



Cyclophosphamide for Injection, USP

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 as amended by (EC) No. 2015/830 and US OSHA HCS 2015

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Product name : Cyclophosphamide for Injection, USP
Other Product Codes : NDC 81298-8110-1, NDC 81298-8112-1, NDC 81298-8114-1

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Antineoplastic Agent
Product Type: : Prescription Drug

1.3 Details of the supplier of the safety data sheet

Company : Long Grove Pharmaceuticals, LLC.
9450 W. Bryn Mawr Ave., Suite 200
Rosemont, IL 60018
Telephone : 847-999-0600

1.4 Emergency telephone number

Emergency Phone # CHEMTREC: 1-800-424-9300 (North America 24/7 advice for spill, leak, fire, exposure or accident)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Acute Toxicity: Oral, Category 3

Carcinogenicity, Category 1B

2.2 Label elements



GHS Signal Word: Danger

GHS Hazard Phrases:

H301: Toxic if swallowed.

H350: May cause cancer.

GHS Precaution Phrases:

P201: Obtain special instructions before use.

P202: Do not handle until all safety precautions have been read and understood.

P264: Wash {hands} thoroughly after handling.

P280: Wear {protective gloves/protective clothing/eye protection/face protection}.

GHS Response Phrases:

P301+310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.

P308+313: IF exposed or concerned: Get medical attention/advice.

P330: Rinse mouth.

GHS Storage and Disposal Phrases:.

Please refer to Section 7 for Storage and Section 13 for Disposal information.

2.3 Adverse Human Health Effects and Symptoms:

Material may be irritating to the mucous membranes and upper respiratory tract.

May be harmful by inhalation or skin absorption.

May cause cancer.

May cause eye, skin, or respiratory system irritation.

Toxic if swallowed.

To the best of our knowledge, the toxicological properties have not been thoroughly investigated.

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SECTION 3: Composition/information on ingredients

CAS # / RTECS #	Hazardous Components (Chemical Name)/ REACH Registration No.	Concentration	EC No./ EC Index No.	GHS Classification
6055-19-2 RP6157750	Cyclophosphamide (hydrate)	100.0 %	629-456-4 NA	Acute Tox.(O) 3: H301 Carcinogen 1B: H350

Molecular Formula & Weight: C₇H₁₅Cl₂N₂O₂P • H₂O 279.1

SECTION 4: First aid measures

4.1 Description of first aid measures

If inhaled

Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.

In case of skin contact

Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.

In case of eye contact

Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.

If swallowed

Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.

4.2 Symptoms and Effects of Exposure

For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray.

Media

Use water spray to cool fire-exposed containers.

Unsuitable Extinguishing

A solid water stream may be inefficient.

5.2 Special hazards arising from the substance or mixture

No data available

5.3 Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

5.4 Further information

No data available

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid raising and breathing dust, and provide adequate ventilation. As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).

6.2 Environmental precautions

Take steps to avoid release into the environment, if safe to do so.

6.3 Methods and materials for containment and cleaning up

Contain spill and collect, as appropriate. Transfer to a chemical waste container for disposal in accordance with local regulations.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid prolonged or repeated exposure.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

SECTION 8: Exposure controls/personal protection

No Occupational Exposure Limit (OEL) or Short Term Exposure Limit (STEL) has been identified.

8.1 Control parameters

Components with workplace control parameters

8.2 Exposure controls

Engineering Controls (Ventilation etc.):

Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.

Personal protective equipment

Eye/face protection

Safety glasses

Protective Gloves

Compatible chemical-resistant gloves

Other Protective Clothing

Lab coat

Respiratory protection

NIOSH approved respirator, as conditions warrant.

Work/Hygienic/Maintenance Practices

Do not take internally. Facilities storing or utilizing this material should be equipped with an eyewash and a safety shower. Wash thoroughly after handling. No data available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical States: [] Gas [] Liquid [X] Solid

Appearance and Odor: A crystalline solid

pH: No data.

Melting Point: No data.

Boiling Point: No data.

Flash Pt: No data.

Evaporation Rate: No data

Flammability (solid, gas): No data available.

Explosive Limits: LEL: No data. UEL: No data.

Vapor Pressure (vs. Air or mmHg): No data.

Vapor Density (vs. Air = 1): No data.

Solubility in Water: 40mg/mL.

Solubility Notes: ~1.6 mg/ml in PBS (pH 7.2); ~1 mg/ml in EtOH; ~5 mg/ml in DMSO; ~1.4 mg/ml in DMF

Octanol/Water Partition Coefficient: No data.

Autoignition Pt: No data.

Decomposition Temperature: No data.

Viscosity: No data.

9.2 Other safety information

No data available

Molecular Formula & Weight: C₇H₁₅Cl₂N₂O₂P • H₂O 279.1

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

No data available

10.5 Incompatible materials

Strong acids; Strong bases; Strong oxidizing agents

10.6 Hazardous decomposition products

carbon dioxide; carbon monoxide; hydrogen chloride gas; nitrogen oxides; phosphorous oxides

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity (Species, Route, End Point, Dose)

Rat Oral LD 50 160 mg/kg

Rat Para-periosteal LD 50 148 mg/kg

Mouse Oral LD 50 137 mg/kg

Mouse Intravenous LD 50 140 mg/kg

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Embryo / Fetal Development Rat Intraperitoneal 10 mg/kg LOAEL Teratogenic

Embryo / Fetal Development Rat Intraperitoneal 30 mg/kg LOAEL Fetotoxicity

Embryo / Fetal Development Mouse Intravenous 10 mg/kg LOAEL Teratogenic

Embryo / Fetal Development Mouse Intraperitoneal 5 mg/kg LOAEL Fetotoxicity, Fertility

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

In Vivo Micronucleus Rodent Positive

In Vivo Chromosome Aberration Rodent Positive

In Vivo Sister Chromatid Exchange Rodent Positive

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

2 Year(s) Rat Intravenous Benign tumors, Malignant tumors

2 Year(s) Rat Intraperitoneal Benign tumors, Malignant tumors, Female reproductive system

2 Year(s) Mouse Intraperitoneal Benign tumors, Malignant tumors

Carcinogen Status: See below

IARC: Group 1 (Carcinogenic to Humans)

NTP: Known Human Carcinogen

OSHA: Listed

SECTION 12: Ecological information

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

No data available

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SECTION 13: Disposal considerations

13.1 Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

RCRA - U Series Wastes Listed

SECTION 14: Transport information

14.1 LAND TRANSPORT (US DOT):

DOT Proper Shipping Name: Organophosphorus compound, toxic, solid, n.o.s. (Cyclophosphamide monohydrate)

DOT Hazard Class: 6.1 POISON

UN/NA Number: UN3464 **Packing Group:** III



14.2 LAND TRANSPORT (European ADR/RID):

ADR/RID Shipping Name: Organophosphorus compound, toxic, solid, n.o.s. (Cyclophosphamide monohydrate)

UN Number: 3464

Packing Group: III

Hazard Class: 6.1 - POISON

14.3 AIR TRANSPORT (ICAO/IATA):

ICAO/IATA Shipping Name: Organophosphorus compound, toxic, solid, n.o.s. (Cyclophosphamide monohydrate)

UN Number: 3464

Packing Group: III

Hazard Class: 6.1 - POISON

IATA Classification: 6.1

Additional Transport Information:

Transport in accordance with local, state, and federal regulations. 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.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out

SECTION 16: Other information

None.