



# Material Safety Data Sheet

MSDS Number: 1118057  
Revision date: 02/10/2009  
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## 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

MSDS Number: 1118057  
Product name: Cyclophosphamide for Injection, USP  
Product Codes: NDC 10019-955-01, NDC 10019-956-01, NDC 10019-957-01  
Synonyms: Endoxan; Sendoxan; Genoxal  
Chemical Family: Antineoplastic Agent  
Product Type: Regulated Prescription Drug  
Container Information: 500mg, 1g, and 2g vials  
Product Use: Pharmaceutical.

Supplier:  
BAXTER HEALTHCARE CORPORATION  
DEERFIELD, ILLINOIS 60015  
(800) 422-9837 or (847) 948-4770

Emergency telephone number: PROSAR: USA (888) 990-0996 OUTSIDE USA (615)917-6114  
CHEMTREC: USA (800) 424-9300 OUTSIDE USA (743)741-6089

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

Component	Weight %	UN Number:	Classification:
Cyclophosphamide 50-18-0	100	None	None

## 3. HAZARDS IDENTIFICATION

**Emergency overview:** WARNING! HARMFUL IF SWALLOWED. MAY CAUSE CANCER. REPRODUCTIVE HAZARD THAT MAY CAUSE ADVERSE REPRODUCTIVE EFFECTS. DEVELOPMENTAL HAZARD THAT MAY ADVERSLEY EFFECT THE DEVELOPING FETUS. Risk of serious damage to eyes. Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin, and if swallowed. Can be absorbed through the skin.

**Principle routes of exposure:** Absorbed through skin. Eye contact. Ingestion. Inhalation.

**Inhalation:** Toxic: danger of serious damage to health by prolonged exposure through inhalation. Irritating to respiratory system.

**Ingestion:** Harmful if swallowed. Toxic: danger of serious damage to health by prolonged exposure if swallowed. Gastrointestinal effects (may include nausea/vomiting, abdominal pain, diarrhea, dry mouth, colic). Dermatologic effects (may include exfoliative dermatitis, photosensitivity, rash, itching). Hair loss. Blood effects (may include anemia, neutropenia (decreased number of neutrophils), thrombocytopenia (decreased number of platelets), bone marrow depression). Immune system effects.

**Skin contact:** Toxic: danger of serious damage to health by prolonged exposure with skin.

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### 3. HAZARDS IDENTIFICATION

**Eye contact:** Risk of serious damage to eyes

### 4. FIRST AID MEASURES

**Inhalation:** If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.

**Skin contact:** In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. Get medical attention

**Ingestion:** Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention

**Eye contact:** In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention

**Notes to physician:** See patient package insert in shipping carton for complete information.

### 5. FIRE FIGHTING MEASURES

<b>Suitable extinguishing media:</b>	Use foam or all purpose dry chemicals to extinguish.
<b>Special protective equipment for firefighters:</b>	Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.
<b>Specific methods:</b>	No information available
<b>Flash point:</b>	Not determined
<b>Autoignition temperature:</b>	Not available
<b>Flammable limits in air-lower (%):</b>	750 g/m <sup>3</sup> (dust)
<b>Flammable limits in air-upper (%):</b>	3000 g/m <sup>3</sup> (dust)

### 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions:** Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).

**Environmental precautions:** Do not discharge product unmonitored into the environment.

**Methods for cleaning up:** If emergency personnel are unavailable, contain spilled material. Absorb with vacuum cleaner approved for carcinogenic substances. Place spilled material in an appropriate container for disposal. Avoid production of dust. Clean contaminated surface thoroughly.

### 7. HANDLING AND STORAGE

**Handling:**

**Technical measures/precautions:** Do not ingest. Avoid skin contact. Avoid eye contact. Wash thoroughly after handling.

**Storage:**

**Technical measures/Storage conditions:** Store at or below 25°C (77°F). Keep containers tightly closed in a cool, well-ventilated place. Store in original container. Keep away from heat.

## 7. HANDLING AND STORAGE

**Incompatible products:** No special restrictions on storage with other products.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Occupational Exposure Limits

Component	OSHA- Time Weighted Average:	OSHA- Short Term Exposure Limit:	OSHA- Ceiling Limits	ACGIH- Time Weighted Average:	ACGIH- Short Term Exposure Limit:	ACGIH- Ceiling Limit Value:
Cyclophosphamide 50-18-0	None	None	None	None	None	None

**Engineering measures:** Provide general or local exhaust ventilation. Open handling must be limited.

### Personal protective equipment:

**Respiratory protection:** No personal respiratory protective equipment normally required.

**Hand protection:** Use chemical resistant, impervious gloves.

**Skin and body protection:** Disposable close-front gown or coveralls.

**Eye protection:** Goggles, face shield, or other full-face protection if potential exists for direct exposure to dust.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical state:** Solid.  
**Appearance:** Crystalline  
**Color:** White  
**Odor:** Odorless  
**pH:** 4.0 - 6.0  
**Molecular weight:** 279.1  
**Boiling point/range:** Not available.  
**Melting point/range:** 49 - 53 °C  
**Density:** Not available.  
**Vapor pressure:** 0.0000033 kPa  
**Evaporation rate:** Not available.  
**Solubility:** Soluble in water.  
**Partition coefficient (n-octanol/water):** Not available.  
**Viscosity:** Not available.  
**% Volatile by Volume:** Not available.

## 10. STABILITY AND REACTIVITY

**Stability:** Stable under recommended storage conditions.

**Polymerization:** Not applicable

**Hazardous decomposition products:** Halogenated hydrocarbons. Organic compounds of phosphoric compounds. Organic nitrogenous products of decomposition.

## 10. STABILITY AND REACTIVITY

**Materials to avoid:** Acids. Alkali metals. Oxidizing agents.

## 11. TOXICOLOGICAL INFORMATION

Component	LD50s and LC50s
Cyclophosphamide 50-18-0	Oral LD50 Mouse = 137 mg/kg Oral LD50 Rat = 342 mg/kg Dermal LD50 Rat > 2000 mg/kg

**Acute toxicity:** Gastrointestinal effects (may include nausea/vomiting, abdominal pain, diarrhea, dry mouth, colic). Dermatologic effects (may include exfoliative dermatitis, photosensitivity, rash, itching). Hair loss. Blood effects (may include anemia, neutropenia (decreased number of neutrophils), thrombocytopenia (decreased number of platelets), bone marrow depression). Immune System effects. Irritating to eyes.

**Chronic toxicity:** No data is available on the product itself.

**Carcinogenic effects:** Cancer Hazard. Can cause cancer. Carcinogenic Category 1. See patient package insert for additional information.

**Mutagenic effects:** May be mutagenic. Mutagenic category 2.

**Reproductive toxicity:** Can impair fertility. Considered fetotoxic. May be teratogenic. May cause birth defects. Reproductive category 1. See patient package insert for additional information.

**FDA Pregnancy Category** D

## 12. ECOLOGICAL INFORMATION

**Environmental properties:**

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Ecotoxicity - Microtox Data
Cyclophosphamide 50-18-0	None.	None.	None.	None.

**Ecotoxicity effects:** NOEC (96 h): > 984 mg/l *Salmo gairdneri*; NOEC (48 h): >987 mg/l *Daphnia magna*; EC 10 (16h): >10000 mg/l *Pseudomonas putida*.

**Bioaccumulation:** Not easily biodegradable.

## 13. DISPOSAL CONSIDERATIONS

**Waste Classification:** Hazardous waste.

### 13. DISPOSAL CONSIDERATIONS

**Waste from residues / unused products:**

Waste disposal must be in accordance with appropriate Federal, State, and local regulations.

### 14. TRANSPORT INFORMATION

**DOT:**

DOT shipping name: None  
UN Number: None  
DOT Packing Group: None  
DOT Hazard class: None

**TDG (Canada):**

TDG Proper shipping name: None  
TDG UN/NA Number: None  
TDG Packing Group: None  
TDG Hazard class: None

**ADR/RID:**

ADR Official Transport Name: Not Available.  
ADR Proper shipping name: Not Available.  
ADR UN/NA number: Not Available.  
ADR Hazard Class: Not Available.

**ICAO / IATA:**

IATA Proper shipping name: None  
IATA UN NUMBER: None  
IATA Primary Hazard: None  
IATA Packing group: None  
ICAO ERG Code: None

**IMO / IMDG:**

IMDG Proper Shipping Name: Not Available.  
IMDG Hazard Class and Division: Not Available.  
IMDG Packing Group: Not Available.  
IMDG Subsidiary Risks: Not Available.

### 15. REGULATORY INFORMATION

**U.S. Regulations:**

**TSCA Inventory List -**

The product is exempt from TSCA, it is FDA Regulated

**OTHER REGULATIONS:**

**Japanese Inventory (ENCS)**

This product does not comply with JPENCS

Component	Weight %	RCRA Status:	CERCLA Reportable Quantity:	CERCLA/SARA - 302 Ext. haz. substances:	Listed as Sara 313 title III:
Cyclophosphamide	100	Listed	10 lb 4.54 kg	Not Listed	Not Listed

**STATE REGULATIONS:**

Component	California Prop 65:	Minnesota Right-To - Know:	Florida Right-to-Know Reporting List:	Rhode Island Right-to-Know List:	Massachusetts Right-to-Know List:	Pennsylvania Right-to-Know:	New Jersey Right-to-Know:
Cyclophosphamide	carcinogen, initial date 2/27/87 developmental toxicity, initial date 1/1/89 male reproductive toxicity, initial date 1/1/89 female reproductive toxicity, initial date 1/1/89	Carcinogen	Not Listed	Carcinogen	Carcinogen; Extraordinarily hazardous; Teratogen	Environmental hazard; Special hazardous substance	sn 0587

This product contains component(s) known to the State of California to cause cancer or reproductive/developmental harm.

**CANADIAN REGULATIONS:**

**Canada DSL Inventory List -** This product does not comply with DSL

**EU EINECS List -** This product complies with EINECS

**Risk Phrases:**

- R22 - Harmful if swallowed.
- R41 - Risk of serious damage to eyes.
- R45 - May cause cancer.
- R46 - May cause heritable genetic damage.
- R48/23/24/25 - Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed.
- R61 - May cause harm to the unborn child.

**Safety Phrases:**

- S53 - Avoid exposure - obtain special instructions before use.
- S15 - Keep away from heat.
- S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- S45 - In case of accident or if you feel unwell, seek medical advice immediately (show label where possible).

**16. OTHER INFORMATION**

**This data sheet contains changes from the previous version in section(s)?:**

Changes to Section 8. Changes to Section 1.

**Additional information:**

NOEC = No observable effect concentration

**Prepared by:** Technology Resources, Baxter Healthcare Corporation

## **16. OTHER INFORMATION**

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

**End of safety data sheet:**