

1. IDENTIFICATION

Product name: cyclophosphamide

CAS No. : 50-18-0

Brand: Macklin

Company: Shanghai Macklin Biochemical Co.,Ltd.

Address: Shanghai Pudong Zhangjiang High-tech Park; 1st Building, 68 Huatuo Road; SHANGHAI CHINA

Zip code: 201206

Telephone: +86 21-50706066

Fax: +86 21-50706099

E-mail: sales@macklin.cn; tech@macklin.cn

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2. HAZARDS IDENTIFICATION

GHS classification

PHYSICAL HAZARDS

no data available

HEALTH HAZARDS

no data available

ENVIRONMENTAL HAZARDS

no data available

GHS label elements, including precautionary statements

Pictograms or hazard symbols

Signal word

no data available

Hazard statements

no data available

Precautionary statements

Prevention

no data available

Response

no data available

Storage

no data available

Disposal

no data available

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components:cyclophosphamide

CAS No.:50-18-0

Chemical Formula:C₇H₁₅Cl₂N₂O₂P

4. FIRST AID MEASURES

4.1

Description of necessary first-aid measures

If inhaled

Fresh air, rest. Refer for medical attention.

Following skin contact

Remove contaminated clothes. Rinse skin with plenty of water or shower. Refer for medical attention .

Following eye contact

First rinse with plenty of water for several minutes (remove contact lenses if easily possible), then refer for medical attention.

Following ingestion

Rinse mouth. Induce vomiting (ONLY IN CONSCIOUS PERSONS!). Refer for medical attention .

4.2

Most important symptoms/effects, acute and delayed

SYMPTOMS: Symptoms of exposure to this compound may include nausea, vomiting, leukopenia, thrombocytopenia, alopecia and anorexia. Other symptoms may include pigmentation of the skin, oral mucosal ulcerations and sterile hemorrhagic cystitis. It can cause non-specific dermatitis, pigmentation of the nails, regrowth of hair, anemia, hematuria, fibrosis of the ovaries, gonadal suppression resulting in amenorrhea or azoospermia, hemorrhagic colitis and jaundice. It can also cause damage to the hair follicles, dizziness of short duration, transverse ridging of the nails and hepatic toxicity. Secondary neoplasia and nephrotoxicity have been reported. Other symptoms may include irritation of the skin, gastrointestinal disturbances and hepatic dysfunction. High doses over a prolonged period can cause interstitial pulmonary fibrosis. Other symptoms of exposure may include granulocytopenia, myocardial damage, interstitial pneumonia and hypoplasia of all elements of bone marrow. It has been known to cause blurred vision, pulmonary fibrosis, cardiomyopathy and sterility. Fetal abnormalities can occur if ingested while pregnant. Eye contact can cause transient blurring of vision, dry eye syndrome, viral and other keratitis and severe keratoconjunctivitis associated with graft-versus-host disease leading to scarring of the corneas. It may also cause lymphocytopenia. **ACUTE/CHRONIC HAZARDS:** This compound is a skin irritant. When heated to decomposition it emits highly toxic fumes of PO_x, NO_x and chloride ion. (NTP, 1992)

4.3

Indication of immediate medical attention and special treatment needed, if necessary

Basic treatment: Establish a patent airway. Suction if necessary. Watch for signs of respiratory insufficiency and assist ventilations if needed. Administer oxygen by nonrebreather mask at 10 to 15 L/min. Monitor for pulmonary edema and treat if necessary . Monitor for shock and treat if necessary . Anticipate seizures and treat if necessary . For eye contamination, flush eyes immediately with water. Irrigate each eye continuously with normal saline during transport . Do not use emetics. For ingestion, rinse mouth and administer 5 ml/kg up to 200 ml of water for dilution if the patient can swallow, has a strong gag reflex, and does not drool . Cover skin burns with dry sterile dressings after decontamination . **Poison A and B**

5. FIRE-FIGHTING MEASURES

5.1

Suitable extinguishing media

Fires involving this material can be controlled with a dry chemical, carbon dioxide or Halon extinguisher. (NTP, 1992)

5.2

Specific hazards arising from the chemical

Flash point data for this chemical are not available; however, it is probably combustible. (NTP, 1992)

5.3

Special protective actions for fire-fighters

Use water spray, powder, foam, carbon dioxide.

6. ACCIDENTAL RELEASE MEASURES

6.1

Personal precautions, protective equipment and emergency procedures

Personal protection: particulate filter respirator adapted to the airborne concentration of the substance. Sweep spilled substance into covered sealable containers. If appropriate, moisten first to prevent dusting. Carefully collect remainder. Then store and dispose of according to local regulations.

6.2

Environmental precautions

Consult an expert! Personal protection: particulate filter respirator adapted to the airborne concentration of the substance. Sweep spilled substance into covered sealable containers. If appropriate, moisten first to prevent dusting. Carefully collect remainder. Then store and dispose of according to local regulations.

6.3

Methods and materials for containment and cleaning up

PRECAUTIONS FOR "CARCINOGENS": A high efficiency particulate arrestor (HEPA) or charcoal filters can be used to minimize amt of carcinogen in exhausted air ventilated safety cabinets, lab hoods, glove boxes or animal rooms ... Filter housing that is designed so that used filters can be transferred into plastic bag without contaminating maintenance staff is available commercially. Filters should be placed in plastic bags immediately after removal ... The plastic bag should be sealed immediately ... The sealed bag should be labelled properly ... Waste liquids ... should be placed or collected in proper containers for disposal. The lid should be secured & the bottles properly labelled. Once filled, bottles should be placed in plastic bag, so that outer surface ... is not contaminated ... The plastic bag should also be sealed & labelled. ... Broken glassware ... should be decontaminated by solvent extraction, by chemical destruction, or in specially designed incinerators. Chemical Carcinogens

7. HANDLING AND STORAGE

Precautions for safe handling

NO open flames. Handling in a well ventilated place. Wear suitable protective clothing. Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Use non-sparking tools. Prevent fire caused by electrostatic discharge steam.

Conditions for safe storage, including any incompatibilities

Separated from food and feedstuffs. See Chemical Dangers. Dry. Keep in the dark. Well closed. Cyclophosphamide should be preserved in tight containers, at a temperature between 2 & 32 deg C.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure limit values

no data available

Biological limit values

no data available

Ensure adequate ventilation. Handle in accordance with good industrial hygiene and safety practice. Set up emergency exits and the risk-elimination area.

Personal protective equipment

Eye/face protection

Wear face shield or eye protection in combination with breathing protection.

Skin protection

Protective gloves. Protective clothing.

Respiratory protection

Use closed system and ventilation.

Thermal hazards

no data available

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state

no data available

Colour

no data available

Odour

no data available

Melting point/freezing point

41-45°C

Boiling point or initial boiling point and boiling range

336.1°C at 760 mmHg

Flammability

Combustible. Gives off irritating or toxic fumes (or gases) in a fire.

Lower and upper explosion limit/flammability limit

no data available

Flash point

157.1°C

Auto-ignition temperature

no data available

Decomposition temperature

no data available

pH

no data available

Kinematic viscosity

no data available

Solubility

10 to 50 mg/mL at 73° F (NTP, 1992)

Partition coefficient n-octanol/water

0.63

Vapour pressure

0.006 Pa(calculated)(25°C)

Density and/or relative density

1.33 g/cm³

Relative vapour density

no data available

Particle characteristics

no data available

10. STABILITY AND REACTIVITY

10.1

Reactivity

Decomposes on burning. This produces toxic fumes including phosphorus oxides and nitrogen oxides.

10.2

Chemical stability

Aq soln keeps for a few hr @ room temp, but hydrolysis occurs above 30 deg c, removes chlorine atoms; darkens on exposure to light monohydrate

10.3

Possibility of hazardous reactions

CYCLOPHOSPHAMIDE is sensitive to exposure to light (darkens). Also sensitive to oxidation. Aqueous solutions may be kept for a few hours at room temperature, but hydrolysis occurs at temperatures above 86°F. Solutions in DMSO, 95% ethanol or acetone are stable for 24 hours under normal lab conditions. Incompatible with benzyl alcohol. Undergoes both acid and base hydrolysis at extreme pHs (NTP, 1992)

10.4

Conditions to avoid

no data available

10.5

Incompatible materials

It was/ reported that immersion of a needle with an aluminum component in cyclophosphamide 20 mg/ml resulted in a slight darkening of the aluminum & gas production after a few days at 24 deg C with protection from light.

10.6

Hazardous decomposition products

When heated to decomposition it emits highly toxic fumes of /phosphorus oxides, nitrogen oxides, & hydrogen chloride/.

11. TOXICOLOGICAL INFORMATION

Acute toxicity

Oral: LD50 Rat oral 160 mg/kg

Inhalation: no data available

Dermal: no data available

Skin corrosion/irritation

no data available

Serious eye damage/irritation

no data available

Respiratory or skin sensitization

no data available

Germ cell mutagenicity

no data available

Carcinogenicity

Classification of carcinogenicity: 1) evidence in humans: sufficient; 2) evidence in animals: sufficient.

Overall summary evaluation of carcinogenic risk to humans is Group 1: The agent is carcinogenic to humans. From table

Reproductive toxicity

no data available

STOT-single exposure

The substance may cause effects on the blood, bladder, central nervous system and heart.

STOT-repeated exposure

The substance may have effects on the blood, bladder, lungs and bone marrow. This may result in leucopenia, cystitis and pulmonary fibrosis. This substance is carcinogenic to humans. May cause heritable genetic damage to human germ cells. Causes serious reproductive toxicity in humans.

Aspiration hazard

A harmful concentration of airborne particles can be reached quickly when dispersed, especially if powdered.

12. ECOLOGICAL INFORMATION

12.1

Toxicity

Toxicity to fish: no data available

Toxicity to daphnia and other aquatic invertebrates: no data available

Toxicity to algae: no data available

Toxicity to microorganisms: no data available

12.2

Persistence and degradability

AEROBIC: Cyclophosphamide has been shown to be non-biodegradable in a laboratory-scale sewage treatment studies(1-3). During 29 days of 10 ug/l compound addition, a mean effluent recovery of 83% was established(2). Cyclophosphamide, present at 160 mg/l, indicated no DOC elimination in four weeks using an activated sludge inoculum at 0.2 g/l and the Zahn-Wellens test(2). The compound is confirmed to be non-biodegradable according to the OECD confirmatory test using both single compound and compound mixtures run from a period of 10-14 days at concentrations ranging from 150 to 750 mg/l and that employs a sewage sludge inoculum(3).

12.3

Bioaccumulative potential

An estimated BCF of 3 was calculated for cyclophosphamide(SRC), using a log Kow of 0.63(1) and a regression-derived equation(2). According to a classification scheme(3), this BCF suggests the potential for bioconcentration in aquatic organisms is low(SRC).

12.4

Mobility in soil

The Koc of cyclophosphamide is estimated as 52(SRC), using a log Kow of 0.63(1) and a regression-derived equation(2). According to a classification scheme(3), this estimated Koc value suggests that cyclophosphamide is expected to have high mobility in soil.

12.5

Other adverse effects

no data available

13. DISPOSAL CONSIDERATIONS

Product

The material can be disposed of by removal to a licensed chemical destruction plant or by controlled incineration with flue gas scrubbing. Do not contaminate water, foodstuffs, feed or seed by storage or disposal. Do not discharge to sewer systems.

Contaminated packaging

Containers can be triply rinsed (or equivalent) and offered for recycling or reconditioning. Alternatively, the packaging can be punctured to make it unusable for other purposes and then be disposed of in a sanitary landfill. Controlled incineration with flue gas scrubbing is possible for combustible packaging materials.

14. TRANSPORT INFORMATION

14.1

UN Number

ADR/RID: no data available

IMDG: no data available

IATA: no data available

14.2

UN Proper Shipping Name

ADR/RID: no data available

IMDG: no data available

IATA: no data available

14.3

Transport hazard class(es)

ADR/RID: no data available

IMDG: no data available

IATA: no data available

14.4

Packing group, if applicable

ADR/RID: no data available

IMDG: no data available

IATA: no data available

14.5

Environmental hazards

ADR/RID: no data available

IMDG: no data available

IATA: no data available

14.6

Special precautions for user

no data available

14.7

Transport in bulk according to IMO instruments

no data available

15. REGULATORY INFORMATION

Safety, health and environmental regulations specific for the product in question

EC number

200-015-4

European Inventory of Existing Commercial Chemical Substances (EINECS)

Listed.

EC Inventory

Listed.

United States Toxic Substances Control Act (TSCA) Inventory

Not Listed.

China Catalog of Hazardous chemicals 2015

Not Listed.

New Zealand Inventory of Chemicals (NZIoC)

Not Listed.

Philippines Inventory of Chemicals and Chemical Substances (PICCS)

Not Listed.

Vietnam National Chemical Inventory

Not Listed.

Chinese Chemical Inventory of Existing Chemical Substances (China IECSC)

Not Listed.

Korea Existing Chemicals List (KECL)

Not Listed.

16. OTHER INFORMATION

This SDS was prepared sincerely on the basis of the information we could obtained, however, any warranty shall not be given regarding the data contained and the assessment of hazards and toxicity. Prior to use, please investigate not only the hazards and toxicity information but also the laws and regulations of the organization, area and country where the products are to be used, which shall be given the first priority. The products are supposed to be used promptly after purchase in consideration of safety. Some new information or amendments may be added afterwards. If the products are to be used far behind the expected time of use or you have any questions, please feel free to contact us. The stated cautions are for normal handling only. In case of special handling, sufficient care should be taken, in addition to the safety measures suitable for the situation. All chemical products should be treated with the recognition of "having unknown hazards and toxicity", which differ greatly depending on the conditions and handling when in use and/or the conditions and duration of storage. The products must be handled only by those who are familiar with specialized knowledge and have experience or under the guidance of those specialists throughout use from opening to storage and disposal. Safe usage conditions shall be set up on each user's own responsibility.