



SAFETY DATA SHEET

Revision date 16-Jun-2025

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Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Cyclophosphamide Powder for Injection
Product Code(s) PZ00021
Trade Name: CYCLOPHOSPHAMIDE
Chemical Family: Alkylating Agent
Cyclophosphamide
CAS No. 50-18-0

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

Recommended Use Pharmaceutical product used as Antineoplastic

1.3. Details of the supplier of the safety data sheet

Pfizer Inc
66 Hudson Boulevard East
New York, New York 10001
1-800-879-3477

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

Acute toxicity - Oral	Category 3 - (H301)
Germ cell mutagenicity	Category 1B - (H340)
Carcinogenicity	Category 1A - (H350)
Reproductive toxicity	Category 1A - (H360FD)
Effects on or via lactation	Yes - (H362)
Specific target organ toxicity (repeated exposure)	Category 1 - (H372)

OSHA Classification

Hazards not otherwise classified (HNOC)
Not applicable

Hazards classified under paragraph (d)(1)(ii) of 1910.1200

Not applicable

2.2. Label elements

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Signal word

Hazard statements

Danger

H301 - Toxic if swallowed
H350 - May cause cancer
H340 - May cause genetic defects
H360FD - May damage fertility. May damage the unborn child
H362 - May cause harm to breast-fed children
H372 - Causes damage to organs through prolonged or repeated exposure:

Precautionary Statements - EU (§28, P201 - Obtain special instructions before use

1272/2008)

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

P264 - Wash hands thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

P281 - Use personal protective equipment as required

P308 + P313 - IF exposed or concerned: Get medical advice/attention

P263 - Avoid contact during pregnancy/while nursing

P405 - Store locked up

P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

2.3. Other hazards

Other hazards

An Occupational Exposure Value has been established for this substance (see Section 8).

PBT & vPvB

The product does not contain any substance(s) classified as PBT or vPvB.

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors.

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances

No information available

3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)

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Cyclophosphamide (CAS #: 50-18-0)	100		200-015-4	Acute Tox.3 (H301) Carc.1A (H350) Muta.1B (H340) Repr.1A (H360FD) Lact.(H362) STOT RE.1 (H372)	Not classified	No data available	No data available
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Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Cyclophosphamide 50-18-0	94	No data available	No data available	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59).

Additional information

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

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

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

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Suitable Extinguishing Media Dry chemical, CO₂, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products Carbon dioxide, carbon monoxide, and oxides of nitrogen phosphorous

Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information available.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Contain the source of the spill or leak. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean contaminated surface thoroughly.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Minimize dust generation and accumulation. Avoid breathing dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. When handling, use appropriate personal protective equipment (see Section 8). Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

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7.3. Specific end use(s)

Specific use(s) Pharmaceutical product used as. Antineoplastic.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

Refer to available public information for specific member state Occupational Exposure Limits.

Cyclophosphamide

Pfizer OEL TWA-8 Hr: 2 µg/m³

Cyclophosphamide

Bulgaria

Poland

TWA: 0.002 mg/m³;

TWA-NDS: 0.01 mg/m³;

Sk

8.2. Exposure controls

Engineering controls

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or aerosols. Keep airborne contamination levels below the exposure limits listed above in this section.

Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Eye/face protection

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection

Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection

Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.).

Thermal hazards

No information available.

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Environmental exposure controls No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	Crystalline powder
Physical state	Powder
Color	White
Odor	No information available.
Odor threshold	No information available
Property	Values
Melting point / freezing point	41
Boiling point or initial boiling point and boiling range	No data available
Flammability (solid, gas)	No data available
Lower and upper explosion limit/flammability limit	
Lower explosion limit	No data available
Upper explosion limit	No data available
Flash point	No data available
Autoignition temperature	No data available
Decomposition temperature	
SADT (°C)	No data available
pH	No data available
pH (as aqueous solution)	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Solubility	No data available
Vapor pressure	No data available
Density and/or relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Vapor density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available

Partition Coefficient: (Method, pH, Endpoint, Value)

Cyclophosphamide

Predicted 7.4 Log D 0.526

9.2. Other information

Molecular formula	C7 H15 Cl2 N2 O2 P
Molecular weight	261.09

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

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Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Long Term:

The use of this drug during pregnancy has resulted in birth defects. Animal studies have shown a potential to cause adverse effects on the fetus. Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system. Effects on blood and blood-forming organs have also occurred.

Known Clinical Effects:

Acute toxicity

Serious eye damage/eye irritation

Skin corrosion/irritation

Respiratory or skin sensitization

STOT - single exposure

STOT - repeated exposure

Reproductive toxicity

Germ cell mutagenicity

Carcinogenicity

Aspiration hazard

Toxic if swallowed

Based on available data, the classification criteria are not met.

Based on available data, the classification criteria are not met.

Based on available data, the classification criteria are not met.

Based on available data, the classification criteria are not met.

Causes damage to organs through prolonged or repeated exposure.

May damage fertility. May damage the unborn child. May cause harm to breast-fed children.

May cause genetic defects.

May cause cancer.

Based on available data, the classification criteria are not met.

Acute Toxicity: (Species, Route, End Point, Dose)

Cyclophosphamide

Rat Oral LD 50 94 mg/kg

Rat Para-periosteal LD 50 148 mg/kg

Mouse Oral LD 50 350 mg/kg

Mouse Intravenous LD 50 265-828 mg/kg

Rat Intravenous LD50 160 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Cyclophosphamide	= 94 mg/kg (Rat)	-	-

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Cyclophosphamide

80 Day(s) Rat Gavage 12 mg/kg/day Lungs, Bladder, Blood, Gastrointestinal System

6 Week(s) Dog Oral 5 mg/kg/day Bladder, Brain, Bone Marrow, Liver, Lymphoid tissue, Gastrointestinal system

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Cyclophosphamide

Embryo / Fetal Development Rat Intraperitoneal 5 mg/kg LOAEL Teratogenic

Embryo / Fetal Development Rat Intraperitoneal 7 mg/kg LOAEL Fetotoxicity

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Embryo / Fetal Development Mouse Intravenous 10 mg/kg LOAEL Teratogenic
Embryo / Fetal Development Mouse Intraperitoneal 5 mg/kg LOAEL Fetotoxicity, Fertility
Embryo / Fetal Development Rabbit Intravenous 30 mg/kg LOAEL Fetotoxicity, Teratogenic
Fertility & Early Embryonic Development - Males Rat Oral 1.4 (fetal); 3.4 (parental) mg/kg LOAEL Fertility, Teratogenic

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

Cyclophosphamide

In Vivo Micronucleus Rodent Positive
In Vivo Chromosome Aberration Rodent Positive
In Vivo Sister Chromatid Exchange Rodent Positive
In Vitro Chromosome Aberration Human Lymphocytes Positive
Dominant Lethal Assay Drosophila Positive

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

Cyclophosphamide

2 Year(s) Rat Intravenous Benign tumors, Malignant tumors
2 Year(s) Rat Oral 0.31 mg/kg/day LOAEL Malignant tumors
2 Year(s) Mouse Intraperitoneal Benign tumors, Malignant tumors
93 Week(s) Mouse Oral 1 mg/kg/day NOAEL Malignant tumors

Carcinogenicity See below

Cyclophosphamide

IARC	Group 1
NTP	Known

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

Partition Coefficient: (Method, pH, Endpoint, Value)

Cyclophosphamide

Predicted 7.4 Log D 0.526

12.4. Mobility in soil

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Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment Based on available data, the classification criteria are not met.

12.6. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

12.7. Other adverse effects

Other adverse effects No information available.
PMT or vPvM properties Based on available data, the classification criteria are not met.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products

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 wastewater 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.

Chemical name	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Cyclophosphamide	-	-	-	U058

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

This material is regulated for transportation as a hazardous material/dangerous good.

UN number: UN 2811
UN proper shipping name: Toxic solid, organic, n.o.s. (cyclophosphamide)
Transport hazard class(es): 6.1
Packing group: III
Environmental Hazard(s): Not applicable

Section 15: REGULATORY INFORMATION

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

Cyclophosphamide

CERCLA/SARA Section 313 de minimus %

Hazardous Substances RQs

California Proposition 65

Not Listed

10 lb

Carcinogen

Developmental

Female Reproductive

Male Reproductive

200-015-4

Schedule 4

EINECS

Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)

National regulations

Germany

Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

TRGS 905

Not applicable

Chemical name	Carcinogenicity	Concentration limits (Classification thresholds)	Mutagenicity	Developmental effects	Fertility effects
Cyclophosphamide 50-18-0	Category 1A Category 1B				

Chemical name	Netherlands - List of Carcinogens	Netherlands - List of Mutagens	Netherlands - List of Reproductive Toxins
Cyclophosphamide 50-18-0	Present	-	-

Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018 Not applicable

Storage of Hazardous Material Not applicable

WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20 Not applicable

Major Accidents Ordinance SR 814.012 Not applicable

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorizations and/or restrictions on use:

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Cyclophosphamide 50-18-0	75	-

Persistent Organic Pollutants

Not applicable

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Ozone-depleting substances (ODS) Regulation (EU) 2024/590

Not applicable.

Explosives Precursors Marketing and Use (2019/1148)

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing Chemicals Inventory

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

TCSI - Taiwan Chemical Substance Inventory

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of any hazard and/or precautionary statements referred to under Sections 2-15

H301 - Toxic if swallowed H350 - May cause cancer H340 - May cause genetic defects H360FD - May damage fertility. May damage the unborn child H372 - Causes damage to organs through prolonged or repeated exposure H362 - May cause harm to breast-fed children

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reason for revision Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information.

Revision date 16-Jun-2025

Prepared By Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.