

Palonosetron Formulation

Version 1.9 Revision Date: 30.09.2023 SDS Number: 4720323-00010 Date of last issue: 04.04.2023
Date of first issue: 02.08.2019

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Palonosetron Formulation

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number : +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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

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 which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

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

4. FIRST AID MEASURES

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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.

5. FIREFIGHTING 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 firefighters : Wear self-contained breathing apparatus for firefighting if necessary.
Use personal protective equipment.

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 dyking or other appropriate containment to keep material from spreading. If dyked material can

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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.

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.
- Conditions for safe storage : Keep in properly labelled containers.
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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 rec-

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| | | |
|--------------------------|---|--|
| Filter type | : | ommended guidelines, use respiratory protection. |
| Hand protection | : | Particulates type |
| 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. |
| 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. |

9. PHYSICAL AND CHEMICAL PROPERTIES

| | | |
|---|---|-------------------|
| Appearance | : | Aqueous solution |
| Colour | : | clear |
| Odour | : | No data available |
| Odour 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 |

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Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : 1.015 g/cm³

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Auto-ignition 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

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.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

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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

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 sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

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

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

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Components:

Palonosetron Hydrochloride:

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

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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
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

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Experience with human exposure

Components:

Palonosetron Hydrochloride:

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

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

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.

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

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Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

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

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

| | | |
|-------|---|----------------|
| AICS | : | not determined |
| DSL | : | not determined |
| IECSC | : | not determined |

16. OTHER INFORMATION

Revision Date : 30.09.2023

Further information

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

Date format : dd.mm.yyyy

Full text of other abbreviations

AIC - 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 Develop-

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ment; 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 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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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