



Boehringer Ingelheim
Roxane Laboratories

IN CASE OF EMERGENCY
Emergency Phone: (614) 276-4000

Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Common/Trade Name: Cyclophosphamide Tablets USP 25 mg and 50 mg
Chemical Name: 2H-1,3,2-oxazaphosphorin-2-amine
Formula: $C_7H_{15}Cl_2N_2O_2P \cdot H_2O$
Synonyms: cyclophosphan, cyclophosphane, cyclophosphamide monohydrate
Manufacturer's Name: **Roxane Laboratories Inc.**
Address: 1809 Wilson Road
Columbus, Ohio 43228

2. COMPOSITION / INFORMATION ON INGREDIENTS

Composition	CAS#	%	Exposure Limit
Cyclophosphamide Monohydrate	6055-19-2		None established
			None established

REFER to PHYSICIAN'S DESK REFERENCE for common components present as <1% of solution

3. HAZARDS IDENTIFICATION

Primary Route(s) of Entry	Inhalation; Skin or Eye Absorption
Effects of Overexposure:	The potential for exposure is reduced in finished pharmaceutical form. Side effects of therapeutic use may include nausea and vomiting.

4. FIRST AID MEASURES

Eye Exposure	Flush with running water for 15 minutes holding eyelids open
Skin Exposure	Wash contaminated area twice with soap
Ingestion	Seek medical attention. Never induce vomiting on an unconscious or convulsing person.
Inhalation	Remove to fresh air. Restore and/or support breathing as needed

5. FIRE AND EXPLOSION HAZARDS

Flammability	Lower: N/A	Upper: N/A
Flash Point	Not Applicable	
Extinguishing Media	Use media suitable for fire in surrounding area	
Special Fire Fighting Procedures	Wear full protective clothing and self-contained breathing apparatus	
Unusual Fire/Explosion Hazards	Not Applicable	

6. ACCIDENTAL RELEASE INFORMATION

Using appropriate protective equipment (see Section 8). Clean up spill wearing protective clothing, double latex surgical gloves and eye protection. Clean area by wiping the material with wet absorbent gauze. The spill areas then should be cleaned (three times) using a detergent solution followed by clean water.
Any glass fragments should be placed in a small cardboard or plastic container and then into a Cytotoxic Drug (CD) disposal bag, along with used absorbent pads and any non-cleanable contaminated items.
Glassware or other contaminated reusable items should be placed in a plastic bag and washed in a sink with detergent by a trained employee wearing double surgical latex gloves. Disposal of Cyclophosphamide material should be done by incineration. Dispose of in accordance with Federal, State and Local Regulations

7. PRECAUTIONS FOR SAFE HANDLING AND USE

Precautions	Ensure good ventilation/exhaust at the workplace with raw material. Use Cytotoxic OSHA approved procedures for handling finished product.
Storage	Store only in the original container. Store away from foodstuffs. Keep container tightly sealed.

8. CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Engineering Controls	None needed for finished product. Use adequate ventilation when working with raw materials.
Personal Protection	Goggles, Lab coat, Gloves

9. PHYSICAL / CHEMICAL CHARACTERISTICS

Appearance	blue	Melting point	Not available	Solubility in water	20 mg/mL
Odor	Odorless	Boiling point	Not available	Specific Gravity	Not available
Taste	Not available	Vapor Pressure	Not available		
pH	Not available	Density	Not available		

10. STABILITY AND REACTIVITY DATA

Stability	Stable, May polymerize when heated
Incompatibility	Oxidizing materials
Hazardous Decomposition	Thermal decomposition products halogenated compounds, oxides of phosphorous, nitrogen carbon
Conditions to avoid	Avoid heat, flames, sparks, and other sources of ignition.

11. TOXICOLOGICAL INFORMATION

Carcinogen status : Known human carcinogen
 Target Organs : immune system (blood) teratogen

12. ENVIRONMENTAL IMPACT INFORMATION

Does not bioconcentrate in aquatic organisms.

13. DISPOSAL INFORMATION

Dispose of product by incineration at an approved USEPA Incinerator. Observe and follow all Federal, State and Local environmental regulations. Hazardous Waste (U058)

14. TRANSPORTATION INFORMATION

Not regulated by the United States Department of Transportation (USDOT). Ship according to state and local regulations if applicable.

15. REGULATORY INFORMATION

For 25 mg tablets (light blue)	NDC 0054-8089	For 50 mg tablets (light blue)	NDC 0054-8130
	NDC 0054- 4129		NDC 0054-4130

16. OTHER DATA

Note to Physician: See Package Insert Product is a Cytotoxic Agent

Date: March 21st 2000 Cyclophosphamide Tablets 25 and 50 mg

The information provided is believed to be complete and accurate. If this product is combined with other materials, deteriorates or becomes contaminated, it may pose hazards not mentioned in this MSDS. It is the users' responsibility to use the information according to the application. Roxane Laboratories Inc. assumes no responsibility or liability resulting from the use of this information.