

Cyclophosphamide Injection

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product name: Cyclophosphamide for Injection, USP

Synonyms: Cyphos

Chemical Family: Antineoplastic Agent

Product Type: Regulated Prescription Drug

Container Information: 200mg, 500mg, and 1g vials

Product Use: Pharmaceutical.

Supplier: Getwell Pharmaceuticals
474, Udyog Vihar, Phase-V,
Gurgaon - 122 016, Haryana, INDIA

Emergency telephone number: +91 124 4014 403 / 04

2. COMPOSITION/INFORMATION ON INGREDIENTS

Component	Weight %	UN Number:	Classification:
Cyclophosphamide	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

Suitable extinguishing media:	Use foam or all purpose dry chemicals to extinguish.
Special protective equipment for firefighters:	Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.
Specific methods:	No information available
Flash point:	Not determined
Autoignition temperature:	Not available
Flammable limits in air-lower (%):	750 g/m ³ (dust)
Flammable limits in air-upper (%):	3000 g/m ³ (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 below 25°C (77°F). Keep containers tightly closed in a cool, well-ventilated place. Protect from light. Do not freeze. Store in original container. Keep away from heat. Product can withstand brief exposure at 30°C.

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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	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.

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10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

Component	LD50s and LC50s
Cyclophosphamide	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	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.

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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:

Product name: Cyclophosphamide for Injection, USP

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:

Getwell Pharmaceuticals
474, Udyog Vihar, Phase-V, Gurgaon - 122 016, Haryana, INDIA

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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: