

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Substance

Product Name: Cyclophosphamide for injection

CAS-No.: 6055-19-2

1.2. Intended Use of the Product

Used as alkylating antineoplastic agents and raw materials.

1.3. Name, Address, and Telephone of the Responsible Party

Distributor

Fresenius Kabi USA, LLC

Three Corporate Drive

Lake Zurich, IL 60047

General Phone Number: (847) 550-2300

Customer Service Phone Number: (888) 386-1300

Health Issues Information: (800) 551-7176

<http://www.fresenius-kabi.com/us/>

Manufacturer

Jiangsu Hengrui Pharmaceuticals Co., Ltd.

Jinqiao Road, Dapu Industrial park, Economic & Technological

Development Zone, Lianyungang, Jiangsu, China

222047

Phone number: +86-518-85473511

Fax: +86-518-85465746

ibd@hengrui.com

1.4. Emergency Telephone Number

Emergency Number : VelocityEHS

(800)255-3924 (North America)

+1 (813)248-0585 (International)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US/CA Classification

Acute toxicity (oral) Category 3 H301

Germ cell mutagenicity Category 1B H340

Carcinogenicity Category 1A H350

Reproductive toxicity Category 1A H360

Reproductive toxicity, Additional category, Effects on or via lactation H362

Specific target organ toxicity (repeated exposure) Category 1 H372

2.2. Label Elements

GHS-US/CA Labeling

Hazard Pictograms (GHS-US/CA)



Signal Word (GHS-US/CA)

: Danger

Hazard Statements (GHS-US/CA)

: H301 - Toxic if swallowed.
H340 - May cause genetic defects.
H350 - May cause cancer (oral).
H360 - May damage fertility or the unborn child (oral).
H362 - May cause harm to breast-fed children.
H372 - Causes damage to organs (bone marrow, heart, liver, immune system, systemic toxicity) through prolonged or repeated exposure.

Precautionary Statements (GHS-US/CA)

: P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P260 - Do not breathe vapors, mist, or spray.
P263 - Avoid contact during pregnancy/while nursing.
P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.

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P280 - Wear protective gloves, protective clothing, and eye protection.
P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P314 - Get medical advice/attention if you feel unwell.
P321 - Specific treatment (see section 4 on this SDS).
P330 - Rinse mouth.
P405 - Store locked up.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US/CA)

No additional information available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Name : Cyclophosphamide for injection
CAS-No. : 6055-19-2

Name	Synonyms	Product Identifier	% *	GHS Ingredient Classification
Cyclophosphamide monohydrate	Cyclophosphamide (hydrated) / 2H-1,3,2-Oxazaphosphorin-2-amine, N,N-bis(2-chloroethyl)tetrahydro-, 2-oxide, monohydrate / 2H-1,3,2-Oxazaphosphorine, tetrahydro-2-(bis(2-chloroethyl)amino)-, 2-oxide, monohydrate / 2H-1,3,2-Oxazaphosphorin-2-amine, N,N-bis(2-chloroethyl)tetrahydro-, 2-oxide, hydrate (1:1) / Cyclophosphamide hydrate / Endoxan monohydrate / cyclophosphamide / Cyclophosphamide	(CAS-No.) 6055-19-2	100	Acute Tox. 3 (Oral), H301 Muta. 1B, H340 Carc. 1A, H350 Repr. 1A, H360 Lact, H362 STOT RE 1, H372

Full text of H-statements: see section 16

3.2. Mixture

Not applicable

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

Skin Contact: Remove contaminated clothing. If exposed or concerned: Get medical advice/attention. Drench affected area with water for at least 15 minutes.

Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

Ingestion: Do NOT induce vomiting. Rinse mouth. Immediately call a POISON CENTER or doctor.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: May cause cancer (oral). May damage fertility or the unborn child. May cause genetic defects (oral). May cause harm to breast-fed children. Toxic if swallowed. Causes damage to organs ((bone marrow, heart, liver, immune system, systemic toxicity)) through prolonged or repeated exposure.

Inhalation: Prolonged exposure may cause irritation.

Skin Contact: Prolonged exposure may cause skin irritation.

Eye Contact: May cause slight irritation to eyes.

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Ingestion: This material is toxic in small amounts orally, and can cause adverse health effects or death.

Chronic Symptoms: May damage fertility or the unborn child (oral). May cause genetic defects. May cause cancer (oral). Causes damage to organs ((bone marrow, heart, liver, immune system, systemic toxicity)) through prolonged or repeated exposure.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂). Nitrogen oxides. Phosphorous oxide. Chlorides. Phosphine. Hydrogen chloride.

5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not breathe dust. Do not get in eyes, on skin, or on clothing. Do not handle until all safety precautions have been read and understood. If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain solid spills with appropriate barriers and prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Recover the product by vacuuming, shoveling or sweeping. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Accidental injection may cause pain and swelling at the injection site. Sharps should be handled appropriately to minimize risk of accidents.

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust. Avoid contact with eyes, skin and clothing. Do not get in eyes, on skin, or on clothing. Avoid contact during pregnancy/while nursing. Handle empty containers with care because they may still present a hazard.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

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Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store locked up/in a secure area.

Incompatible Materials: Strong acids, strong bases, strong oxidizers. Moisture. Benzyl Alcohol.

Storage Temperature: < 25 °C (77 °F) DO NOT FREEZE

7.3. Specific End Use(s)

Used as alkylating antineoplastic agents and raw materials.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

8.2. Exposure Controls

Appropriate Engineering Controls: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure.

Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment: Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.



Materials for Protective Clothing: Chemically resistant materials and fabrics.

Hand Protection: Wear protective gloves.

Eye and Face Protection: Chemical safety goggles.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Consumer Exposure Controls: Avoid contact during pregnancy/while nursing

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Solid
Appearance	: Fine white crystalline powder
Odor	: None
Odor Threshold	: No data available
pH	: 3.0 – 7.0 (Solution)
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: 48 – 51 °C (118.4 – 123.8 °F)
Flash Point	: 230 °F (110 °C)
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Lower Flammable Limit	: No data available
Upper Flammable Limit	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
Specific Gravity	: No data available
Solubility	: Water: 10 – 50 (mg/mL) at 73 °F (22 °C)
Partition Coefficient: N-Octanol/Water	: 0.6 20 °C (68 °F)
Viscosity	: No data available

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SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:

Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability:

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions:

Hazardous polymerization will not occur. Polymerization can occur at temperatures >120 °F (48 °C).

10.4. Conditions to Avoid:

Direct sunlight, extremely high or low temperatures, and incompatible materials. Exposure to moisture or moist air.

10.5. Incompatible Materials:

Strong acids, strong bases, strong oxidizers. Moisture. Benzyl Alcohol.

10.6. Hazardous Decomposition Products:

Thermal decomposition may produce: Carbon oxides (CO, CO₂). Nitrogen oxides. Chlorides. Phosphorus oxides. Phosphine. Hydrogen chloride.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Acute Toxicity (Oral): Toxic if swallowed.

Acute Toxicity (Dermal): Not classified

Acute Toxicity (Inhalation): Not classified

LD50 and LC50 Data:

Cyclophosphamide for injection (6055-19-2)	
ATE US/CA (oral)	94.00 mg/kg body weight

Skin Corrosion/Irritation: Not classified

pH: 3.0 – 7.0 (Solution)

Eye Damage/Irritation: Not classified

pH: 3.0 – 7.0 (Solution)

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: May cause genetic defects.

Carcinogenicity: May cause cancer (oral).

Specific Target Organ Toxicity (Repeated Exposure): Causes damage to organs ((bone marrow, heart, liver, immune system, systemic toxicity)) through prolonged or repeated exposure.

Reproductive Toxicity: May damage fertility or the unborn child (oral). May cause harm to breast-fed children.

Specific Target Organ Toxicity (Single Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: This material is toxic in small amounts orally, and can cause adverse health effects or death.

Chronic Symptoms: May damage fertility or the unborn child (oral). May cause genetic defects. May cause cancer (oral). Causes damage to organs ((bone marrow, heart, liver, immune system, systemic toxicity)) through prolonged or repeated exposure.

Potential Adverse human health effects and symptoms: Toxic if swallowed.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

Cyclophosphamide monohydrate (6055-19-2)	
LD50 Oral Rat	94 mg/kg
Cyclophosphamide monohydrate (6055-19-2)	
IARC Group	1
OSHA Hazard Communication Carcinogen List	In OSHA Hazard Communication Carcinogen list.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Not classified.

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12.2. Persistence and Degradability

Cyclophosphamide for injection (6055-19-2)	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Cyclophosphamide for injection (6055-19-2)	
Bioaccumulative Potential	Not established.

12.4. Mobility in Soil

No additional information available

12.5. Other Adverse Effects

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

Additional Information: Contaminated sharps should be discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT

Proper Shipping Name : ORGANOPHOSPHORUS COMPOUND, SOLID, TOXIC, N.O.S. (Cyclophosphamide)
Hazard Class : 6.1
Identification Number : UN3464
Label Codes : 6.1
Packing Group : III
ERG Number : 151



14.2. In Accordance with IMDG

Proper Shipping Name : ORGANOPHOSPHORUS COMPOUND, SOLID, TOXIC, N.O.S. (Cyclophosphamide)
Hazard Class : 6.1
Identification Number : UN3464
Label Codes : 6.1
Packing Group : III
EmS-No. (Fire) : F-A
EmS-No. (Spillage) : S-A



14.3. In Accordance with IATA

Proper Shipping Name : ORGANOPHOSPHORUS COMPOUND, SOLID, TOXIC, N.O.S. (Cyclophosphamide)
Hazard Class : 6.1
Identification Number : UN3464
Label Codes : 6.1
Packing Group : III
ERG Code (IATA) : 6L



14.4. In Accordance with TDG

Proper Shipping Name : ORGANOPHOSPHORUS COMPOUND, SOLID, TOXIC, N.O.S. (Cyclophosphamide)
Hazard Class : 6.1
Identification Number : UN3464
Label Codes : 6.1
Packing Group : III



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SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Cyclophosphamide for injection (6055-19-2)	
SARA Section 311/312 Hazard Classes	Health hazard - Carcinogenicity Health hazard - Specific target organ toxicity (single or repeated exposure) Health hazard - Germ cell mutagenicity Health hazard - Reproductive toxicity Health hazard - Acute toxicity (any route of exposure)

15.2. US State Regulations

California Proposition 65



WARNING: This product can expose you to Cyclophosphamide monohydrate, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

Chemical Name (CAS No.)	Carcinogenicity	Developmental Toxicity	Female Reproductive Toxicity	Male Reproductive Toxicity
Cyclophosphamide monohydrate (6055-19-2)	X	X	X	X

15.3. Canadian Regulations

This product or its components are not listed on the Canadian Domestic Substances List (DSL) or the Non-Domestic Substances List (NDSL), or are not required to be disclosed.

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 05/30/2023

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2015-17.

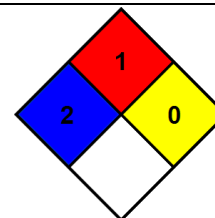
GHS Full Text Phrases:

H301	Toxic if swallowed
H340	May cause genetic defects
H350	May cause cancer
H360	May damage fertility or the unborn child
H362	May cause harm to breast-fed children
H372	Causes damage to organs through prolonged or repeated exposure

NFPA Health Hazard : 2 - Materials that, under emergency conditions, can cause temporary incapacitation or residual injury.

NFPA Fire Hazard : 1 - Materials that must be preheated before ignition can occur.

NFPA Reactivity Hazard : 0 - Material that in themselves are normally stable, even under fire conditions.



HMIS III Rating

Health : 2 Moderate Hazard - Temporary or minor injury may occur
* Chronic - Chronic (long-term) health effects may result from repeated overexposure

Flammability : 1 Slight Hazard

Physical : 0 Minimal Hazard

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.