

## SAFETY DATA SHEET

Cyclophosphamide for Injection, USP 500mg/vial

### 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

**Material Name:** Cyclophosphamide for Injection, USP 500mg/vial

**Trade Name:** Cyclophosphamide for Injection, USP 500mg/vial  
**Chemical Family:** Alkylating Agent  
**Intended Use:** Pharmaceutical product used as Antineoplastic

#### Manufacturer Name and Address

Amneal Oncology Pvt. Ltd.  
TSIIC-SEZ, Plot No. S-3, S-4, S-5A,  
Polepally (Vil), Jadcherla (Mdl),  
Mahaboobnagar (Dist); Telangana, India, Pin - 509301  
Emergency Telephone number : +91-8542-302000

### 2. HAZARDS IDENTIFICATION

**Appearance:** White Powder  
**Signal Word:** DANGER

**Statement of Hazard:** Toxic if swallowed.  
May cause cancer.  
May damage fertility or the unborn child.  
May cause genetic defects.

**Additional Hazard Information:**  
**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.

#### EU Classification

**EU Indication of danger:** Toxic  
Toxic to reproduction : Category 1  
Carcinogenic : Category 1  
Mutagenic : Category 1

**EU Hazard Symbols:**



**EU Risk Phrases:**

R25 - Toxic if swallowed.  
R45 - May cause cancer.  
R46 - May cause heritable genetic damage.  
R60 - May impair fertility.  
R61 - May cause harm to the unborn child.



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**Australian Hazard Classification (NOHSC):**

Hazardous Substance. Dangerous Goods.

**Note:**

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Hazardous**

| Ingredient                   | CAS Number | EU EINECS/ELINCS List | EU Classification   | Qty / Unit | % W/W |
|------------------------------|------------|-----------------------|---|------------|-------|
| Cyclophosphamide Monohydrate | 50-18-0    | 200-015-4             | T;R25<br>Repr.Cat.1;R60-61<br>Carc. Cat.1;R45<br>Mut. Cat.1;R46 | 534.5 mg   | 100   |

**Additional Information:**

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

**For the full text of the R phrases mentioned in this Section, see Section 16**

### 4. FIRST AID MEASURES

**Eye Contact:**

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:**  
Seek

Remove contaminated clothing. Flush area with large amounts of water. Use soap. 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.

**Inhalation:**

Remove to fresh air and keep patient at rest. Seek medical attention immediately.

**Symptoms and Effects of Exposure:**

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

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:**

Use carbon dioxide, dry chemical, or water spray.

**Hazardous Combustion Products:** Carbon dioxide, carbon monoxide, and oxides of nitrogen phosphorous

**Fire Fighting Procedures:**

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**Fire / Explosion Hazards:**

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



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#### 6. ACCIDENTAL RELEASE MEASURES

|   |  |
|---|--|
| <b>Health and Safety Precautions:</b>             | Personnel involved in clean-up should wear appropriate personal protective equipment (See Section 8). Minimize exposure.   |
| <b>Measures for Cleaning / Collecting:</b>        | Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly. |
| <b>Measures for Environmental Protections:</b>    | Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.   |
| <b>Additional Consideration for Large Spills:</b> | Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.   |

#### 7. HANDLING AND STORAGE

|                            |  |
|----------------------------|--|
| <b>General Handling:</b>   | Restrict access to work area. Designate a change area to facilitate 'good Manufacturing, decontamination practices. Ground and bond all bulk transfer equipment. No open handling permitted. All operations should be fully enclosed. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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. Store at room temperature in properly labelled containers. Keep away from heat, sparks and flames. |
| <b>Storage Conditions:</b> |  |

#### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

|  |  |
|--|--|
| <b>No Occupational Exposure Limit (OEL) or Short Term Exposure Limit (STEL) has been identified.</b> |  |
| <b>Engineering Controls:</b>   | Engineering controls should be used as the primary means to control exposures. Use Process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. All operations should be fully enclosed. No air recirculation permitted. |
| <b>Environmental Exposure Controls:</b>  | Refer to specific Member State legislation for requirements under Community Environmental legislation.   |
| <b>Personal Protective Equipment:</b>  | Refer to applicable national standards and regulations in the selection and use of Personal Protective Equipment (PPE).  |
| <b>Hands:</b>  | Wear impervious, disposable gloves as minimum protection (double recommended).   |
| <b>Eyes:</b>   | Wear safety glasses as minimum protection.   |
| <b>Skin:</b>   | Wear impervious disposable protective clothing when handling this compound.  |
| <b>Respiratory protection:</b>   | Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure.   |

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

|                           |  |                          |        |
|---------------------------|--|--------------------------|--------|
| <b>Physical State:</b>    | Powder   | <b>Color:</b>            | White  |
| <b>Molecular Formula:</b> | C <sub>7</sub> H <sub>15</sub> Cl <sub>2</sub> N <sub>2</sub> O <sub>2</sub> P | <b>Molecular Weight:</b> | 261.09 |
| <b>Water solubility:</b>  | 4%   |                          |        |



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## 9. PHYSICAL AND CHEMICAL PROPERTIES

Melting/Freezing Point (°C): 41

## 10. STABILITY AND REACTIVITY

**Chemical Stability:** Stable under normal conditions of use.  
**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

## 11. TOXICOLOGICAL INFORMATION

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

#### Cyclophosphamide

|       |                 |       |           |
|-------|-----------------|-------|-----------|
| Rat   | Oral            | LD 50 | 160 mg/kg |
| Rat   | Para-periosteal | LD 50 | 148 mg/kg |
| Mouse | Oral            | LD 50 | 137 mg/kg |
| Mouse | Intravenous     | LD 50 | 140 mg/kg |

### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

#### Cyclophosphamide

|                            |       |                 |          |       |                         |
|----------------------------|-------|-----------------|----------|-------|-------------------------|
| Embryo / Fetal Development | Rat   | Intraperitoneal | 10 mg/kg | LOAEL | Teratogenic             |
| Embryo / Fetal Development | Rat   | Intraperitoneal | 30 mg/kg | LOAEL | Fetotoxicity            |
| Embryo / Fetal Development | Mouse | Intravenous     | 10 mg/kg | LOAEL | Teratogenic             |
| Embryo / Fetal Development | Mouse | Intraperitoneal | 5 mg/kg  | LOAEL | Fetotoxicity, Fertility |

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

#### Cyclophosphamide

|  |                   |          |
|--|-------------------|----------|
| <i>In Vivo</i> Micronucleus              | Rodent            | Positive |
| <i>In Vivo</i> Chromosome Aberration     | Rodent            | Positive |
| <i>In Vivo</i> Sister Chromatid Exchange | Rodent            | Positive |
| <i>In Vitro</i> 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   | Intraperitoneal | Benign tumors, Malignant tumors, Female reproductive system |
| 2 Year(s) | Mouse | Intraperitoneal | Benign tumors, Malignant tumors                             |

**Carcinogen Status:** See below

#### Cyclophosphamide

|              |                                  |
|--------------|----------------------------------|
| <b>IARC:</b> | Group 1 (Carcinogenic to Humans) |
| <b>NTP:</b>  | Known Human Carcinogen           |
| <b>OSHA:</b> | Listed                           |



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#### 12. ECOLOGICAL INFORMATION

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

#### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** Dispose of waste in accordance with all applicable laws and regulations. Member 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 waste water 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.

Cyclophosphamide  
RCRA - U Series Wastes

Listed

#### 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

#### 15. REGULATORY INFORMATION

**EU Symbol:** T  
**EU Indication of danger:** Toxic  
Toxic to reproduction: Category 1  
Carcinogenic: Category 1  
Mutagenic: Category 1

**EU Risk Phrases:**  
R25 - Toxic if swallowed.  
R45 - May cause cancer.  
R46 - May cause heritable genetic damage. R60 - May impair fertility.  
R61 - May cause harm to the unborn child.

**EU Safety Phrases:**  
S22 - Do not breathe dust.  
S53 - Avoid exposure - obtain special instructions before use.  
S36/37 - Wear suitable protective clothing and gloves.



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### 15. REGULATORY INFORMATION

**OSHA Label:**

DANGER

Toxic if swallowed.

May cause cancer.

May damage fertility or the unborn child.

May cause genetic defects.

### 16. OTHER INFORMATION

**Text of R phrases and GHS Classification abbreviations mentioned in Section 3**

R25 - Toxic if swallowed.

R45 - May cause cancer.

R46 - May cause heritable genetic damage.

R60 - May impair fertility.

R61 - May cause harm to the unborn child.

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