



# 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.

<b>Acute toxicity - Oral</b>	Category 3 - (H301)
<b>Germ cell mutagenicity</b>	Category 1B - (H340)
<b>Carcinogenicity</b>	Category 1A - (H350)
<b>Reproductive toxicity</b>	Category 1A - (H360FD)
<b>Effects on or via lactation</b>	Yes - (H362)
<b>Specific target organ toxicity (repeated exposure)</b>	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, 1272/2008)

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

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  $\geq 0.1\%$  (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**

<b>Inhalation</b>	Remove to fresh air. Seek immediate medical attention/advice.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion</b>	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**

<b>Most important symptoms and effects</b>	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
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### **4.3. Indication of any immediate medical attention and special treatment needed**

<b>Note to physicians</b>	None.
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## **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/m<sup>3</sup>

#### Cyclophosphamide

Bulgaria  
Poland

TWA: 0.002 mg/m<sup>3</sup>;  
TWA-NDS: 0.01 mg/m<sup>3</sup>;  
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.

#### Personal protective equipment

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

<b>Appearance</b>	Crystalline powder
<b>Physical state</b>	Powder
<b>Color</b>	White
<b>Odor</b>	No information available.
<b>Odor threshold</b>	No information available

#### Property

#### Values

<b>Melting point / freezing point</b>	41
<b>Boiling point or initial boiling point and boiling range</b>	No data available
<b>Flammability (solid, gas)</b>	No data available
<b>Lower and upper explosion limit/flammability limit</b>	
Lower explosion limit	No data available
Upper explosion limit	No data available
<b>Flash point</b>	No data available
<b>Autoignition temperature</b>	No data available
<b>Decomposition temperature</b>	
SADT (°C)	No data available
<b>pH</b>	No data available
pH (as aqueous solution)	No data available
<b>Kinematic viscosity</b>	No data available
Dynamic viscosity	No data available
<b>Solubility</b>	No data available
<b>Vapor pressure</b>	No data available
<b>Density and/or relative density</b>	No data available
Bulk density	No data available
Liquid Density	No data available
<b>Vapor density</b>	No data available
<b>Particle characteristics</b>	
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

<b>Molecular formula</b>	C7 H15 Cl2 N2 O2 P
<b>Molecular weight</b>	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

**Known Clinical Effects:** Effects on blood and blood-forming organs have also occurred.

**Acute toxicity**

Toxic if swallowed

**Serious eye damage/eye irritation**

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

**Skin corrosion/irritation**

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

**Respiratory or skin sensitization**

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

**STOT - single exposure**

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

**STOT - repeated exposure**

Causes damage to organs through prolonged or repeated exposure.

**Reproductive toxicity**

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

**Germ cell mutagenicity**

May cause genetic defects.

**Carcinogenicity**

May cause cancer.

**Aspiration hazard**

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 LOEL Teratogenic  
Embryo / Fetal Development Mouse Intraperitoneal 5 mg/kg LOEL Fetotoxicity, Fertility  
Embryo / Fetal Development Rabbit Intravenous 30 mg/kg LOEL Fetotoxicity, Teratogenic  
Fertility & Early Embryonic Development - Males Rat Oral 1.4 (fetal); 3.4 (parental) mg/kg LOEL 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 LOEL Malignant tumors  
2 Year(s) Mouse Intraperitoneal Benign tumors, Malignant tumors  
93 Week(s) Mouse Oral 1 mg/kg/day NOEL 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

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