

Palonosetron Formulation

Version 1.9 Revision Date: 30.09.2023 SDS Number: 4720325-00010 Date of last issue: 04.04.2023
Date of first issue: 02.08.2019

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Palonosetron Formulation

Manufacturer or supplier's details

Company name of supplier : MSD
Address : Avenida 16 de Septiembre No. 301
Xaltocan - Xochimilco Mexico 16090
Telephone : +52 55 57284444
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Not a hazardous substance or mixture.

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Palonosetron Hydrochloride	135729-62-3	< 0.1

SECTION 4. FIRST AID MEASURES

If inhaled : If inhaled, remove to fresh air.
Get medical attention if symptoms occur.

In case of skin contact : Wash with water and soap as a precaution.
Get medical attention if symptoms occur.

In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : None known.

Protection of first-aiders : No special precautions are necessary for first aid responders.

Notes to physician : Treat symptomatically and supportively.

Palonosetron Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.9	30.09.2023	4720325-00010	Date of first issue: 02.08.2019

SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.
- Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.
Use personal protective equipment.
-

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g., by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material.
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
-

SECTION 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE
-

Palonosetron Formulation

Version 1.9 Revision Date: 30.09.2023 SDS Number: 4720325-00010 Date of last issue: 04.04.2023
Date of first issue: 02.08.2019

		CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	:	Use only with adequate ventilation.
Advice on safe handling	:	Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Take care to prevent spills, waste and minimize release to the environment.
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
Conditions for safe storage	:	Keep in properly labeled containers. Store in accordance with the particular national regulations.
Materials to avoid	:	Do not store with the following product types: Strong oxidizing agents Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Palonosetron Hydrochloride	135729-62-3	TWA	0.4 µg/m ³ (OEB 5)	Internal
		Wipe limit	4 µg/100 cm ²	Internal

Engineering measures : Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace.
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
No open handling permitted.
Totally enclosed processes and materials transport systems are required.
Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection

Palonosetron Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.9	30.09.2023	4720325-00010	Date of first issue: 02.08.2019

Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
Eye protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	:	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	Aqueous solution
Color	:	clear
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	4.5 - 5.5
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	1.015 g/cm ³

Palonosetron Formulation

Version 1.9 Revision Date: 30.09.2023 SDS Number: 4720325-00010 Date of last issue: 04.04.2023
Date of first issue: 02.08.2019

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity
Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION**Information on likely routes of exposure**

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:**Palonosetron Hydrochloride:**

Acute oral toxicity : LDLo (Rat): 250 mg/kg
LDLo (Mouse): 100 mg/kg
LDLo (Dog): 50 mg/kg

Palonosetron Formulation

Version 1.9 Revision Date: 30.09.2023 SDS Number: 4720325-00010 Date of last issue: 04.04.2023
Date of first issue: 02.08.2019

Skin corrosion/irritation

Not classified based on available information.

Components:**Palonosetron Hydrochloride:**

Remarks : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Components:**Palonosetron Hydrochloride:**

Genotoxicity in vitro : Test Type: Ames test
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster ovary cells
Result: negative

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster cells
Result: positive

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Mouse
Result: negative

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

Components:**Palonosetron Hydrochloride:**

Effects on fertility : Test Type: Fertility
Species: Rat, male
Application Route: Intravenous

Palonosetron Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.9	30.09.2023	4720325-00010	Date of first issue: 02.08.2019

Fertility: NOAEL: 10 mg/kg body weight
Symptoms: No adverse effects.

Test Type: Fertility
Species: Rat
Application Route: Oral
Fertility: NOAEL: > 30 mg/kg body weight
Symptoms: No effects on fertility.

Effects on fetal development : Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 18 mg/kg body weight
Embryo-fetal toxicity.: LOAEL: > 60 mg/kg body weight
Symptoms: Reduced body weight, No effects on fetal development., Reduced fetal weight.

Test Type: Development
Species: Rabbit
Application Route: Oral
General Toxicity Maternal: LOAEL: 120 mg/kg body weight
Developmental Toxicity: NOAEL: 90 mg/kg body weight
Symptoms: No effects on fetal development.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Components:**Palonosetron Hydrochloride:**

Routes of exposure : Ingestion
Target Organs : Gastrointestinal tract, Kidney, Central nervous system, Testis
Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity**Components:****Palonosetron Hydrochloride:**

Species : Mouse
NOAEL : 60 mg/kg
LOAEL : 150 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : Kidney, male reproductive organs
Remarks : May cause damage to organs.

Species : Rat
NOAEL : 18 mg/kg
LOAEL : > 60 mg/kg
Application Route : Oral

Palonosetron Formulation

Version 1.9 Revision Date: 30.09.2023 SDS Number: 4720325-00010 Date of last issue: 04.04.2023
 Date of first issue: 02.08.2019

Exposure time : 3 Months
 Target Organs : male reproductive organs, Liver
 Remarks : Significant toxicity observed in testing

Species : Dog
 LOAEL : 20 mg/kg
 Application Route : Oral
 Exposure time : 3 Months
 Target Organs : Central nervous system, Testis
 Remarks : Significant toxicity observed in testing

Species : Rat
 NOAEL : 7 mg/kg
 Application Route : Intravenous
 Exposure time : 6 Months
 Target Organs : Central nervous system, Gastrointestinal tract
 Remarks : Significant toxicity observed in testing

Species : Dog
 NOAEL : 6 mg/kg
 Application Route : Intravenous
 Exposure time : 9 Months
 Target Organs : Central nervous system, Gastrointestinal tract
 Symptoms : Vomiting
 Remarks : Significant toxicity observed in testing

Aspiration toxicity

Not classified based on available information.

Components:

Palonosetron Hydrochloride:

Not applicable

Experience with human exposure

Components:

Palonosetron Hydrochloride:

Ingestion : Symptoms: The most common side effects are:, Headache, Diarrhea, Dizziness, Weakness, anxiety

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Palonosetron Hydrochloride:

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic effects cannot be excluded, No data available

Chronic aquatic toxicity : Toxic effects cannot be excluded, No data available

Palonosetron Formulation

Version 1.9 Revision Date: 30.09.2023 SDS Number: 4720325-00010 Date of last issue: 04.04.2023
Date of first issue: 02.08.2019

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.
Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

NOM-002-SCT

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills. : Not applicable

The ingredients of this product are reported in the following inventories:

Palonosetron Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.9	30.09.2023	4720325-00010	Date of first issue: 02.08.2019

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

SECTION 16. OTHER INFORMATION

Revision Date	:	30.09.2023
Date format	:	dd.mm.yyyy

Full text of other abbreviations

AllC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECl - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to compile the Material Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/
--	---	---

SAFETY DATA SHEET



Palonosetron Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.9	30.09.2023	4720325-00010	Date of first issue: 02.08.2019

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8