

NAME OF PRODUCT Cyclophosphamide

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product/Catalog Number(s):		
60-113	1 mg/vial, 5 vials/pack	
60-113.15	1.5 mg/vial, 5 vials/pack	
60-113.25	0.25 mg/vial, 5 vials/pack	
60-113.75	1.75 mg/vial, 5 vials/pack	
60-113.6	0.6 mg/vial, 5 vials/pack	
60-113.8	0.8 mg/vial, 5 vials/pack	
60-113A100	100 μL of 1 mg/mL, 5 vials/pack	
60-119	100 μL of 1 mg/mL, 5 vials/pack	
60-133	150 μL of 1.0 mg/mL, 5 vials/pack	
60-171	10 mg/ml, 1.0 ml/vial, 5 vials/pack	
Product name:	Cyclophosphamide	
Product name: Synonyms:	Cyclophosphamide N,N-bis(2-chloroethyl)tetrahydro-2H-1,3,2-oxazaphosphorin-2-amine, monohydrate; Endoxan	
	N,N-bis(2-chloroethyl)tetrahydro-2H-1,3,2-oxazaphosphorin-2-amine,	
Synonyms:	N,N-bis(2-chloroethyl)tetrahydro-2H-1,3,2-oxazaphosphorin-2-amine, monohydrate; Endoxan	
Synonyms: Manufacturer:	N,N-bis(2-chloroethyl)tetrahydro-2H-1,3,2-oxazaphosphorin-2-amine, monohydrate; Endoxan Molecular Toxicology Inc.	
Synonyms: Manufacturer: Address:	N,N-bis(2-chloroethyl)tetrahydro-2H-1,3,2-oxazaphosphorin-2-amine, monohydrate; Endoxan Molecular Toxicology Inc. 157 Industrial Park Drive, Boone, North Carolina, 28607	
Synonyms: Manufacturer: Address: Phone:	N,N-bis(2-chloroethyl)tetrahydro-2H-1,3,2-oxazaphosphorin-2-amine, monohydrate; Endoxan Molecular Toxicology Inc. 157 Industrial Park Drive, Boone, North Carolina, 28607 (1) 828 264 9099 (8:30 – 17:00 EST) 828 264 0103 Contact 1800-424-9300 (USA) or 703 527 3887 (International) at other times	
Synonyms: Manufacturer: Address: Phone: Fax: Emergency contact	N,N-bis(2-chloroethyl)tetrahydro-2H-1,3,2-oxazaphosphorin-2-amine, monohydrate; Endoxan Molecular Toxicology Inc. 157 Industrial Park Drive, Boone, North Carolina, 28607 (1) 828 264 9099 (8:30 – 17:00 EST) 828 264 0103 Contact 1800-424-9300 (USA) or 703 527 3887 (International) at other times Email: <u>chemtrec@chemtrec.com; http://www.chemtrec.com/</u>	
Synonyms: Manufacturer: Address: Phone: Fax: Emergency contact (Chemtrec):	N,N-bis(2-chloroethyl)tetrahydro-2H-1,3,2-oxazaphosphorin-2-amine, monohydrate; Endoxan Molecular Toxicology Inc. 157 Industrial Park Drive, Boone, North Carolina, 28607 (1) 828 264 9099 (8:30 – 17:00 EST) 828 264 0103 Contact 1800-424-9300 (USA) or 703 527 3887 (International) at other times	

SECTION 2. HAZARDS IDENTIFICATION

Classification of the substance or mixture per GSH and EU Directive 1272/2008



None known Acute Toxicity, Oral (Category 3) Carcinogenicity (Category 1B) See eco-toxicity section 12.

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Molecular Toxicology 828-264-9099

Physical hazards Health hazards

Environmental hazards



Labelling

Hazard Statements	H301 Toxic if swallowed H350 May cause cancer
Precautionary Statements	 P201 Receive special instructions before use P202 Do not handle until all safety precautions are understood P264 Wash hands thoroughly after handling P270 Do not eat, drink or smoke when using this product P281 Use personal protection as required P301+310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician P308+313 IF exposed or concerned: Get medical advice/attention P321 Specific treatment (reference Section 4, First Aid Measures, if exposed) P330 Rinse mouth P405 Store locked up P501 Dispose of contents/container to a licensed disposal company

Hazards not otherwise None classified or not covered by GHS

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance

Component	Purpose	CAS-No	EC-No.	Weight %
C7H15Cl2N2O2P·H2O Cyclophosphamide	Biochemical used in the study of carcinogenesis	6055-19-2	200-015-4	Varies by product

SECTION 4. FIRST AID MEASURES

Description of first aid measures

Eye Contact	Get medical attention immediately. Rinse eyes and under eyelids immediately with plenty of water. Consult a doctor.
Skin Contact	Get medical attention immediately. Wash off immediately with plenty of soap and water and rinse thoroughly.
Ingestion	Get medical attention immediately. Rinse mouth with plenty of water. Never give anything by mouth to an unconscious person.
Inhalation	Get medical attention immediately. Move to fresh air. If required, provide artificial respiration. Keep patient warm.
Protection of first-aiders	Not required

In the event that symptoms develop or persists, obtain medical attention.

Most important symptoms and effects, both acute and delayed

Acute: No data available

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Chronic: May cause cancer in humans. May cause reproductive and fetal effects. May result in myelosuppression, gastrointestinal issues, cystitis, hair loss, or disorders of spermatogenesis or ovulation

Indication of any immediate medical attention and special treatment needed

Seek medical attention if ingested or if breathing difficulties are observed.

SECTION 5. FIREFIGHTING MEASURES

Extinguishing media

Not flammable; use media suitable for extinguishing surrounding fire (carbon dioxide, extinguishing powder or water spray). Fight larger fires with water spray or alcohol resistant foam. A solid water stream may be insufficient.

Special hazards arising from the substance or mixture

Hazardous thermal decomposition products: Carbon oxides, nitrogen oxides, oxides of phosphorus, hydrogen chloride gas

Advice for firefighters

Fire-fighters should wear fully protective impervious protective equipment and self-contained breathing apparatus (SCBA).

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation. Evacuate surrounding areas. Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas.

Environmental precautions

Do not release material into drains.

Methods and material for containment and cleaning up

Dispose contaminated material as waste according to section 13. Pick up and arrange disposal without creating dust. Keep in suitable, closed containers for disposal.

Reference to other sections

Refer to Sections 7 for information on safe handling See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7. HANDLING AND STORAGE

Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.

Conditions for safe storage, including any incompatibilities

Store according to product packaging, tightly sealed. Protect from light. Keep in a dry, well-ventilated place. Recommended storage temperature 2-8°C. Store under inert gas.

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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure limits

Contains no substances with occupational exposure limit values.

Monitoring methods N/A

Exposure controls

Engineering Measures

Ensure adequate ventilation, especially in confined areas

Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimize release or contact, and the use of properly designed ventilation systems, should be adopted to control hazardous materials at source. Use of a properly operating chemical fume hood designed for hazardous chemicals is recommended.

Personal protective equipment

Eye Protection: Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Hand Protection

Chemical resistant gloves; nitrile rubber recommended. Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves (refer to manufacturer/supplier for information). If material is solubilized, account for solvent in glove assessment.

Remove gloves with care avoiding skin contamination.

Skin and body protection

Impervious clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory Protection

Exposure risk assessment must be performed by a qualified Industrial Hygienist. Where risk assessment shows air purifying respirators are appropriate use a dust mask type N95 (US) or type P1 (EN 143) respirator. NIOSH approved Respiratory Protection is required by EPA. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle respirator.For higher level protection use type OV/AG/P99 (US) or type ABEK-P2 (EU EN 143) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (EU).

Hygiene Measures - Handle in accordance with good industrial hygiene and safety practice. Wash hands, forearms and face thoroughly after handling chemical products, before smoking, eating and using lavatory, and at the end of the work period. Employ techniques to avoid contamination of clothing. Keep away from food, beverages, and feed.

Environmental exposure controls – Properly operating chemical fume hood designed for hazardous chemicals.

Exposure limits

Permissible Exposure Limits and Threshold Limit Values not specified by OSHA.

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SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Ap	pearance
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Appearance		
	60-113	
	60-113.15	
	60-113.25	
	60-113.6	Crystalline, white
	60-113.75	
	60-113.8	
	60-113A100	
	60-119	
	60-133	Liquid, clear
	60-171	
Auto-ignition temperature	no data available	
Boiling point	no data available	
Decomposition temperature	90°C	
Evaporation Rate	no data available	
Flammable limits in air	no data available	
Flash point	113ºC	
Formula	$C_7H_{15}CI_2N_2O_2P\cdot H_2O$	
Melting point	49-51°C	
Molecular weight	279.09 g/mol	
Odor threshold	Odorless	
Osmolality	no data available	
Partition coefficient	no data available	
рН	no data available	
Solubility in water	40 g/L	
Specific gravity	no data available	
Vapor density	no data available	
Vapor pressure	0.000033 HPa at 20°C	
Viscosity	no data available	
Other information		

Other information

SECTION 10. STABILITY AND REACTIVITY

Reactivity

Not reactive.

Chemical stability

Stable under normal conditions. Decomposition will not occur if used and stored appropriately.

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Possibility of hazardous reactions

No hazardous reactions known.

Conditions to avoid

Dust generation, excess heat

Incompatible materials

Strong oxidizers, strong bases, strong acids

Hazardous decomposition products

Hydrogen chloride gas, nitrogen oxides, phosphine, carbon monoxide, oxides of phosphorus, carbon dioxide

SECTION 11. TOXICOLOGICAL INFORMATION

Information on toxicological effects

Acute toxicity

LD ₅₀	oral, rat:	94 mg/kg
LD ₅₀	oral, mouse	350 mg/kg
TDLO	oral, rat	140 mg/kg/2W (intermittent)
TDLO	oral, mouse	240 mg/kg/4W (intermittent)
TDLO	intraperitoneal, rat	50 mg/kg
TDLO	intraperitoneal, mouse	480 mg/kg/24D(continuous)

Other information on acute toxicity

None available

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

Investigated as a mutagen. May alter genetic material.

Carcinogenicity

This substance is carcinogenic according to IARC, ACGIH, NTP, and OSHA classifications

- IARC: 1-Group 1: Carcinogenic to humans (Cyclophosphamide)
- ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.
- NTP: Known to be human carcinogen (Cyclophosphamide)
- OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity

Investigated as a reproductive effector and tumorigen. May cause congenital malformation in the fetus.

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Teratogenicity

No data available

Specific target organ toxicity - single exposure (Globally Harmonized System) Stomach irregularities

Specific target organ toxicity - repeated exposure (Globally Harmonized System) No data available

Aspiration hazard No data available

Potential health effects

Inhalation May be harmful if inhaled.
Ingestion Toxic if swallowed.
Skin Causes skin irritation.
Eyes Causes eye irritation.
Synergistic effects
No data available

Additional toxicological information: RTECS: RP6157750

SECTION 12. ECOLOGICAL INFORMATION

Toxicity

Aquatic ecotoxicity: No further relevant information available.

Persistance and degradability:

Degradation (28 days) <1%, not easily biodegradable, OECD 301 E

Behavior in environment systems: No further relevant information available.

Bioaccumulative potential: No further relevant information available.

Mobility in soil: No further relevant information available.

Additional ecological information:

General notes:

Do not allow undiluted product or large quantities of it to reach ground water, water course, or sewage system. Do not allow material to be released to the environment without proper governmental permits.

Results of PBT and vPVB Assessment

PBT: Not applicable **vPvB:** Not applicable

Other adverse effects: No further relevant information available.

SECTION 13. DISPOSAL CONSIDERATIONS

Product

Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material.

Contaminated packaging

Dispose of as unused product.

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SECTION 14. TRANSPORT INFORMATION

DOT regulations:

UN Number: UN 3464 Class: 6.1 Packing Group: III Proper shipping name: Organophosphorus compound, solid, toxic, n.o.s. (Cyclophosphamide) Reportable Quantity: 10 lbs Marine pollutant: No Poison inhalation hazard: No

Land transport ADR/RID (cross-border)

UN Number: UN 3464 Class: 6.1 Packing Group: III Proper shipping name: Organophosphorus compound, solid, toxic, n.o.s. (Cyclophosphamide)

Maritime transport IMDG:

UN Number: UN 3464 Class: 6.1 Packing Group: III Proper shipping name: Organophosphorus compound, solid, toxic, n.o.s. (Cyclophosphamide) EMS-No: F-A, S-A Marine pollutant: No

Air transport ICAO_TI and IATA-DGR:

UN Number: UN 3464 Class: 6.1 Packing Group: III Proper shipping name: Organophosphorus compound, solid, toxic, n.o.s. (Cyclophosphamide)

Special precautions for user: Not applicable

Transport/Additional information:

When sold in quantities of less than or equal to 1 mL, or 1 g, with an Excepted Quantity Code of E1, E2, E4, or E5, this item meets the De Minimis Quantities exemption, per IATA 2.6.10. Therefore packaging does not have to be labeled as Dangerous Goods/Excepted Quantity

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable

SECTION 15. REGULATORY INFORMATION

OSHA Hazards

No chemicals in this product are considered highly hazardous by OSHA

SARA 302 Components

SARA 302: No chemicals in this product are subject to reporting requirements of SARA Title III, Section 302.

SARA 313 Components

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SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards

Acute Health Hazard, Chronic Health Hazard

Massachusetts Right To Know Components

6055-19-2 Cyclophosphamide

Pennsylvania Right To Know Components

6055-19-2 Cyclophosphamide

New Jersey Right To Know Components

6055-19-2 Cyclophosphamide

California Prop. 65 Components

WARNING! This product contains a chemical known to the State of California to cause cancer.

6055-19-2 Cyclophosphamide

SECTION 16. OTHER INFORMATION

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Molecular Toxicology, Inc. shall not be held liable for any damage resulting from handling or from contact with the above product. See <u>www.moltox.com</u> and/or the invoice or packing slip for additional terms and conditions of sale.