

SAFETY DATA SHEET

Creation Date 04-May-2010

Revision Date 28-Mar-2024

Revision Number 3

1. Identification

Product Name Cyclophosphamide monohydrate

Cat No. : L11508

CAS No 6055-19-2
Synonyms N,N-Bis(2-chloroethyl)tetrahydro-2H-1,3,2-oxazaphosphorin-2-amine 2-oxide monohydrate

Recommended Use Laboratory chemicals.
Uses advised against Food, drug, pesticide or biocidal product use.

Details of the supplier of the safety data sheet

Company

Thermo Fisher Scientific Chemicals, Inc.
30 Bond Street
Ward Hill, MA 01835-8099
Tel: 800-343-0660
Fax: 800-322-4757

Emergency Telephone Number

For information **US** call: 001-800-227-6701 / **Europe** call: +32 14 57 52 11
Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99
CHEMTREC Tel. No. **US**:001-800-424-9300 / **Europe**:001-703-527-3887

2. Hazard(s) identification

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute oral toxicity	Category 3
Germ Cell Mutagenicity	Category 1B
Carcinogenicity	Category 1A
Reproductive Toxicity	Category 1B

Label Elements

Signal Word

Danger

Hazard Statements

Toxic if swallowed
May cause genetic defects

May cause cancer
May damage the unborn child

**Precautionary Statements****Prevention**

Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Use personal protective equipment as required
Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product
Do not breathe dust/fume/gas/mist/vapors/spray
Use only outdoors or in a well-ventilated area

Response

IF exposed or concerned: Get medical attention/advice

Inhalation

IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing

Ingestion

IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician

Rinse mouth

Storage

Store locked up
Store in a well-ventilated place. Keep container tightly closed

Disposal

Dispose of contents/container to an approved waste disposal plant

Hazards not otherwise classified (HNOC)

WARNING. Cancer and Reproductive Harm - <https://www.p65warnings.ca.gov/>.

3. Composition/Information on Ingredients

Component	CAS No	Weight %
Cyclophosphamide monohydrate	6055-19-2	>95
Cyclophosphamide	50-18-0	-

4. First-aid measures

General Advice

Show this safety data sheet to the doctor in attendance. Immediate medical attention is required.

Eye Contact

In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Skin Contact

Wash off immediately with plenty of water for at least 15 minutes. Immediate medical attention is required.

Inhalation

Remove to fresh air. If not breathing, give artificial respiration. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Immediate medical attention is required.

Ingestion	Do NOT induce vomiting. Call a physician or poison control center immediately.
Most important symptoms and effects	None reasonably foreseeable.
Notes to Physician	Treat symptomatically

5. Fire-fighting measures

Suitable Extinguishing Media	Water spray, carbon dioxide (CO ₂), dry chemical, alcohol-resistant foam.
Unsuitable Extinguishing Media	No information available
Flash Point	> 110 °C / > 230 °F
Method -	No information available
Autoignition Temperature	No information available
Explosion Limits	
Upper	No data available
Lower	No data available
Sensitivity to Mechanical Impact	No information available
Sensitivity to Static Discharge	No information available

Specific Hazards Arising from the Chemical

Keep product and empty container away from heat and sources of ignition.

Hazardous Combustion Products

Carbon monoxide (CO). Carbon dioxide (CO₂). Nitrogen oxides (NO_x). Oxides of phosphorus. Hydrogen chloride gas.

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear. Thermal decomposition can lead to release of irritating gases and vapors.

NFPA

Health
2

Flammability
1

Instability
0

Physical hazards
N/A

6. Accidental release measures

Personal Precautions	Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation. Keep people away from and upwind of spill/leak. Evacuate personnel to safe areas.
Environmental Precautions	Should not be released into the environment.

Methods for Containment and Clean Up Sweep up and shovel into suitable containers for disposal. Avoid dust formation.

7. Handling and storage

Handling	Wear personal protective equipment/face protection. Do not get in eyes, on skin, or on clothing. Avoid dust formation. Use only under a chemical fume hood. Do not breathe (dust, vapor, mist, gas). Do not ingest. If swallowed then seek immediate medical assistance.
Storage.	Keep containers tightly closed in a dry, cool and well-ventilated place. To maintain product quality: Keep refrigerated. Incompatible Materials. Strong oxidizing agents.

8. Exposure controls / personal protection

Exposure Guidelines	This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.
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Engineering Measures Use only under a chemical fume hood. Ensure that eyewash stations and safety showers are close to the workstation location.

Personal Protective Equipment

Eye/face Protection Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.

Skin and body protection Wear appropriate protective gloves and clothing to prevent skin exposure.

Respiratory Protection Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

Recommended Filter type: Particulates filter conforming to EN 143.

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

9. Physical and chemical properties

Physical State	Solid
Appearance	Off-white
Odor	Odorless
Odor Threshold	No information available
pH	4.0-6.0 2% aq.sol
Melting Point/Range	49 - 53 °C / 120.2 - 127.4 °F
Boiling Point/Range	No information available
Flash Point	> 110 °C / > 230 °F
Evaporation Rate	Not applicable
Flammability (solid,gas)	No information available
Flammability or explosive limits	
Upper	No data available
Lower	No data available
Vapor Pressure	No information available
Vapor Density	Not applicable
Specific Gravity	No information available
Solubility	Soluble in water
Partition coefficient; n-octanol/water	No data available
Autoignition Temperature	No information available
Decomposition Temperature	90 °C
Viscosity	Not applicable
Molecular Formula	C7 H15 Cl2 N2 O2 P . H2 O
Molecular Weight	279.09

10. Stability and reactivity

Reactive Hazard None known, based on information available

Stability Stable under normal conditions.

Conditions to Avoid Incompatible products. Excess heat.

Incompatible Materials Strong oxidizing agents

Hazardous Decomposition Products Carbon monoxide (CO), Carbon dioxide (CO₂), Nitrogen oxides (NO_x), Oxides of phosphorus, Hydrogen chloride gas

Hazardous Polymerization Hazardous polymerization does not occur.

Hazardous Reactions None under normal processing.

11. Toxicological information

Acute Toxicity

Product Information Component Information

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Cyclophosphamide monohydrate	LD50 = 94 mg/kg (Rat)	Not listed	Not listed
Cyclophosphamide	LD50 = 100 mg/kg (Rat)	Not listed	Not listed

Toxicologically Synergistic Products No information available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Irritation Irritating to eyes, respiratory system and skin

Sensitization No information available

Carcinogenicity Possible cancer hazard. May cause cancer based on animal data. The table below indicates whether each agency has listed any ingredient as a carcinogen.

Component	CAS No	IARC	NTP	ACGIH	OSHA	Mexico
Cyclophosphamide monohydrate	6055-19-2	Group 1	Not listed	Not listed	X	Not listed
Cyclophosphamide	50-18-0	Group 1	Known	Not listed	X	Not listed

IARC (International Agency for Research on Cancer)

IARC (International Agency for Research on Cancer)

Group 1 - Carcinogenic to Humans

Group 2A - Probably Carcinogenic to Humans

Group 2B - Possibly Carcinogenic to Humans

NTP: (National Toxicity Program)

Known - Known Carcinogen

Reasonably Anticipated - Reasonably Anticipated to be a Human Carcinogen

NTP: (National Toxicity Program)

Mutagenic Effects May cause heritable genetic damage

Reproductive Effects Experiments have shown reproductive toxicity effects on laboratory animals.

Developmental Effects May cause harm to the unborn child.

Teratogenicity No information available.

STOT - single exposure None known

STOT - repeated exposure None known

Aspiration hazard No information available

Symptoms / effects, both acute and delayed No information available

Endocrine Disruptor Information

Component	EU - Endocrine Disruptors Candidate List	EU - Endocrine Disruptors - Evaluated Substances	Japan - Endocrine Disruptor Information
Cyclophosphamide	Group III Chemical	Not applicable	Not applicable

Other Adverse Effects The toxicological properties have not been fully investigated.

12. Ecological information

Ecotoxicity

Do not empty into drains.

Persistence and Degradability Soluble in water Persistence is unlikely based on information available.**Bioaccumulation/ Accumulation** No information available.**Mobility** Will likely be mobile in the environment due to its water solubility.**13. Disposal considerations****Waste Disposal Methods** Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

Component	RCRA - U Series Wastes	RCRA - P Series Wastes
Cyclophosphamide - 50-18-0	U058	-

14. Transport information**DOT**

UN-No UN3464
Proper Shipping Name ORGANOPHOSPHORUS COMPOUND, TOXIC, SOLID, N.O.S.
Technical Name Cyclophosphamide monohydrate ,Cyclophosphamide
Hazard Class 6.1
Packing Group III

TDG

UN-No UN3464
Proper Shipping Name ORGANOPHOSPHORUS COMPOUND, TOXIC, SOLID, N.O.S.
Hazard Class 6.1
Packing Group III

IATA

UN-No UN3464
Proper Shipping Name Organophosphorus compound, toxic, solid, n.o.s.
Hazard Class 6.1
Packing Group III

IMDG/IMO

UN-No UN3464
Proper Shipping Name Organophosphorus Compound, toxic, solid, n.o.s.
Hazard Class 6.1
Packing Group III

15. Regulatory information**United States of America Inventory**

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	TSCA - EPA Regulatory Flags
Cyclophosphamide monohydrate	6055-19-2	-	-	-
Cyclophosphamide	50-18-0	-	-	-

Legend:**TSCA** US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

X - Listed

-' - Not Listed

TSCA - Per 40 CFR 751, Regulation of Certain Chemical Substances & Mixtures, Under TSCA Section 6(h) (PBT)

Not applicable

TSCA 12(b) - Notices of Export

Not applicable

International Inventories

Canada (DSL/NDL), Europe (EINECS/ELINCS/NLP), Philippines (PICCS), Japan (ENCS), Japan (ISHL), Australia (AICS), China (IECSC), Korea (KECL).

Component	CAS No	DSL	NDL	EINECS	PICCS	ENCS	ISHL	AICS	IECSC	KECL
Cyclophosphamide monohydrate	6055-19-2	-	-	-	-	-		-	-	-
Cyclophosphamide	50-18-0	X	-	200-015-4	-	X		-	-	-

KECL - NIER number or KE number (<http://ncis.nier.go.kr/en/main.do>)

U.S. Federal Regulations**SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act) Not applicable

Clean Air Act Not applicable

OSHA - Occupational Safety and Health Administration Not applicable

CERCLA

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355).

Component	Hazardous Substances RQs	CERCLA Extremely Hazardous Substances RQs	SARA Reportable Quantity (RQ)
Cyclophosphamide	10 lb	-	10 lb 4.54 kg

California Proposition 65

This product contains the following Proposition 65 chemicals.

Component	CAS No	California Prop. 65	Prop 65 NSRL	Category
Cyclophosphamide monohydrate	6055-19-2	Carcinogen Developmental Female Reproductive Male Reproductive	1 µg/day	Developmental Carcinogen
Cyclophosphamide	50-18-0	Carcinogen Developmental Female Reproductive Male Reproductive	1 µg/day	Developmental Carcinogen

U.S. State Right-to-Know Regulations

Component	Massachusetts	New Jersey	Pennsylvania	Illinois	Rhode Island
Cyclophosphamide	X	-	X	X	X

U.S. Department of Transportation

Reportable Quantity (RQ): Y
DOT Marine Pollutant N
DOT Severe Marine Pollutant N

U.S. Department of Homeland Security

This product does not contain any DHS chemicals.

Other International Regulations

Mexico - Grade

Slight risk, Grade 1

Authorisation/Restrictions according to EU REACH

Component	CAS No	REACH (1907/2006) - Annex XIV - Substances Subject to Authorization	REACH (1907/2006) - Annex XVII - Restrictions on Certain Dangerous Substances	REACH Regulation (EC 1907/2006) article 59 - Candidate List of Substances of Very High Concern (SVHC)
Cyclophosphamide monohydrate	6055-19-2	-	-	-
Cyclophosphamide	50-18-0	-	Use restricted. See item 75. (see link for restriction details)	-

REACH links

<https://echa.europa.eu/substances-restricted-under-reach>

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

Component	CAS No	OECD HPV	Persistent Organic Pollutant	Ozone Depletion Potential	Restriction of Hazardous Substances (RoHS)
Cyclophosphamide monohydrate	6055-19-2	Not applicable	Not applicable	Not applicable	Not applicable
Cyclophosphamide	50-18-0	Not applicable	Not applicable	Not applicable	Not applicable

Contains component(s) that meet a 'definition' of per & poly fluoroalkyl substance (PFAS)?

Not applicable

Other International Regulations

Component	CAS No	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements	Rotterdam Convention (PIC)	Basel Convention (Hazardous Waste)
Cyclophosphamide monohydrate	6055-19-2	Not applicable	Not applicable	Not applicable	Not applicable
Cyclophosphamide	50-18-0	Not applicable	Not applicable	Not applicable	Not applicable

16. Other information

Prepared By

Health, Safety and Environmental Department
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04-May-2010

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28-Mar-2024

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28-Mar-2024

Revision Summary

New emergency telephone response service provider.

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of SDS