

	Document Type: Safety Data Sheet	Cyclophosphamide for Injection, USP		
	Effective Date: 31 OCT 2025	SDS No.: SDS033	Revision No: 01	Page 1 of 10

Section 1 - Identification

- (a) **Product Identifier:** Cyclophosphamide for Injection, USP
- (b) **Product Code:** 83634-205-50; 83634-206-51; 83634-207-51
- Common/Trade Name:** NA
- Chemical Name:** 2-[bis(2-chloroethyl)amino]tetrahydro-2H-1,3,2-oxazaphosphorine 2-oxide monohydrate
- Chemical Family:** Alkylating Agent
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Avenacy 10 N. Martingale Road, Suite 225, Schaumburg, IL 60173, 847-773-4901
- (e) **Emergency Telephone:** 855-283-6229

Section 2 - Hazards Identification

- (a) **GHS Classification of substance or mixture:** Acute toxicity (oral) Category 3
Germ cell mutagenicity Category 1B
Carcinogenicity Category 1A
Reproductive toxicity Category 1A
Reproductive toxicity, Additional category, Effects on or via lactation
Specific target organ toxicity (repeated exposure) Category 1

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
GHS Signal Word:	Danger
GHS Hazard Statement:	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 (bone marrow, heart, liver, immune system, systemic toxicity) through prolonged or repeated exposure
GHS Symbols:	 

	Document Type: Safety Data Sheet	Cyclophosphamide for Injection, USP		
	Effective Date: 31 OCT 2025	SDS No.: SDS033	Revision No: 01	Page 2 of 10

GHS Precautionary Statements:	P203 - Obtain, read and follow all safety instructions before use. P260 - Do not breathe dust/fume/gas/mist/vapors/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. P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection. P301+P316 - IF SWALLOWED: Get emergency medical help immediately. P318 - If exposed or concerned, get medical advice. P319 - Get medical help if you feel unwell. P321 - Specific treatment (see information on this label and safety datasheet)). P330 - Rinse mouth. P405 - Store locked up. P501 - Dispose of contents/container per applicable local, national and international laws and regulations.
Other Hazards	Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
2-[bis(2-chloroethyl)amino]tetrahydro-2H-1,3,2-oxazaphosphorine 2-oxide monohydrate	Cyclophosphamide monohydrate	534.5 mg (equivalent to 500 mg cyclophosphamide) 1,069.0 mg (equivalent to 1 gram cyclophosphamide) 2,138.0 mg (equivalent to 2 grams cyclophosphamide)	6055-19-2	N/A

	Document Type: Safety Data Sheet	Cyclophosphamide for Injection, USP		
	Effective Date: 31 OCT 2025	SDS No.: SDS033	Revision No: 01	Page 3 of 10

Section 4 – 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.
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.
- Eye Exposure:** 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.
May cause slight irritation to eyes.
- Skin Exposure:** Remove contaminated clothing. If exposed or concerned: Get medical advice/attention. Drench affected area with water for at least 15 minutes. Prolonged exposure may cause skin irritation.
- Ingestion:** Do NOT induce vomiting. Rinse mouth. Immediately call a POISON CENTER or doctor.
This material is toxic in small amounts orally, and can cause adverse health effects or death.
- Inhalation:** When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.
Prolonged exposure may cause irritation.

Section 5 – Fire-fighting Measures

- (a) **Extinguishing Media:** Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.
Do not use heavy water stream. Use of heavy stream of water may spread fire.
- (b) **Hazardous Combustion Products:** Carbon oxides (CO, CO₂). Nitrogen oxides. Phosphorus oxide. Chlorides. Phosphine. Hydrogen chloride.
Hazardous reactions will not occur under normal conditions.
- (c) **Special Protective Equipment / Precautions:** **Advice for Fire-Fighters:** Exercise caution when fighting any chemical fire. Use water spray or fog for cooling exposed containers. Do not enter fire area without proper protective equipment, including respiratory protection.
- (d) **Fire / Explosion Hazards:** Not considered flammable but may burn at high temperatures.
Product is not explosive.

Section 6 - Accidental Release Measures

	Document Type: Safety Data Sheet	Cyclophosphamide for Injection, USP		
	Effective Date: 31 OCT 2025	SDS No.: SDS033	Revision No: 01	Page 4 of 10

Health and Safety Precautions:	Do not breath 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.
Measures for Cleaning / Collecting:	Use appropriate personal protective equipment (PPE). Evacuate unnecessary personnel. Equip cleanup crew with proper protection. 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.
Measures for Environmental Protections:	Prevent entry to sewers and public waters. Contain solid spills with appropriate barriers and prevent migration and entry into sewers or streams. 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. See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

Section 7 - Handling and Storage

General Handling:	Accidental injection may cause pain and swelling at the injection site. Sharps should be handled appropriately to minimize risk of accidents. 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. Avoid contact during pregnancy/while nursing. Handle empty containers with care because they may still present a hazard. Handle in accordance with good industrial hygiene and safety procedures.
Incompatible Materials:	Strong acids, strong bases, strong oxidizers. Moisture. Benzyl Alcohol.
Storage Conditions:	Comply with applicable regulations. 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. Store as directed by product packaging.

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

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

	Document Type: Safety Data Sheet	Cyclophosphamide for Injection, USP		
	Effective Date: 31 OCT 2025	SDS No.: SDS033	Revision No: 01	Page 5 of 10

including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

(b) 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.

(c) Individual Protection Measures

Personal Protective Equipment:	Gloves, protective clothing (chemically resistant materials and fabrics), protective goggles. Insufficient ventilation: wear respiratory protection.
Hand Protection:	Wear protective gloves.
Eye Protection:	Chemical safety goggles.
Skin 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.
Additional Information:	Avoid contact during pregnancy/while nursing. When using, do not eat, drink or smoke.

Section 9 - Physical and Chemical Properties

(a)	Appearance	Fine white crystalline powder
(b)	Odor	None
(c)	Odor Threshold	Not available
(d)	pH	3.0 to 7.0 (solution)
(e)	Melting Point:	Not available
(f)	Initial Boiling Point:	Not determined
(g)	Boiling Point:	48 – 51°C (118.4 – 123.8°F)
(h)	Flash Point (Liquid) (°C)	230°C (110°F)
(i)	Evaporation Rate:	Not determined
(j)	Flammability	Not determined
(k)	Upper Lower Flammability or Explosion Limits	Not determined
(l)	Vapor Pressure (kPa):	Not determined
(m)	Vapor Density:	Not determined
(n)	Relative Density	Not determined
(o)	Solubility(ies)	Water: 10 – 50 (mg/mL) at 73°F (22°C)

	Document Type: Safety Data Sheet	Cyclophosphamide for Injection, USP		
	Effective Date: 31 OCT 2025	SDS No.: SDS033	Revision No: 01	Page 6 of 10

(p)	Partition Coefficient: n-octanol/water	0.6 20°C (68°F)
(q)	Auto-ignition Temperature	Not available
(r)	Decomposition Temperature	Not available
(s)	Viscosity	Not available

Section 10 - Stability and Reactivity

(a)	Reactivity	Hazardous reactions will not occur under normal conditions.
(b)	Chemical Stability	Stable under recommended handling and storage conditions (see Section 7).
(c)	Possibility of Hazardous Reactions	Hazardous polymerization will not occur. Polymerization can occur at temperatures >120°F (48°C).
(d)	Conditions to Avoid	Direct sunlight, extremely high or low temperatures, and incompatible materials. Exposure to moisture or moist air.
(e)	Incompatible Materials	Strong acids, strong bases, strong oxidizers, moisture, benzyl alcohol.
(f)	Hazardous Decomposition Products	Thermal decomposition may produce: Carbon oxides (CO, CO ₂). Nitrogen oxides. Chlorides, Phosphorus oxides. Phosphine. Hydrogen chloride.

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Skin, eyes, ingestion, inhalation
(b)	Symptoms related to the physical, chemical and toxicological characteristics	Skin: Prolonged exposure may cause skin irritation. Eye: May cause slight irritation to eyes. Ingestion: This material is toxic in small amounts orally, and can cause adverse health effects or death. Inhalation: Prolonged exposure may cause irritation. Toxic if swallowed.
(c)	Delayed and immediate effects and chronic effects from short and long term exposure	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.

	Document Type: Safety Data Sheet	Cyclophosphamide for Injection, USP		
	Effective Date: 31 OCT 2025	SDS No.: SDS033	Revision No: 01	Page 7 of 10

(d) Acute Toxicity:

Component	Route	Study Type	Dosage
Cyclophosphamide monohydrate	Oral	ATE US/CA (LD50; LC50)	94.00 mg/kg body weight

IARC Group – 1

OSHA Hazard Communication Carcinogen List – listed.

Section 12 - Ecological Information

The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

(a)	Ecotoxicity	N/A
(b)	Persistence and degradability	N/A
(c)	Bioaccumulative potential	N/A
(d)	Mobility in soil	N/A
(e)	Other Adverse Effects	Avoid release to environment.

Section 13 - Disposal Considerations

Waste Disposal: 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 waste water.

Section 14 - Transport Information

DOT – ORGANOPHOSPHORUS COMPOUND, SOLID, TOXIC, N.O.S.

(Cyclophosphamide)

Hazard Class: 6.1

Identification Number: UN3464

Packing Group: III

ERG Number: 151



IMDG - ORGANOPHOSPHORUS COMPOUND, SOLID, TOXIC, N.O.S.

(Cyclophosphamide)

Hazard Class: 6.1

Identification Number: UN3464

Packing Group: III

EmS No. (Fire): F-A

EmS No. (Spillage): S-A



	Document Type: Safety Data Sheet	Cyclophosphamide for Injection, USP		
	Effective Date: 31 OCT 2025	SDS No.: SDS033	Revision No: 01	Page 8 of 10

IATA - ORGANOPHOSPHORUS COMPOUND, SOLID, TOXIC, N.O.S.

(Cyclophosphamide)

Hazard Class: 6.1

Identification Number: UN3464

Packing Group: III

ERG Code (IATA): 6L



TDG - ORGANOPHOSPHORUS COMPOUND, SOLID, TOXIC, N.O.S.

(Cyclophosphamide)

Hazard Class: 6.1

Identification Number: UN3464

Label Codes: 6.1

Packing Group: III



Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Avenacy usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

Cyclophosphamide monohydrate:

SARA Section 311/312 Hazard Classes: Carcinogenicity; Specific target organ toxicity (single or repeated exposure); Germ cell mutagenicity; Reproductive toxicity; Acute toxicity (any route of exposure)

California Proposition 65: Carcinogenicity, Developmental Toxicity; Female Reproductive Toxicity; Male Reproductive Toxicity.

Section 16 - Other Information

As of the date of effectiveness, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information
contact:

Avenacy
10 N. Martingale Road, Suite 225
Schaumburg, IL 60173
847-773-4901

	Document Type: Safety Data Sheet	Cyclophosphamide for Injection, USP		
	Effective Date: 31 OCT 2025	SDS No.: SDS033	Revision No: 01	Page 9 of 10

Glossary: This glossary contains definitions of general terms used in a Safety Data Sheet (SDS). Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted

	Document Type: Safety Data Sheet	Cyclophosphamide for Injection, USP		
	Effective Date: 31 OCT 2025	SDS No.: SDS033	Revision No: 01	Page 10 of 10

UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System