

**Palonosetron Formulation**

Version 2.1      Revision Date: 2023/09/30      SDS Number: 4720322-00010      Date of last issue: 2023/04/04  
Date of first issue: 2019/08/02

---

**1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Palonosetron Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : JL Raya Pandaan KM. 48  
Pandaan, Jawa Timur - Indonesia

Telephone : 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****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 | < 10                  |

---

**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.

## Palonosetron Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 4720322-00010 | Date of first issue: 2019/08/02 |

---

|   |   |   |
|---|---|---|
| In case of eye contact                                      | : | Get medical attention if symptoms occur.<br>Flush eyes with water as a precaution.  |
| If swallowed  | : | Get medical attention if irritation develops and persists.<br>If swallowed, DO NOT induce vomiting.<br>Get medical attention if symptoms occur.<br>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<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>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.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for firefighters | : | Wear self-contained breathing apparatus for firefighting if necessary.<br>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.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g. by containment or oil barriers).<br>Retain and dispose of contaminated wash water.<br>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.<br>For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.   |

## Palonosetron Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 4720322-00010 | Date of first issue: 2019/08/02 |

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<br>(Form of exposure) | Control parameters / Permissible concentration | Basis    |
|----------------------------|-------------|----------------------------------|--|----------|
| Palonosetron Hydrochloride | 135729-62-3 | TWA                              | 0.4 µg/m <sup>3</sup> (OEB 5)                  | Internal |
|                            |             | 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

- Respiratory protection : If adequate local exhaust ventilation is not available or expo-

## Palonosetron Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 4720322-00010 | Date of first issue: 2019/08/02 |

---

sure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection

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

**Palonosetron Formulation**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 4720322-00010 | Date of first issue: 2019/08/02 |

---

|  |   |  |
|--|---|--|
| Flammability (liquids)                           | : | No data available  |
| 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/cm <sup>3</sup>                                  |
| 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**

**Palonosetron Formulation**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 4720322-00010 | Date of first issue: 2019/08/02 |

---

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

**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

## Palonosetron Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 4720322-00010 | Date of first issue: 2019/08/02 |

---

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  
 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.

## Palonosetron Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 4720322-00010 | Date of first issue: 2019/08/02 |

---

### 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.

### 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



**Palonosetron Formulation**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 4720322-00010 | Date of first issue: 2019/08/02 |

---

**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, 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.

---

## Palonosetron Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 4720322-00010 | Date of first issue: 2019/08/02 |

---

---

**14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

|                      |   |                |
|----------------------|---|----------------|
| UN number            | : | Not applicable |
| Proper shipping name | : | Not applicable |
| Class                | : | Not applicable |
| Subsidiary risk      | : | Not applicable |
| Packing group        | : | Not applicable |
| Labels               | : | Not applicable |

**IATA-DGR**

|  |   |                |
|--|---|----------------|
| UN/ID No.                                | : | Not applicable |
| Proper shipping name                     | : | Not applicable |
| Class                                    | : | Not applicable |
| Subsidiary risk                          | : | Not applicable |
| Packing group                            | : | Not applicable |
| Labels                                   | : | Not applicable |
| Packing instruction (cargo aircraft)     | : | Not applicable |
| Packing instruction (passenger aircraft) | : | Not applicable |

**IMDG-Code**

|                      |   |                |
|----------------------|---|----------------|
| UN number            | : | Not applicable |
| Proper shipping name | : | Not applicable |
| Class                | : | Not applicable |
| Subsidiary risk      | : | Not applicable |
| Packing group        | : | Not applicable |
| Labels               | : | Not applicable |
| EmS Code             | : | Not applicable |
| Marine pollutant     | : | Not applicable |

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

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**

**Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.**

**Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health**

Hazardous substances that must be registered : Not applicable

---

## Palonosetron Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 4720322-00010 | Date of first issue: 2019/08/02 |

---

**Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances**

Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

**Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials**

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

**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 : 2023/09/30

**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 : yyyy/mm/dd

**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

**Palonosetron Formulation**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2023/04/04  |
| 2.1     | 2023/09/30     | 4720322-00010 | Date of first issue: 2019/08/02 |

---

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 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.

ID / EN