

according to the Hazardous Products Regulations

Palonosetron Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
1.10	09/28/2024	4720316-00011	Date of first issue: 08/02/2019

SECTION 1. IDENTIFICATION

Product name	:	Palonosetron Formulation
Other means of identification	:	No data available

Manufacturer or supplier's details

Company name of supplier	:	Merck & Co., Inc
Address	:	126 E. Lincoln Avenue
		Rahway, New Jersey U.S.A. 07065
Telephone	:	908-740-4000
Emergency telephone	:	1-908-423-6000
E-mail address	:	EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use	: Ph	armaceutical
Restrictions on use	: No	ot applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations

Not a hazardous substance or mixture.

GHS label elements

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

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	Common	CAS-No.	Concentration (% w/w)
	Name/Synonym		
Palonosetron Hydro-	No data availa-	135729-62-3	>= 0 - < 0.1 *
chloride	ble		>= 0 - < 0.1

* Actual concentration or concentration range is withheld as a trade secret

SECTION 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. 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	 Get medical attention in mation develops and persists. If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.



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Most important symptoms and effects, both acute and delayed		:	None known.		
	Protection of first-aiders Notes to physician		:		tions are necessary for first aid responders. cally and supportively.
SE	CTION 5	. FIRE-FIGHTING ME	ASU	IRES	
	Suitabl	e extinguishing media	:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical	
	Unsuita media	able extinguishing	:	None known.	
	Specific fighting	c hazards during fire	:	Exposure to comb	pustion products may be a hazard to health.
	Hazard ucts	lous combustion prod-	:	Carbon oxides	
	Specific ods	c extinguishing meth-	:	cumstances and t Use water spray t	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do
	•	l protective equipment fighters	:	Wear self-contain necessary. Use personal prot	ed breathing apparatus for firefighting if ective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- tive equipment and emer- gency procedures	:	Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g., by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.



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		absorbent. Local or nation disposal of this employed in the determine whic Sections 13 an	ining materials from spill with suitable al regulations may apply to releases and material, as well as those materials and items e cleanup of releases. You will need to th regulations are applicable. d 15 of this SDS provide information regarding national requirements.
SECTION	7. HANDLING AND ST	TORAGE	
Tech	nical measures	5	ng measures under EXPOSURE ERSONAL PROTECTION section.
Local	/Total ventilation	: Use only with a	adequate ventilation.
	e on safe handling	: Handle in acco	rdance with good industrial hygiene and safety on the results of the workplace exposure
Cand	litions for safe storage	environment.	revent spills, waste and minimize release to the

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

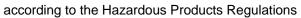
SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Palonosetron Hydrochloride	135729-62-3	TWA	0.4 μg/m3 (OEB 5)	Internal
		Wipe limit	4 µg/100 cm²	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





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Filter type Hand protection			recommended guidelines, use respiratory protection. Particulates type		
Ma	aterial	: Chemical-re	sistant gloves		
Remarks Eye protection		: Wear safety If the work e mists or aero Wear a face	Consider double gloving. 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 Additional be task being p disposable s	n or laboratory coat. ody garments should be used based upon the erformed (e.g., sleevelets, apron, gauntlets, uits) to avoid exposed skin surfaces. iate degowning techniques to remove potentially d clothing.		
Hygie	ne measures	: If exposure t eye flushing working plac When using Wash conta The effective engineering appropriate industrial hy	o chemical is likely during typical use, provide systems and safety showers close to the		

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	Aqueous solution
Color	:	clear
Odor	:	No data available
Odor Threshold	:	No data available
рН	:	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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		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Vapor p	oressure	:	No data available	•
	Relative	e vapor density	:	No data available	•
	Relative	e density	:	No data available	
	Density	/	:	1.015 g/cm ³	
	Solubili Wat	ity(ies) er solubility	:	No data available	
	Partitio octanol	n coefficient: n-	:	Not applicable	
		nition temperature	:	No data available	
	Decom	position temperature	:	No data available	
	Viscosi Visc	ty cosity, kinematic	:	No data available	
	Explosi	ve properties	:	Not explosive	
	Oxidizii	ng properties	:	The substance of	mixture is not classified as oxidizing.
	Molecu	lar weight	:	No data available	•
	Particle Particle	e characteristics e size	:	Not applicable	

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	Can react with strong oxidizing agents.
tions		
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.



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SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Components:

Acute oral toxicity

Palonosetron Hydrochloride:

: 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 sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

:

Components:

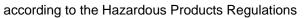
Palonosetron Hydrochloride:

Genotoxicity in vitro

Test Type: Ames test Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Result: negative

Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster ovary cells





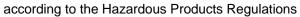
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rsion 0	Revision Date: 09/28/2024	SDS Number: 4720316-00011	Date of last issue: 09/30/2023 Date of first issue: 08/02/2019
		Result: negative	9
			omosome aberration test in vitro hinese hamster cells
Geno	toxicity in vivo	: Test Type: In vi Species: Mouse Result: negative	
	nogenicity lassified based on availa	able information	
	oductive toxicity		
-	lassified based on availa	able information.	
Comp	oonents:		
Palon	osetron Hydrochlorid	e:	
Effect	s on fertility		nale
Effect	s on fetal development	Embryo-fetal to Symptoms: Rec	
		Developmental	t

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.





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<u>Comp</u>	oonents:		
Palon	osetron Hydrochlo	ide:	
Route	s of exposure	: Ingestion	
	t Organs		estinal tract, Kidney, Central nervous system, Test
Asses	ssment	: May caus exposure	e damage to organs through prolonged or repeate
Repe	ated dose toxicity		
<u>Comp</u>	oonents:		
Palon	osetron Hydrochlo	ide:	
Speci	es	: Mouse	
NOAE		: 60 mg/kg	
LOAE		: 150 mg/k	g
	ation Route	: Oral	
	sure time	: 3 Months	
	t Organs		nale reproductive organs
Rema	Irks	: May caus	e damage to organs.
Speci		: Rat	
NOAE		: 18 mg/kg	
LOAE		: > 60 mg/k	kg
	cation Route	: Oral	
	sure time	: 3 Months	aduativo organo. Livor
Rema	it Organs Irks		oductive organs, Liver t toxicity observed in testing
Speci	es	: Dog	
LÖAE		: 20 mg/kg	
Applic	ation Route	: Oral	
	sure time	: 3 Months	
	t Organs		ervous system, Testis
Rema	irks	: Significan	t toxicity observed in testing
Speci		: Rat	
NOAE		: 7 mg/kg	
	cation Route	: Intraveno	us
	sure time	: 6 Months	nueve eventere. Contraintentine l'un et
Rema	t Organs irks		ervous system, Gastrointestinal tract t toxicity observed in testing
Speci	es	: Dog	
NOAE		: 6 mg/kg	
	ation Route	: Intraveno	us
Expos	sure time	: 9 Months	
	t Organs		ervous system, Gastrointestinal tract
Symp		: Vomiting	
Rema	irks	: Significan	t toxicity observed in testing

Aspiration toxicity

Not classified based on available information.





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	Palon	onents: osetron Hydrochlorid plicable	e:		
	Exper	ience with human exp	osi	ure	
	<u>Comp</u>	onents:			
	Palon	osetron Hydrochlorid	e:		
	Ingest	on	:		nost common side effects are:, Headache, ss, Weakness, anxiety
SEC		12. ECOLOGICAL INF	ORI	MATION	
	Feete				
	Ecoto	-			
	<u>Comp</u>	onents:			
	Palon	osetron Hydrochlorid	e:		
	Ecoto	xicology Assessment			
	Acute	aquatic toxicity	:	Toxic effects can	not be excluded, No data available
	Chron	c aquatic toxicity	:	Toxic effects can	not be excluded, No data available
		a available	ity		
		cumulative potential a available			
	Mobili	ty in soil			
	No dat	a available			
		adverse effects			
	No dat	a available			

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods	
Waste from residues	Do not dispose of waste into sewer.
	Dispose of in accordance with local regulations.
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal.
	If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG Not regulated as a dangerous good





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IATA-DGR

Not regulated as a dangerous good

IMDG-Code Not regulated as a dangerous good

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

Not applicable for product as supplied.

Domestic regulation

TDG

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

The ingredients of this pro	duct	are reported in the following inventories:
AICS	:	not determined
DSL	:	not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substanc-



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es; (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

Sources of key data used to compile the Material Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/
Revision Date Date format	:	09/28/2024 mm/dd/yyyy

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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