
 - BCF = Bioconcentration Factor
 - GHS = Globally Harmonized System of Classification and Labelling of Chemicals
 - IATA = International Air Transport Association
 - IBC = Intermediate Bulk Container
 - IMDG = International Maritime Dangerous Goods
 - LogPow = logarithm of the octanol/water partition coefficient
 - MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
 - N/A = Not available
 - UN = United Nations
- References** :
 - HCS (U.S.A.)- Hazard Communication Standard
 - International transport regulations

Indicates information that has changed from previously issued version.

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.