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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING**Product Identifier**

MSDS Number: 1118057
Product Name: Cyclophosphamide for Injection, USP

Other means of identification

Product Code(s): NDC 10019-955-01, NDC 10019-956-01, NDC 10019-957-01
Synonyms: Endoxan; Sendoxan; Genoxal

Recommended use of the chemical and restrictions on use

Product Use: Antineoplastic Agent.
Product Type: Regulated Prescription Drug
Uses advised against No information available

Details of the supplier of the safety data sheet

BAXTER HEALTHCARE CORPORATION
1 BAXTER PARKWAY
DEERFIELD, ILLINOIS 60015
US: (800) 933-0303
Canada: (855)-584-1368

Emergency telephone number

Carechem24 International
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2. HAZARDS IDENTIFICATION**Classification****OSHA Regulatory Status**

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

Acute toxicity - Oral	Category 4
Serious eye damage/eye irritation	Category 1
Skin Sensitization	Category 1
Germ Cell Mutagenicity	Category 1A
Carcinogenicity	Category 1A
Reproductive Toxicity	Category 1A Yes
Specific target organ toxicity (repeated exposure)	Category 1

Label Elements**Emergency Overview****Danger****Hazard Statements**

Harmful if swallowed
Causes serious eye damage
May cause an allergic skin reaction
May cause genetic defects
May cause cancer
May damage fertility or the unborn child
May cause harm to breast-fed children
Causes damage to organs through prolonged or repeated exposure



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
 Do not breathe dust/fume/gas/mist/vapors/spray
 Avoid contact during pregnancy/while nursing
 Wash face, hands and any exposed skin thoroughly after handling
 Do not eat, drink or smoke when using this product
 Contaminated work clothing should not be allowed out of the workplace
 Wear protective gloves

Precautionary Statements - Response

If exposed or concerned: Get medical advice/attention
 Specific treatment (see supplemental first aid instructions on this label)
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
 Immediately call a POISON CENTER or doctor/physician
 IF ON SKIN: Wash with plenty of soap and water
 If skin irritation or rash occurs: Get medical advice/attention
 Wash contaminated clothing before reuse
 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
 Rinse mouth

Precautionary Statements - Storage

Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Hazards not otherwise classified (HNOC)

Other Information

• Causes mild skin irritation
 Unknown Acute Toxicity 0 % of the mixture consists of ingredient(s) of unknown toxicity

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS-No	Weight-%
Cyclophosphamide	50-18-0	100

4. FIRST AID MEASURES

First Aid Measures

General Advice Treat symptomatically and supportively.

Eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get 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.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. 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.

Most important symptoms and effects, both acute and delayed

Contains a known or suspected carcinogen. Contains a known or suspected mutagen. Contains a known or suspected reproductive toxin.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically. See patient package insert in shipping carton for complete information.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Use foam or all purpose dry chemicals to extinguish.

Specific hazards arising from the chemical

No information available.

Special protective equipment for firefighters

Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

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

Environmental Precautions

See Section 12 for environmental precautions.

Methods and material for containment and cleaning up**Methods for Containment:**

If emergency personnel are unavailable, contain spilled material. Absorb with vacuum cleaner approved for carcinogenic substances.

Methods for cleaning up

Place spilled material in an appropriate container for disposal. Avoid production of dust. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for Safe Handling

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

Conditions for safe storage, including any incompatibilities**Technical measures and 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.

Incompatible materials

No special restrictions on storage with other products.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

Exposure Limits: This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

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

Appropriate engineering controls

Engineering Measures Provide general or local exhaust ventilation. Open handling must be limited.

Individual protection measures, such as personal protective equipment

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

Hand protection Latex gloves. Nitrile rubber.

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

Respiratory protection No personal respiratory protective equipment normally required. In the case of respirable dust and/or fumes, use a properly fitted air-purifying respirator.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state: Solid.
Appearance: Crystalline
Color: White
Odor: Odorless
Odor Threshold: No information available
pH: 4.0 - 6.0
Melting point / melting range: 49 - 53 °C
Boiling point / boiling range: No information available
Flash point: No information available
Evaporation rate: No information available
Flammability (solid, gas): No information available
Flammable limits
in air-upper (%): 3000 g/m³
Flammable limits
in air-lower (%): 750 g/m³
Vapor pressure: 0.0000033 kPa
Vapor Density: No information available
Density: No information available
Solubility: Soluble in water.
Partition coefficient (n-octanol/water): log Kow = 0.63
Autoignition temperature: No information available
Decomposition Temperature: No information available
Viscosity: No information available
Explosive Properties: No information available
Oxidizing Properties: No information available

Other Information

Molecular weight: 279.1

10. STABILITY AND REACTIVITY

Reactivity

No data available

Chemical Stability

Stable under recommended storage conditions

Possibility of Hazardous Reactions

None under normal processing

Conditions to Avoid

Do not freeze.

Incompatible materials

Acids. Alkali metals. Oxidizing agents.

Hazardous Decomposition Products

Halogenated hydrocarbons. Organic compounds of phosphoric compounds. Organic nitrogenous products of decomposition.

11. TOXICOLOGICAL INFORMATION

Component	Inhalation LC50	Dermal LD50	Oral LD50
Cyclophosphamide 50-18-0	-	-	342 mg/kg (rat)

Information on likely routes of exposure

- Inhalation:** Toxic: danger of serious damage to health by prolonged exposure through inhalation. Irritating to respiratory system.
- Eye contact:** Risk of serious damage to eyes
- Skin contact:** Toxic: danger of serious damage to health by prolonged exposure with skin.
- 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.

Information on Toxicological Effects

- Symptoms:** No information available.

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

- Irritation:** Causes serious eye damage. Causes skin irritation.
- Corrosivity:** Not classified.
- Sensitization:** May cause an allergic skin reaction.
- Mutagenic effects:** Contains a known or suspected mutagen
- Carcinogenic effects:** Contains a known or suspected carcinogen.

Component	ACGIH	IARC	NTP	OSHA
Cyclophosphamide 50-18-0	-	Group 1	Known	Present

Reproductive toxicity: May impair fertility. May cause harm to the unborn child. May cause harm to breastfed babies.

STOT - single exposure: Not classified.

STOT - repeated exposure: Bladder. Bone marrow.

Aspiration Hazard: Not classified.

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity 0 % of the mixture consists of ingredient(s) of unknown toxicity

The following values are calculated based on chapter 3.1 of the GHS document.

ATEmix (oral) 342 mg/kg

12. ECOLOGICAL INFORMATION

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

Ecotoxicity

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

100 % of the mixture consists of components(s) of unknown hazards to the aquatic environment

Persistence and degradability

Not readily biodegradable.

Bioaccumulative potential

No information available

Mobility in soil

High mobility in soil.

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Waste from residues/unused products In accordance with local and national regulations

Contaminated Packaging In accordance with local and national regulations.

14. TRANSPORT INFORMATION

DOT Not regulated

15. REGULATORY INFORMATION

U.S. Regulations:

TSCA Inventory List -

The product is exempt from TSCA, it is FDA Regulated

OTHER REGULATIONS:

Component	Weight-%	RCRA Status:	CERCLA Reportable Quantity:	CERCLA/SARA - 302 Ext. haz. substances:	Listed as Sara 313 title III:
Cyclophosphamide 50-18-0	100	Not 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 50-18-0	Present	Present	Not Listed	Present	Present	Present	Not Listed

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 complies with DSL

16. OTHER INFORMATION

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

New GHS format. Changes to Section 1.

Additional information:

NOEC = No observable effect concentration

Prepared by Baxter Research & Development

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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