according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Palonosetron Formulation**

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# SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Palonosetron Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub- : Pharmaceutical

stance/Mixture

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

Piercetown

A86 HD21 Dunboyne, Ireland

Telephone : 908-740-4000

E-mail address of person

responsible for the SDS

: EHSDATASTEWARD@msd.com

### 1.4 Emergency telephone number

1-908-423-6000

#### **SECTION 2: Hazards identification**

### 2.1 Classification of the substance or mixture

# Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

#### 2.2 Label elements

# Labelling (REGULATION (EC) No 1272/2008)

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

#### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

# **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Palonosetron Hydrochloride	135729-62-3	STOT RE 2; H373 (Gastrointestinal tract, Kidney, Central nervous system, Tes- tis)	< 0.1

For explanation of abbreviations see section 16.

#### **SECTION 4: First aid measures**

### 4.1 Description of first aid measures

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

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, DO NOT induce vomiting.

Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

# 4.2 Most important symptoms and effects, both acute and delayed

None known.

# 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

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# **SECTION 5: Firefighting measures**

5.1 Extinguishing media

Suitable extinguishing media : Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

5.2 Special hazards arising from the substance or mixture

fighting

Specific hazards during fire- : Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- : Carbon oxides

ucts

5.3 Advice for firefighters

Special protective equipment:

for firefighters

Wear self-contained breathing apparatus for firefighting if nec-

essary. Use personal protective equipment.

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

Evacuate area.

### **SECTION 6: Accidental release measures**

### 6.1 Personal precautions, protective equipment and emergency procedures

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

tective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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.

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

# **SECTION 7: Handling and storage**

#### 7.1 Precautions for safe 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.

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 contami-

nated 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.

# 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

: Keep in properly labelled containers. Store in accordance with

the particular national regulations.

Advice on common storage : Do not store with the following product types:

Strong oxidizing agents

Gases

7.3 Specific end use(s)

Specific use(s) : No data available

# **SECTION 8: Exposure controls/personal protection**

### 8.1 Control parameters

**Occupational Exposure Limits** 

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Palonosetron Hy- drochloride	135729-62- 3	TWA	0.4 μg/m3 (OEB 5)	Internal
		Wipe limit	4 μg/100 cm <sup>2</sup>	Internal

#### 8.2 Exposure controls

# **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

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.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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.

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

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Equipment should conform to I.S. EN 143

Filter type : Particulates type (P)

# **SECTION 9: Physical and chemical properties**

# 9.1 Information on basic physical and chemical properties

Physical state : Aqueous solution

Colour : clear

Odour : No data available

Odour Threshold : No data available

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Melting point/freezing point : No data available

Initial boiling point and boiling

range

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

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 4.5 - 5.5

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure : No data available

Relative density : No data available

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

Relative vapour density : No data available

Particle characteristics

Particle size : Not applicable

9.2 Other information

Explosives : Not explosive

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Evaporation rate : No data available

Molecular weight : No data available

# **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

Not classified as a reactivity hazard.

# 10.2 Chemical stability

Stable under normal conditions.

# 10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

#### 10.4 Conditions to avoid

Conditions to avoid : None known.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

#### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

### **SECTION 11: Toxicological information**

### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of : Inhalation exposure 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.

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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

Application Route: Intravenous

Fertility: NOAEL: 10 mg/kg body weight

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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.

 Species
 : Rat

 NOAEL
 : 18 mg/kg

 LOAEL
 : > 60 mg/kg

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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

#### 11.2 Information on other hazards

# **Endocrine disrupting properties**

### **Product:**

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

#### **Experience with human exposure**

# **Components:**

### Palonosetron Hydrochloride:

Ingestion : Symptoms: The most common side effects are:, Headache,

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Diarrhoea, Dizziness, Weakness, anxiety

# **SECTION 12: Ecological information**

# 12.1 Toxicity

#### **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

#### 12.2 Persistence and degradability

No data available

# 12.3 Bioaccumulative potential

No data available

#### 12.4 Mobility in soil

No data available

# 12.5 Results of PBT and vPvB assessment

#### **Product:**

Assessment : This substance/mixture contains no components considered

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

# 12.6 Endocrine disrupting properties

#### **Product:**

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

#### 12.7 Other adverse effects

No data available

# **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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discussion with the waste disposal authorities.

Do not dispose of waste into sewer.

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.

# **SECTION 14: Transport information**

#### 14.1 UN number or ID number

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

### 14.2 UN proper shipping name

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

#### 14.3 Transport hazard class(es)

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

### 14.4 Packing group

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA (Cargo) : Not regulated as a dangerous good
IATA (Passenger) : Not regulated as a dangerous good

#### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Not applicable

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#### 14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

#### **SECTION 15: Regulatory information**

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) Conditions of restriction for the following entries should be considered: Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or

not.

Not applicable

Not applicable

Not applicable

Not applicable

: Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).

Regulation (EC) on substances that deplete the ozone

aver

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast)

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import

of dangerous chemicals

REACH - List of substances subject to authorisation

(Annex XIV)

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

#### **SECTION 16: Other information**

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Other information : Items where changes have been made to the previous version

are highlighted in the body of this document by two vertical

lines.

**Full text of H-Statements** 

H373 : May cause damage to organs through prolonged or repeated

exposure if swallowed.

Full text of other abbreviations

STOT RE : Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways: ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

#### **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 Agentus has also accepted to the company of th

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

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

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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.

IE / EN