


 <b>Pharmaceutical Division</b>	<b>Palonosetron Hydrochloride Injection</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: 06DEC2022	SDS No.: SDS056	Revision No: 01	Page 1 of 8

### Section 1 - Identification

- (a) **Product Identifier:** Palonosetron Hydrochloride Injection
- (b) **Product Code:** 70860-785
- Common/Trade Name:** Palonosetron Hydrochloride Injection
- Chemical Name:** (3aS)-2-[(S)-1-Azabicyclo [2.2.2]oct-3-yl]-2,3,3a,4,5,6-hexahydro-1-oxo-1Hbenz[de]isoquinoline hydrochloride
- Chemical Family:** Antiemetic and Antinauseant agent
- (c) **Product Use:** Prevention of chemotherapy induced nausea and vomiting and postoperative nausea and vomiting
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Athenex Pharmaceutical Division, 10 N. Martingale Road, Suite 230, Schaumburg, IL 60173, 847-886-9515
- (e) **Emergency Telephone:** 855-273-0154

### Section 2 - Hazards Identification

<b>Classification:</b>	GHS Classifications: Acute oral toxicity (Category 4) Acute aquatic toxicity (Category 1) Chronic aquatic toxicity (Category 1)
<b>Signal Word:</b>	Warning
<b>Hazard Statement</b>	H302 - Harmful if swallowed. (Category 4) H400 - Acute aquatic toxicity (Category 1) H410 - Very toxic to aquatic life with long lasting effects (Category 1).
<b>Symbols</b>	 

 <b>Pharmaceutical Division</b>	<b>Palonosetron Hydrochloride Injection</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: 06DEC2022	SDS No.: SDS056	Revision No: 01	Page 2 of 8

<b>Precautionary Statement(s)</b>	<b><u>GHS Precautionary Statements:</u></b> P264 - Wash skin thoroughly after handling P270 - Do not eat, drink or smoke when using this product. P273 - Avoid release to the environment. P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. P330 - Rinse mouth. P391 - Collect spillage. P501 - Dispose of contents/ container to an approved waste disposal plant.
<b>Unknown Acute Toxicity</b>	N/A

### Section 3 – Composition / Information on Ingredients

<b>Chemical Name</b>	<b>Common Name / Synonym</b>	<b>% Composition or other measure</b>	<b>CAS No.</b>	<b>Impurities / Stabilizing Additives</b>
Palonosetron Hydrochloride	Palonosetron Hydrochloride	0.056 mg/mL	135729-62-3	N/A
Mannitol USP	Mannitol USP	41.5 mg/mL	69-65-8	N/A
Edetate Disodium USP	Edetate Disodium USP	0.5 mg/mL	6381-92-6	N/A
Sodium Citrate USP	Sodium Citrate USP	3.7 mg/mL	6132-04-3	N/A
Citric Acid Monohydrate USP	Citric Acid Monohydrate USP	1.56 mg/mL	5949-29-1	N/A
Sodium Hydroxide NF	Sodium Hydroxide NF	q.s. for pH adjustment	1310-73-2	N/A
Hydrochloric acid NF	Hydrochloric acid NF	q.s. for pH adjustment	7647-01-0	N/A
Water for Injection USP	Water for Injection USP	q.s. to 1 mL	7732-18-5	N/A
Nitrogen NF <sup>1</sup>	Nitrogen NF	q.s.	7727-37-9	N/A


*Notes:*

*\*0.056 mg Palonosetron Hydrochloride is equivalent to 0.05 mg of Palonosetron base.*

*\*This quantity is theoretical and actual quantities may change based on the assay on as basis of Palonosetron Hydrochloride.*

*1 Nitrogen is used as a processing aid during manufacture.*

q.s. = quantity sufficient

 <b>Pharmaceutical Division</b>	<b>Palonsetron Hydrochloride Injection</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: 06DEC2022	SDS No.: SDS056	Revision No: 01	Page 3 of 8

#### Section 4 – First Aid Measures


<b>Eye Exposure:</b>	Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Consult a doctor.
<b>Skin Exposure:</b>	Remove from source of exposure. Flush with water for at least 15 minutes while removing contaminated clothing and shoes. If irritation persists or signs of toxicity occurs seek medical attention.
<b>Ingestion:</b>	Do NOT induce vomiting. If conscious and alert, rinse mouth and drink 2-4 cups of milk or water. Consult a doctor.
<b>Injection:</b>	See patient package insert in shipping carton for complete information.
<b>Inhalation:</b>	Remove from exposure and move to fresh air immediately. Consult a doctor.
<b>Notes to Physician:</b>	See patient package insert in shipping carton for complete information.

#### Section 5 – Fire-fighting Measures

- |  |  |
|--|--|
| (a) <b>Extinguishing Media</b>                         | As with any fire, use extinguishing media appropriate for primary cause of fire.   |
| (b) <b>Hazardous Decomposition Products:</b>           | None anticipated for this product. Avoid the creation of dusty atmospheres.  |
| (c) <b>Special Protective Equipment / Precautions:</b> | No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self-contained breathing apparatus |

#### Section 6 - Accidental Release Measures

**Spill:** Clean up spills immediately, observing precautions in the Protective Equipment section. Sweep up, then place into a suitable container for disposal. Decontaminate spill site with 10% caustic solution and ventilate area until after disposal is complete.

 <b>Pharmaceutical Division</b>	<b>Palonosetron Hydrochloride Injection</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: 06DEC2022	SDS No.: SDS056	Revision No: 01	Page 4 of 8

**Release to Air:** Avoid breathing vapors, mist, dust or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

**Release to Water:** Try to prevent the material from entering drains or water courses

### Section 7 - Handling and Storage

**General Handling:** Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Avoid contact with eyes, skin, and clothing. Avoid ingestion and inhalation. Keep away from sources of ignition. Avoid prolonged or repeated exposure.

**Storage Conditions:** Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F). [See USP Controlled Room Temperature.]  
Do not freeze.  
Protect from light. Retain in carton until time of use.

### Section 8 - Exposure Controls / Personal Protection

**(a) Exposure Limits:**


Compound	Issuer	Type	Exposure Limit
Palonosetron hydrochloride	N/A	N/A	This product does not contain any hazardous materials with occupational exposure limits established by region-specific regulatory bodies.

**(b) Engineering Controls**

Use adequate general or local exhaust ventilation to keep airborne concentrations below the permissible exposure limits. Use process enclosure, local exhaust ventilation, or other engineering controls to control airborne levels.

**(c) Individual Protection Measures**

Respiratory Protection:	Dust respirator. Follow local and national regulations.
Eye Protection:	Wear safety glasses and chemical goggles if splashing is possible.
Skin Protection:	Wear appropriate protective gloves and clothing to prevent skin exposure.


 <b>Pharmaceutical Division</b>	<b>Palonsetron Hydrochloride Injection</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: 06DEC2022	SDS No.: SDS056	Revision No: 01	Page 5 of 8

### Section 9 - Physical and Chemical Properties

(a)	<b>Appearance</b>	Clear, colorless solution
(b)	<b>Odor</b>	Odorless
(c)	<b>Odor Threshold</b>	Not available
(d)	<b>pH</b>	4.5 to 5.5
(e)	<b>Melting Point:</b>	Not available
(f)	<b>Initial Boiling Point:</b>	100°C (212°F)
(g)	<b>Flash Point</b>	Not available
(h)	<b>Evaporation Rate:</b>	Not available
(i)	<b>Flammability</b>	Not available
(j)	<b>Upper Lower Flammability or Explosion Limits</b>	Not available
(k)	<b>Vapor Pressure:</b>	Similar to water
(l)	<b>Vapor Density:</b>	Similar to water
(m)	<b>Relative Density</b>	1
(n)	<b>Solubility(ies)</b>	Soluble in water
(o)	<b>Partition Coefficient: n-octanol/water</b>	Not available
(p)	<b>Auto-ignition Temperature</b>	Not available
(q)	<b>Decomposition Temperature</b>	Not available
(r)	<b>Viscosity</b>	Not available

### Section 10 - Stability and Reactivity

(a)	<b>Reactivity</b>	Stable under normal conditions of use.
(b)	<b>Chemical Stability</b>	Stable at normal temperatures and pressures
(c)	<b>Possibility of Hazardous Reactions</b>	Not know to occur
(d)	<b>Conditions to Avoid</b>	Strong oxidants and heat.
(e)	<b>Incompatible Materials</b>	Strong oxidizing/reducing agents, strong acids/alkalis.
(f)	<b>Hazardous Decomposition Products</b>	Nitrogen oxides, carbon monoxide, irritating and toxic fumes and gases, carbon dioxide, nitrogen.

 <b>Pharmaceutical Division</b>	<b>Palonsetron Hydrochloride Injection</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: 06DEC2022	SDS No.: SDS056	Revision No: 01	Page 6 of 8

**Section 11 - Toxicological Information**

<b>(a)</b>	<b>Likely Routes of Exposure</b>	Ingestion, Inhalation, skin, eye
<b>(b)</b>	<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	No known significant effects or critical hazards
<b>(c)</b>	<b>Delayed and immediate effects and also chronic effects from short and long term exposure</b>	Headache and constipation. Major signs of overdose are convulsion, gasping, pallor, cyanosis and collapse.

**(d) Acute Toxicity**

Oral LD<sub>50</sub> in rats is 500 mg/kg

**(e) Hazardous Chemical Listings**

NTP: Not Listed      NTP: Not Listed      OSHA: Not Listed      NIOSH: Not Listed

**Section 12 - Ecological Information**


<b>(a)</b>	<b>Ecotoxicity</b>	No applicable ecological information found.
<b>(b)</b>	<b>Persistence and degradability</b>	No applicable ecological information found.
<b>(c)</b>	<b>Bioaccumulative potential</b>	No applicable ecological information found.
<b>(d)</b>	<b>Mobility in soil</b>	No applicable ecological information found.
<b>(e)</b>	<b>Other Adverse Effects</b>	No applicable ecological information found.

**Section 13 - Disposal Considerations**

**Waste Disposal:** To avoid accidental exposure due to waste handling, place waste residue in a segregated, sealed plastic container. Used syringes, needles, and sharps should not be crushed, clipped, or recapped, but placed directly into an approved sharps container. Dispose of any cleanup materials and waste residue per all applicable laws and regulations, e.g., secure chemical landfill disposal.

**Section 14 - Transport Information**

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

 <b>Pharmaceutical Division</b>	<b>Palonsetron Hydrochloride Injection</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: 06DEC2022	SDS No.: SDS056	Revision No: 01	Page 7 of 8

### Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Athenex Pharmaceutical Division usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

#### U.S. Regulations:

**TSCA** – Not on this list

**CERCLA** - Not on this list

**SARA 313** - This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**SARA 302** – No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302

**SARA 311/312:** No SARA Hazards

**RCRA listed** – Not listed

**California Proposition 65** – This product does not contain any chemicals known to State of California to cause cancer, birth defects, or another reproductive harm.

### Section 16 - Other Information


As of the date of effectiveness, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Athenex Pharmaceutical Division  
 10 N. Martingale Road, Suite 230  
 Schaumburg, IL 60173  
 847-886-9515

**Glossary:** This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number

 <b>Pharmaceutical Division</b>	<b>Palonsetron Hydrochloride Injection</b>		<b>Safety Data Sheet (SDS)</b>	
	Effective Date: 06DEC2022	SDS No.: SDS056	Revision No: 01	Page 8 of 8

CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System