

MSDS NAME	PALONOSETRON HYDROCHLORIDE	MSDS #	S-01
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Rev.: 0.0	Date of Issue: 01- September - 2003	Based On: See Section 16
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1. PRODUCT AND COMPANY IDENTIFICATION

Trade Name(s):	ALOXI, ONICIT
Product Name	PALONOSETRON HYDROCHLORIDE
Manufacturer/Supplier	Helsinn Birex Pharmaceuticals, Mulhuddart, Dublin 15, Ireland
Emergency Phone Number	Helsinn Birex Pharmaceuticals. Tel: (353) 1- 822 5404. Fax: (353) 1- 822 5410.

2. COMPOSITION/INFORMATION ON THE COMPONENTS

Synonyms: (3aS)-2-((S)-1-Azabicyclo[2.2.2]oct-3-yl)-2,3,3a,4,5,6-Hexahydro-1-oxo-1H-Benz [de] Isoquinoline Hydrochloride

Component	CAS	Formula	Percentage
Palonosetron	135729-62-3	C ₁₉ H ₂₄ N ₂ O HCl	0.1
Mannitol	69-65-8	C ₆ H ₁₄ O ₆	87.8
Edetate Disodium Dihydrate	6381-92-6	C ₁₀ H ₁₄ N ₂ Na ₂ O ₈ .2H ₂ O	1.0
Trisodium Citrate Dihydrate	6132-04-3	C ₆ H ₅ Na ₃ O ₇ .2H ₂ O	7.8
Citric Acid Monohydrate	77-92-9	HOC OCH ₂ C(OH)(COOH)CH ₂ COOH.H ₂ O	3.3

3. HAZARD IDENTIFICATION

Warning Statement	CAUTION: Potent pharmaceutical product for the treatment of cancer chemotherapy induced nausea and vomiting. Acute or repeated overexposure may affect the central nervous system or cause slight liver enzyme changes. Avoid inhalation, ingestion, skin contact and eye contact. Material intended for human pharmaceutical use by intravenous injection as prescribed by physician.
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4. FIRST AID MEASURES

First Aid – Eye Contact	Immediately flush eyes thoroughly with water for at least 15 minutes and seek medical attention.
First Aid – Inhalation	Immediately move to fresh air and seek medical attention.
First Aid – Skin Contact	Immediately wash thoroughly with soap and water for 15 minutes. If an irritation develops seek medical attention..
First Aid – Ingestion	Give moderate amount (200-300ml) of water and seek medical attention.

5. FIRE FIGHTING MEASURES

Extinguishing Media	Water, multipurpose dry chemical or CO ₂ fire extinguisher
Special Fire Fighting Procedures	Wear full protective clothing and NIOSH/MSHA-approved, positive pressure, self-contained breathing apparatus. Thoroughly wash all equipment after use.

6. ACCIDENTAL RELEASE MEASURES

Measures for Personal Safety	Take proper precautions to minimise exposure by using appropriate personal protective equipment.
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Signed: 
Plant Manager

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Environmental Measures	Not to be released into the environment. If the product has escaped into a watercourse, into the drainage system, or has contaminated the ground or vegetation, notify the competent authorities.
Spill and Release Measures	Contains spills with absorbent.

7. HANDLING AND STORAGE

Handling Precautions	Avoid contact with skin, eyes or clothing. Wash thoroughly after handling.
Storage Conditions	Store in a cool well-ventilated area. Temperature range: 20°C - 25°C (68°F - 77°F) Protect from freezing. Protect from light.

8. EXPOSURE CONTROL/PERSONAL PROTECTION

Eye Protection	Base the choice of eye protection on the job activity and potential for exposure to the eyes and face.
Respiratory Protection	Base the choice of respiratory protection on the job activity and potential for exposure.
Skin Protection	Base the choice of skin protection on the job activity and potential for exposure to the skin.
Exposure Limits for Active Ingredient	1 micrograms/m ³ as an 8-hour time weighted average over a 40 hour week, levels from acute exposure. Ref.: MSDS Syntex 1994

9. PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point	No data
Melting Point	N/A
Molecular Weight	Active Ingredient - 332.9
Solubility in Water	Soluble.
Vapour Pressure	Nil
Special Gravity	No data
pH (of aqueous solution)	4.5 - 5.5
Appearance, Colour, Odour	Clear, colourless, odourless

10. STABILITY AND REACTIVITY

Conditions to avoid	None
Hazardous decomposition products:	When heated to decomposition it emits toxic fumes of CO _x , NO _x , HCl.

11. TOXICOLOGICAL INFORMATION

Swiss Class	3 (estimated by HCB)
LD50 of Active Ingredient	The oral LD50 (dose to kill 50% of test animals) for the active ingredient is greater than 500mg/kg in the rat.
Toxic and Hazard Overview	Potent pharmaceutical product for the treatment of cancer chemotherapy induced nausea and vomiting. Acute or repeated over exposure may affect the central nervous system or cause slight liver enzyme changes. Avoid inhalation, ingestion, skin contact and eye contact. Material intended for human

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MATERIAL SAFETY DATA SHEET

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pharmaceutical use by intravenous injection as prescribed by a physician.

12. ECOLOGICAL/ENVIRONMENTAL INFORMATION

Adopt sound working practices, so that the product is not released into the environment.

Aquatic Toxicity of the Active Ingredient

In an acute toxicity study in Bluegill sunfish, the LC50 (concentration to kill 50% of the test species) was 22mg/L. The EC50 (effective concentration to cause 50% response, usually immobility in an organism) in photoluminescent microorganisms in the Microtox system was 45 mg/L. Based on these values, the active ingredient is considered slightly toxic to the aquatic environment on an acute basis.

13. DISPOSAL

Waste Disposal Methods

All wastes containing the compound should be specially contained, properly labelled, and stored separately from other facility waste discharges. Dispose of in accordance with all applicable local and national regulations. Disposal methods should be used which prevent human exposure to the waste residues.

14. TRANSPORT INFORMATION

Hazard Class

Not regulated

UN Number

Not assigned

Note: On the basis of known data (see paragraph 11) the product is not subjected to dangerous goods transport regulations.

15. REGULATORY INFORMATION

Risk Phrases

R 22: Harmful by Ingestion.

Safety Phrases

None

16. OTHER INFORMATION

Main Bibliographic Sources

MSDS- Syntex 1994
HCB Sheet No.: 283/99
Patient Information Leaflet.

Note:

The information in this document is believed to be correct as of the date here of, but all instructions, recommendations or proposals are given without warranty. As the way of using the product lies beyond our control, Helsinn Birex Pharmaceuticals cannot take any responsibility for loss or damage, which may have arisen as a consequence from using the information.

Signed: 
Plant Manager