SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME: CYCLOPHOSPHAMIDE, USP
PRODUCT CODE: 0506
SUPPLIER: MEDISCA Inc.
Tel.: 1.800.932.1039 | Fax.: 1.855.850.5855
661 Route 3, Unit C, Plattsburgh, NY, 12901
3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118
6641 N. Belt Line Road, Suite 130, Irving, TX, 75063
MEDISCA Pharmaceutique Inc.
Tel.: 1.800.665.6334 | Fax.: 514.338.1693
4509 Rue Dobrin, St. Laurent, QC, H4R 2L8
21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2
MEDISCA Australia PTY LTD
Tel.: 1.300.786.392 | Fax.: 61.2.9700.9047
Unit 7, Heritage Business Park
5-9 Ricketty Street, Mascot, NSW 2020

EMERGENCY PHONE: CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300
NSW Poisons Information Centre: 131 126

USES: Antineoplastic agent; Immunosuppressant

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION:
- Acute Toxicity - Oral (Category 3)
- Carcinogenicity (Category 1A)
- Toxic to Reproduction (Category 1A)
- Toxic to Reproduction - Effects on or via lactation
- Skin Irritation (Category 2)
- Eye Damage (Category 1)
- Germ Cell Mutagenicity (Category 1A)
- Specific Target Organ Toxicity - Repeated Exposure (Category 1) - (bone marrow)
- Chronic Aquatic Toxicity (Category 1)

PICTOGRAM:

SIGNAL WORD: Danger

HAZARD STATEMENT(S):
- Potent cytotoxic agent.
- Toxic if swallowed.
- Causes skin irritation.
- Causes serious eye damage.
- 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.
- Very toxic to aquatic life with long lasting effects.

AUSTRALIA-ONLY HAZARDS: Not Applicable.
PRECAUTIONARY STATEMENT(S)

**Prevention**
- Wash thoroughly after handling.
- Do not eat, drink or smoke when using this product.
- Do not breathe dust/fume/gas/mist/vapors/spray.
- Obtain special instructions before use.
- Do not handle until all safety precautions have been read and understood.
- Wear protective gloves, protective clothing, eye protection, face protection.
- Avoid contact during pregnancy/while nursing.
- Avoid release into the environment.

**Response**
- IF SWALLOWED: Immediately call a poison center or medical professional; Rinse mouth.
- IF ON SKIN (HAIR): Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.
- 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 medical professional.
- IF EXPOSED OR CONCERNED: Get medical advice/attention.

**Storage**
- Store locked up.

**Disposal**
- Dispose of contents and/or container in accordance with local regulations.

HMIS CLASSIFICATION
- **Health Hazard**: 3
- **Flammability**: 1
- **Reactivity**: 0
- **Personal Protection**: G

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

**CHEMICAL NAME**
- 2H-1,3,2-Oxazaphosphorin-2-amine, N,N-bis(2-chloroethyl)tetrahydro-, 2-oxide, monohydrate, (+)

**BOTANICAL NAME**
- Not applicable

**SYNONYM**
- Not applicable

**CHEMICAL FORMULA**
- \(\text{C}_7\text{H}_{15}\text{Cl}_2\text{N}_2\text{O}_2\text{P}_2\text{O}\_\text{H}_2\text{O}\)

**CAS NUMBER**
- 6055-19-2

**ALTERNATE CAS NUMBER**
- Not applicable

**MOLECULAR WEIGHT**
- 279.1023

**COMPOSITION**

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>% BY WEIGHT</th>
</tr>
</thead>
<tbody>
<tr>
<td>CYCLOPHOSPHAMIDE (Monohydrate)</td>
<td>6055-19-2</td>
<td>100</td>
</tr>
</tbody>
</table>

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

**NOTES**
- Chemical family: Tertiary amine; oxazaphosphorinamine.

SECTION 4: FIRST-AID MEASURES

**IN CASE OF EYE CONTACT**
- Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

**IN CASE OF SKIN CONTACT**
- Wash with soap & water for 15 minutes. If irritation persists seek medical aid.

**IF SWALLOWED**
- Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

**IF INHALED**
- Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

**SYMPTOMS AND EFFECTS**
- Not expected to present a significant hazard under anticipated conditions of normal use.
SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL: Not applicable

FLAMMABLE PROPERTIES: May be combustible at high temperature

HAZARDOUS COMBUSTION PRODUCTS: Under fire conditions, hazardous fumes will be present.

EXTINGUISHING MEDIA: Small fire: dry chemical, CO₂ or water spray. Large fire: dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT: On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE: Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING: Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling.

STORAGE CONDITIONS: Store in original container, tightly sealed container, protected from direct sunlight, in a dry, and well-ventilated area, away from incompatible materials. Store in accordance with local regulations. Eliminate all ignition sources. Separate from oxidizing materials. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. Preserve in tight containers, at a temperature between 2°C and 8°C.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Chemical Name: CYCLOPHOSPHAMIDE</th>
<th>CAS #: 8055-19-2</th>
</tr>
</thead>
<tbody>
<tr>
<td>TWA</td>
<td>Ceiling</td>
</tr>
<tr>
<td>HSE</td>
<td>N/L</td>
</tr>
<tr>
<td>OSHA PEL</td>
<td>N/L</td>
</tr>
<tr>
<td>ACGIH TLV</td>
<td>N/L</td>
</tr>
<tr>
<td>NIOSH</td>
<td>N/L</td>
</tr>
<tr>
<td>AIHA WEEL</td>
<td>N/L</td>
</tr>
<tr>
<td>Safe Work Australia HSIS</td>
<td>N/L</td>
</tr>
</tbody>
</table>

N/L = Not Listed
### EXPOSURE GUIDELINES
Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³.

### PERSONAL PROTECTIVE EQUIPMENT
**Eyes:** Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA’s eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

### SPECIFIC ENGINEERING CONTROLS
Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

### NOTES
USP: ELV: Industrial: TWA: 0.001 mg/m³ (Skin)

### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PHYSICAL STATE</strong></td>
<td>Solid</td>
</tr>
<tr>
<td><strong>DESCRIPTION</strong></td>
<td>White, crystalline powder. Liquefies upon loss of its water of crystallization.</td>
</tr>
<tr>
<td><strong>SOLUBILITY</strong></td>
<td>Soluble in water and in alcohol.</td>
</tr>
<tr>
<td><strong>ODOR</strong></td>
<td>Odorless or almost odorless.</td>
</tr>
<tr>
<td><strong>FLAMMABILITY</strong></td>
<td>May be combustible at high temperature</td>
</tr>
<tr>
<td><strong>ODOR THRESHOLD</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>PH</strong></td>
<td>3.9 - 7.1 (1%)</td>
</tr>
<tr>
<td><strong>MELTING POINT</strong></td>
<td>(41-49)°C, (105.8-120.2)°F</td>
</tr>
<tr>
<td><strong>BOILING POINT</strong></td>
<td>336°C, 636.8°F</td>
</tr>
<tr>
<td><strong>FREEZING POINT</strong></td>
<td>(41-49)°C, (105.8-120.2)°F</td>
</tr>
<tr>
<td><strong>SPECIFIC GRAVITY</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>EVAPORATION RATE</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>EXPLOSIVE LIMIT</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>VAPOR DENSITY (AIR = 1)</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>RELATIVE DENSITY (WATER = 1)</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>AUTO-IGNITION TEMPERATURE</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>DECOMPOSITION TEMPERATURE</strong></td>
<td>Not available</td>
</tr>
</tbody>
</table>

### SECTION 10: STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REACTIVITY</strong></td>
<td>Not established</td>
</tr>
<tr>
<td><strong>STABILITY</strong></td>
<td>Stable under recommended storage conditions</td>
</tr>
<tr>
<td><strong>MATERIALS TO AVOID</strong></td>
<td>Strong oxidants. Strong acids. Strong bases.</td>
</tr>
<tr>
<td><strong>HAZARDOUS DECOMPOSITION PRODUCTS</strong></td>
<td>Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur</td>
</tr>
<tr>
<td><strong>HAZARDOUS POLYMERIZATION</strong></td>
<td>Will not occur</td>
</tr>
<tr>
<td><strong>POSSIBILITY OF HAZARDOUS REACTION</strong></td>
<td>Not established</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

CONDITIONS TO AVOID

Moisture, sunlight and extreme temperatures

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY

Oral: Rat: LD50: (mg/kg): 94
Dermal: Rabbit LD50: (mg/kg): Not available
Inhalation: Rat: LD50: (mg/L/4hr): Not available

SKIN CORROSION/IRRITATION

Causes skin irritation.

SERIOUS EYE DAMAGE/EYE IRRITATION

Causes serious eye damage.
Local effects
Eye irritation, OECD 405
Result: Corrosive.
Species: Rabbit

RESPIRATORY OR SKIN SENSITIZATION

Respiratory sensitization: Due to lack of data the classification is not possible.
Skin sensitization: Based on available data, the classification criteria are not met. Suspected skin sensitisr.

GERM CELL MUTAGENICITY

May cause genetic defects.
Cyclophosphamide caused mutations in a battery of genetic toxicity studies in vivo and in vitro.
Mutagenicity
Dominant lethal assay in rodents and Drosophila
Result: Positive.
In vivo induction of unscheduled DNA synthesis in rat spermatocytes
Result: Positive.
Mouse sperm morphology assay
Result: Positive.

CARCINOGENICITY

OSHA
CYCLOPHOSPHAMIDE is listed.

NTP
CYCLOPHOSPHAMIDE is listed.

IARC
CYCLOPHOSPHAMIDE is listed in group 1 (carcinogenic to humans).

California Proposition 65
This product contains the following chemical known to the State of California to cause cancer and birth defects or other reproductive harm: CYCLOPHOSPHAMIDE

ADDITIONAL CARCINOGENICITY INFORMATION

May cause cancer. Secondary malignancies are potential delayed effects of many antineoplastic agents, although it is not clear whether the effect is related to their mutagenic or immunosuppressive action. The effect of dose and duration of therapy is also unknown, although risk seems to increase with long-term use. Although information is limited, available data seem to indicate that the carcinogenic risk is greatest with the alkylating agents.
Carcinogenicity study, administered orally.
Result: Benign and malignant tumors, including bladder tumors.
Species: Rat

Long-term carcinogenicity study, administered intraperitoneally.
Result: Benign and malignant tumors.
Species: Mouse
Test Duration: 2 years

Long-term carcinogenicity study, administered intravenously and intraperitoneally.
Result: Benign and malignant tumors.
Species: Rat
Test Duration: 2 years
May cause congenital malformation in the fetus. Cyclophosphamide has been detected in breast milk, and there are reports of neutropenia, leucopenia and thrombocytopenia in infants who have been breast fed by women receiving cyclophosphamide. Severe gonadal failure with transient or permanent azoospermia is common in men treated with cyclophosphamide.

May damage fertility or the unborn child. Antineoplastic therapy can adversely affect male and female fertility through gonadal suppression, resulting in the absence of menstruation or sperm. The effects appear to be related to dose and length of therapy and may be irreversible. Alkylating agents may cause a slight increase in the risk of birth defects when given during the first trimester and an increase in the risk of growth retardation when given during the second or third trimester. This material has caused adverse fetal effects in animal studies. There have been reports of blood disorders in breast fed infants of mothers treated with this material.

107 mg/kg Reproductivity study, in men.
Result: Changes in spermatogenesis and sperm morphology.
Species: Human
Test Duration: 21 weeks

60 mg/day Reproductivity study, in women.
Result: Changes in menstrual cycle.
Species: Human
Test Duration: 60 days

80 mg/kg Reproductivity study, administered in 4 doses during the first trimester.
Result: Teratogenic with a distinct embryopathic phenotype.
Species: Human

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

Causes damage to organs (bone marrow) through prolonged or repeated exposure.

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

Symptoms related to the physical, chemical, and toxicological characteristics

Delayed and immediate effects of exposure

Medical conditions aggravated by exposure

Inhalation May be harmful if inhaled. May cause respiratory tract irritation.
Ingestion Toxic if swallowed.
Skin May be harmful if absorbed through skin. Causes skin irritation
Eyes Causes serious eye damage.

EC50: 48 Hr: Crustacea (Daphnia magna): (mg/L): <1*
LC50: 96 Hr: Fish: (mg/L): 12.98*
IC50: 72 Hr: Algae: (mg/L): > 100
SAFETY DATA SHEET

PERSISTENCE AND DEGRADABILITY
Suspected persistent in the environment: The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable

BIOACCUMULATIVE POTENTIAL
LogPow: 0.6 (20°C)
LogKow = 0.63
BCF: 3.2

MOBILITY IN SOIL
Water Solubility: 4.00E+04 mg/L (20°C) (Anhydrous)
Henry's Law Constant: 1.40E-11 atm-m³/mole (25°C) (Anhydrous)

OTHER ADVERSE EFFECTS
Not available
This product is not intended to be released into the environment

NOTES
*Danish QSAR database (anhydrous)

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL
Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION

UNITED STATES & CANADA
UN PROPER SHIPPING NAME
TOXIC SOLID, ORGANIC, N.O.S.
UN NUMBER
2811
CLASS
6.1
PACKING GROUP
III

AUSTRALIA
UN PROPER SHIPPING NAME
TOXIC SOLID, ORGANIC, N.O.S.
UN NUMBER
2811
CLASS
6.1
PACKING GROUP
III
HAZCHEM
2X

ENVIRONMENTAL HAZARDS
Not available
SPECIAL SHIPPING INFORMATION
Not applicable

SECTION 15: REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>CERCLA 40 CFR Part 302.4</th>
<th>SARA (Title III) 40 CFR Appendix A</th>
<th>EPA 40 CFR Part 355 Appendix A</th>
<th>Pennsylvania Right-to-know</th>
<th>New Jersey</th>
<th>Massachusetts</th>
<th>California Prop 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>CYCLOPHOSPHAMIDE, 6055-19-2</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>X*</td>
<td>N/L</td>
<td>X*</td>
<td>X</td>
</tr>
</tbody>
</table>

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Last Revision: 04/2017
SECTION 16: OTHER INFORMATION

NOTES

*anhydrous

REFERENCES

ABBREVIATIONS AND ACRONYMS

CAS – Chemical Abstract Service; GHS – Global Harmonized System; OSHA PEL – Occupational Safety & Health Administration Permissible Exposure Limits; TWA – Time Weighted Average; HSIS – Hazardous Substances Information System; STEL – Short Term Exposure Limit; AIHA WEEL – American Industrial Hygiene Association Workplace Environment Exposure Levels; LD50 – Lethal Dose, 50%; IARC – International Agency for Research on Cancer; NTP – National Toxicology Program; WHMIS – Workplace Hazardous Materials Information System; SARA – Superfund Amendments and Reauthorization Act; EPA – Environmental Protection Agency; CERCLA – Comprehensive Environmental Response, Compensation, and Liability Act; HMIS – Hazardous Materials Information System; NIOSH – National Institute for Occupational Safety and Health; MSHA - Mine Safety and Health Administration; ACGIH - American Conference of Governmental Industrial Hygienists; IDHL - Immediately Dangerous to Health or Life; TLV – Threshold Limit Value; HSE – Health and Safety Executive; REL - Recommended Exposure Limit

LAST REVISION

04/2017

SUPERSEDES

05/2015

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.