

# **Palonosetron Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 1.10
 28.09.2024
 4720325-00011
 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 : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000 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.

Wash with water and soap as a precaution.

In case of skin contact : Wash with water and soap as a precaution

Get medical attention if symptoms occur. Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

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

and effects, both acui

In case of eye contact

None known.

delayed

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

Notes to physician : Treat symptomatically and supportively.



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## **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 prod: :

ucts

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 emer-

gency 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



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certain local or national requirements.

#### **SECTION 7. HANDLING AND STORAGE**

Technical measures : See Engineering measures under EXPOSURE

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	Control parame-	Basis
		(Form of	ters / Permissible	
		exposure)	concentration	
Palonosetron Hydrochloride	135729-62-3	TWA	0.4 μg/m3 (OEB	Internal
-			5)	
		Wipe limit	4 μg/100 cm <sup>2</sup>	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



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Respiratory protection If adequate local exhaust ventilation is not available or

exposure assessment demonstrates exposures outside the

recommended guidelines, use respiratory protection.

Filter type

Hand protection

Particulates type

Material Chemical-resistant gloves

Remarks Consider double gloving.

Wear safety glasses with side shields or goggles. Eye protection

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

No data available Odor

Odor Threshold No data available

рΗ 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



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Not applicable

Relative vapor density No data available

Relative density No data available

Density 1.015 g/cm<sup>3</sup>

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

Autoignition temperature

octanol/water

No data available

No data available Decomposition temperature

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 characteristics

Particle size Not applicable

## **SECTION 10. STABILITY AND REACTIVITY**

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions. Can react with strong oxidizing agents.

Possibility of hazardous reac- :

tions

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



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LDLo (Mouse): 100 mg/kg

LDLo (Dog): 50 mg/kg

#### 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 syn-

thesis 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.



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#### **Components:**

#### Palonosetron Hydrochloride:

Effects on fertility : Test Type: Fertility

Species: Rat, male

Application Route: Intravenous

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 devel-

opment., 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



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Target Organs : Kidney, male reproductive organs Remarks : May cause damage to organs.

Species: RatNOAEL: 18 mg/kgLOAEL: > 60 mg/kgApplication Route: OralExposure 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



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#### **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

#### 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



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## 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, : Not applicable essential chemical products and machinery for

producing capsules, tablets and pills.

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

AICS : not determined

DSL : not determined

IECSC : not determined

# **SECTION 16. OTHER INFORMATION**

Revision Date : 28.09.2024 Date format : dd.mm.yyyy

## Full text of other abbreviations

AIIC - 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; KECI - 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; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Sub-



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stances 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 Agen-

cy, http://echa.europa.eu/

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