

SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product identifier used on the label:

Product Name: Palonosetron Hydrochloride Injection

Other means of identification:

Recommended use of the chemical and restrictions on use:

Chemical manufacturer address and telephone number:

Manufacturer Name: Fresenius Kabi Austria GmbH
Address: Hafnerstrasse 36
 Graz , 8055
 Austria
General Phone Number: +43.316.249.0

Chemical distributor, or other responsible party Name, address, and telephone number:

Distributor Name: Fresenius Kabi USA, LLC
Address: Three Corporate Drive
 Lake Zurich, Illinois 60047
General Phone Number: (847) 550-2300
Health Issues Information: (800) 551-7176

SECTION 2 : HAZARD(S) IDENTIFICATION

Classification of the chemical in accordance with CFR 1910.1200(d)(f):

GHS Pictograms:



Signal Word: WARNING!

GHS Class: Eye Irritant, Category 2.

Hazard Statements: Causes serious eye irritation.

Precautionary Statements: Do not breathe dust/fume/gas/mist/vapours/spray. Wash hands thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If skin irritation or rash occurs: Get medical advice/attention.

Hazards not otherwise classified that have been identified during the classification process:

Citric acid

Emergency Overview: This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

Route of Exposure: Inhalation Ingestion Eye contact Skin Absorption. Injection.

Potential Health Effects:

Eye: May cause eye irritation.

Ingestion: May be harmful if swallowed. May cause vomiting.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Mixtures:

Chemical Name	CAS#	Ingredient Percent	EC Num.
Citric acid	77-92-9	1.4 mg/mL by weight	
Palonosetron Hydrochloride	135729-62-3	0.05 mg/mL by weight	
Trisodium Citrate Dihydrate	6132-04-3	3.6 mg/mL by weight	
Sodium Chloride	7647-14-5	8 mg/mL by weight	

SECTION 4 : FIRST AID MEASURES

Description of necessary measures:

Eye Contact:	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
Skin Contact:	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion:	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

Most important symptoms/effects, acute and delayed:

Other First Aid: For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Suitable and unsuitable extinguishing media:

Suitable Extinguishing Media: Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Specific hazards arising from the chemical:

Hazardous Combustion Byproducts: Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

Special protective equipment and precautions for fire-fighters:

Protective Equipment: As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.

Fire Fighting Instructions: Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:

Personal Precautions: Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.

Environmental precautions:

Environmental Precautions: Avoid runoff into storm sewers, ditches, and waterways.

Methods and materials for containment and cleaning up:

Methods for containment: Contain spills with an inert absorbent material such as soil, sand or oil dry.

Methods for cleanup: Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 : HANDLING and STORAGE

Precautions for safe handling:

Handling: When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.

Hygiene Practices: Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

Conditions for safe storage, including any incompatibilities:

Storage: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from freezing. Protect from light.

Specific end use(s):

Work Practices: Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

EXPOSURE GUIDELINES:

Appropriate engineering controls:

Engineering Controls: General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.

Individual protection measures:

Eye/Face Protection: Chemical splash goggles. Wear a face shield also when splash hazard exist.

Skin Protection Description: Protective laboratory coat, apron, or disposable garment recommended.

Hand Protection Description: Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.

Respiratory Protection: No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (<http://www.cdc.gov/niosh/npptl/topics/respirators/>) for a list of respirator types and approved suppliers.

Other Protective: Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

General Hygiene Considerations: Wash thoroughly after handling. Do not eat, drink, smoke or apply cosmetics while handling the product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Work should be performed in a designated area for working with hazardous drugs. Contaminated waste must be properly handled. Work areas must be regularly decontaminated.

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

PHYSICAL AND CHEMICAL PROPERTIES:

Physical State Appearance: Liquid.

Color: Clear

Odor: No information.

Odor Threshold: No information.

Boiling Point: Not established.

Melting Point: Not established.

Density: No information.

Specific Gravity: No information.

Specific Volume: No information.

Solubility: Soluble in most organic solvents. Soluble in water.

Vapor Density: Not established.

Vapor Pressure: Not established.

Percent Volatile: Not established.

Evaporation Point: No information.

pH: 4.5-5.5

Molecular Formula: Mixture

Molecular Weight: 365.86

Viscosity: No information.

Coefficient of Water/Oil Distribution: No information.

Flash Point: Not established.

Flash Point Method: Not established.

Lower Flammable/Explosive Limit: Not established.

Upper Flammable/Explosive Limit: Not established.

Auto Ignition Temperature: Not established.

VOC Content: No information.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:

Chemical Stability:	Stable under normal temperatures and pressures.
<u>Possibility of hazardous reactions:</u>	
Hazardous Polymerization:	Not reported.
<u>Conditions To Avoid:</u>	
Conditions to Avoid:	No conditions contributing to instability are known to exist for normal handling of this product.

SECTION 11 : TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION:

Palonosetron Hydrochloride :

Acute Toxicity: LD50 (oral-rat): >500 mg/kg (OECD Guideline 402, GLP) (ECHA)

Citric acid :

Reproductive Toxicity: Not expected to produce adverse effects on fertility or development under occupational exposure conditions.

Trisodium Citrate Dihydrate :

Eye: No or moderate irritation in rabbits.

Skin: Dermal - Rat LD50: >2000mg/kg (OECD Guideline 402, GLP) (TS : Citric acid) (ECHA)
No irritation in rabbits.

Ingestion: Oral - Rat LD50: >8000 mg/kg (TS : Sodium Citrate) (CHEMINFO)

Sodium Chloride :

RTECS Number: VZ4725000

Eye: Rabbit, Moderate irritation.

Skin: Dermal- Rabbit LD50: > 10000 mg/kg (ECHA)
Slight irritation.

Inhalation: Inhalation - Rat LC50:> 42 mg/L/1h (ECHA)

Ingestion: Oral - Rat LD50: 3550 mg/kg (ECHA)

Other Toxicological Information: Intravenous. - Mouse LD50: 645 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous. - Rabbit LDLo: 1100 mg/kg [Behavioral - convulsions or effect on seizure threshold Behavioral - muscle contraction or spasticity Cardiac - other changes]
Intravenous. - Guinea pig LDLo: 300 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous. - Mouse TDLo: 2.1 mg/kg [Vascular - other changes Blood - hemorrhage Skin and Appendages - dermatitis, irritative (after systemic exposure)]
Intravenous. - Rabbit TDLo: 1.5 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous. - Rabbit TDLo: 0.04 mg/kg [Vascular - other changes Blood - hemorrhage Skin and Appendages - dermatitis, irritative (after systemic exposure)]
Subcutaneous - Rat LDLo: 3500 mg/kg [Behavioral - irritability]
Subcutaneous - Mouse LD50: 3 gm/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Guinea pig LDLo: 2160 mg/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Rabbit TDLo: 0.04 mg/kg [Vascular - other changes Skin and Appendages - dermatitis, irritative (after systemic exposure)]
Subcutaneous - Mouse TDLo: 1900 mg/kg [Reproductive - Effects on Embryo or Fetus - fetal death]
Subcutaneous - Mouse TDLo: 1900 mg/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Subcutaneous - Mouse TDLo: 2500 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)]
Subcutaneous - Mouse TDLo: 13440 mg/kg [Reproductive - Fertility - abortion]
Intraperitoneal. - Mouse LD50: 2602 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Rat LD50: 2600 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Rat LDLo: 3.72 gm/kg [Behavioral - tremor Behavioral - convulsions or effect on seizure threshold]
Intraperitoneal. - Rat TDLo: 1710 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Effects on Embryo or Fetus - fetal death Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intraperitoneal. - Rat TDLo: 10 gm/kg [Reproductive - Effects on Newborn - behavioral]
Intraperitoneal. - Rat Cytogenetic analysis: 2338 mg/kg

SECTION 12 : ECOLOGICAL INFORMATION

Citric acid :

Ecotoxicity:

Ecotoxicity: No ecotoxicity data was found for the product.

Environmental Stability: No environmental information found for this product.

Trisodium Citrate Dihydrate :

Ecotoxicity:

Ecotoxicity: Golden orfe (*Leuciscus idus melanotus*) LC50 (48 h) 440 mg/L (TS : Citric acid)
Water flea (*Ceriodaphnia* sp.) EC50 (48hr) 736 mg/L (TS : Sodium Citrate)
Green algae (*Scenedesmus quadricauda*) Toxicity Threshold (8d) 640 mg/L, NOEC (8d) 425 mg/L (ECHA)

Sodium Chloride :

Ecotoxicity:

Ecotoxicity: Bluegill sunfish (*Lepomis macrochirus*) LC50 (96hr) 5840 mg/L, Fathead minnows (*Pimephales promelas*) NOEC 33 d 252 mg/L
Water flea (*Daphnia magna*) LC50 (48hr) 874 mg/L, Water flea (*Daphnia pulex*) NOEC (21d) 314 mg/L
Marine diatom (*Nitzschia sp.*) EC50 (120hr) 2430 mg/L (ECHA)

SECTION 13 : DISPOSAL CONSIDERATIONS

Description of waste:

Citric acid :

Waste Disposal: Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name: Not Regulated.

DOT UN Number: Not Regulated.

SECTION 15 : REGULATORY INFORMATION

Safety, health and environmental regulations specific for the product:

Sodium Chloride :

TSCA Inventory Status: Listed

EINECS Number: 231-598-3

Canada DSL: Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard: 1
HMIS Fire Hazard: 1
HMIS Reactivity: 0
HMIS Personal Protection: B

Health Hazard	1
Fire Hazard	1
Reactivity	0
Personal Protection	B

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