according to GB/T 16483 and GB/T 17519



## **Palonosetron Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 2.0 2024/09/28 4720320-00012 Date of first issue: 2019/08/02

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Palonosetron Formulation

Manufacturer or supplier's details

Company : MSD

Address : 199 Wenhai North Road

HEDA, Hangzhou - Zhejiang Province - CHINA 310018

Telephone : 908-740-4000

Emergency telephone number : 86-571-87268110

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

### **Emergency Overview**

**Appearance** : Aqueous solution

Colour : clear

Odour : No data available

Not a hazardous substance or mixture.

# **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.

### Physical and chemical hazards

Not classified based on available information.

### **Health hazards**

Not classified based on available information.

### **Environmental hazards**

Not classified based on available information.

according to GB/T 16483 and GB/T 17519



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#### 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

In case of skin contact

If inhaled : If inhaled, remove to fresh air.

> Get medical attention if symptoms occur. : 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

Protection of first-aiders Notes to physician

None known.

No special precautions are necessary for first aid responders.

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 prod: :

ucts

Carbon oxides

Specific extinguishing meth-

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.

according to GB/T 16483 and GB/T 17519



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Special protective equipment :

for firefighters

Wear self-contained breathing apparatus for firefighting if nec-

essary.

Use personal protective equipment.

#### **6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures

Follow safe handling advice (see section 7) and personal pro-

tective 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 be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-

bent.

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

### 7. HANDLING AND STORAGE

Handling

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 as-

sessment

Take care to prevent spills, waste and minimize release to the

environment.

Avoidance of contact : Oxidizing agents

Storage

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:

according to GB/T 16483 and GB/T 17519



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Strong oxidizing agents

Packaging material : Unsuitable material: None known.

#### 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/m3 (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 pre-

vent 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-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type : Particulates type

Eye/face 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, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Hygiene measures : If exposure to chemical is likely during typical use, provide

according to GB/T 16483 and GB/T 17519



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eye flushing systems and safety showers close to the work-

ing 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

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

according to GB/T 16483 and GB/T 17519



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Partition coefficient: n-

octanol/water

Auto-ignition temperature

Not applicable

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 characteristics

Particle size Not applicable

### 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.

#### 11. TOXICOLOGICAL INFORMATION

Exposure routes 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.

according to GB/T 16483 and GB/T 17519



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#### **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 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.

### Components:

### Palonosetron Hydrochloride:

Effects on fertility : Test Type: Fertility

Species: Rat, male

according to GB/T 16483 and GB/T 17519



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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 develop-

ment

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 devel-

opment, 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.

### 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.

according to GB/T 16483 and GB/T 17519



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 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: DogLOAEL: 20 mg/kgApplication Route: OralExposure 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,

Diarrhoea, Dizziness, Weakness, anxiety

according to GB/T 16483 and GB/T 17519



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#### 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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

### 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

Environmentally hazardous : n

IATA-DGR

UN/ID No. : Not applicable Proper shipping name : Not applicable

according to GB/T 16483 and GB/T 17519



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Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo : Not applicable

aircraft)

Packing instruction (passen: Not applicable

ger aircraft)

**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 : no

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

Not applicable for product as supplied.

### **National Regulations**

GB 6944/12268

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

Marine pollutant : no

Special precautions for user

Not applicable

#### 15. REGULATORY INFORMATION

#### **National regulatory information**

Law on the Prevention and Control of Occupational Diseases

### Regulations on Safety Management of Hazardous Chemicals

Catalogue of Hazardous Chemicals : This product is not listed in the cata-

logue of hazardous chemicals and it does not meet the definition of hazardous chemicals and its principles

of determination.

Identification of Major Hazard Installations for Hazardous Chemicals (GB : Not listed

18218)

Hazardous Chemicals for Priority Management under : Not listed

according to GB/T 16483 and GB/T 17519



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SAWS

Regulations on Labour Protection in Workplaces where Toxic Substances are Used

Catalogue of Highly Toxic Chemicals : Not listed

Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

China Severely Restricted Toxic Chemicals for Import : Not listed

and Export

**Regulation on the Administration of Precursor Chemicals** 

Catalogue and Classification of Precursor Chemicals : Not listed

Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

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** 2024/09/28

**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 Agen-

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

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : yyyy/mm/dd

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

according to GB/T 16483 and GB/T 17519



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- 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 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

### **Disclaimer**

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.

CN / EN