

SAFETY DATA SHEETS

According to the UN GHS revision 9

Version: 1.0
Creation Date: July 15, 2019
Revision Date: July 15, 2019

SECTION 1: Identification

1.1 GHS Product identifier

Product name Cyclophosphamide

1.2 Other means of identification

Product number -
Other names ASTA; Clafen; cycloblastin

1.3 Recommended use of the chemical and restrictions on use

Identified uses Industrial and scientific research use.
Uses advised against no data available

1.4 Supplier's details

Company Shanghai Baishun Biotechnology Co., Ltd
Address No. 26, Lane 918, Lianye Road, Zhelin Town, Fengxian District, Shanghai, 201400, China
Telephone +86-21-37581181

1.5 Emergency phone number

Emergency phone number +86-21-37581181
Service hours Monday to Friday, 9am-5pm (Standard time zone: UTC/GMT +8 hours).

SECTION 2: Hazard identification

2.1 Classification of the substance or mixture

Acute toxicity - Category 3, Oral
Germ cell mutagenicity, Category 1B
Carcinogenicity, Category 1B
Reproductive toxicity, Category 1A

2.2 GHS label elements, including precautionary statements

Pictogram(s)



Signal word Danger
Hazard statement(s) H301 Toxic if swallowed
H340 May cause genetic defects
H350 May cause cancer

	H360 May damage fertility or the unborn child
Precautionary statement(s)	
Prevention	P264 Wash ... thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P203 Obtain, read and follow all safety instructions before use. P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...
Response	P301+P316 IF SWALLOWED: Get emergency medical help immediately. P321 Specific treatment (see ... on this label). P330 Rinse mouth. P318 IF exposed or concerned, get medical advice.
Storage	P405 Store locked up.
Disposal	P501 Dispose of contents/container to an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal.

2.3 Other hazards which do not result in classification

no data available

SECTION 3: Composition/information on ingredients

3.1 Substances

Chemical name	Common names and synonyms	CAS number	EC number	Concentration
Cyclophosphamide	Cyclophosphamide	50-18-0	200-015-4	100%

SECTION 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

SECTION 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.

SECTION 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

SECTION 7: Handling and storage

7.1 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.

7.2 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.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure limit values

no data available

Biological limit values

no data available

8.2 Appropriate engineering controls

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

8.3 Individual protection measures, such as personal protective equipment (PPE)

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

SECTION 9: Physical and chemical properties and safety characteristics

Physical state	PHYSICAL DESCRIPTION: Fine white crystalline powder. Odorless with a slightly bitter taste. Melting point 41-45°C. A 2% solution has pH of 4 to 6. Used medicinally as an antineoplastic agent.
Colour	LIQUEFIES ON LOSS OF ITS WATER OF CRYSTALLIZATION
Odour	Odorless
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/cm ³
Relative vapour density	no data available
Particle characteristics	no data available

SECTION 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/.

SECTION 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.

SECTION 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

SECTION 13: Disposal considerations

13.1 Disposal methods

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.

SECTION 14: Transport information

14.1 UN Number

ADR/RID: UN1851 (For reference only, please check.)

IMDG: UN1851 (For reference only, please check.)

IATA: UN1851 (For reference only, please check.)

14.2 UN Proper Shipping Name

ADR/RID: MEDICINE, LIQUID, TOXIC, N.O.S. (For reference only, please check.)

IMDG: MEDICINE, LIQUID, TOXIC, N.O.S. (For reference only, please check.)

IATA: MEDICINE, LIQUID, TOXIC, N.O.S. (For reference only, please check.)

14.3 Transport hazard class(es)

ADR/RID: 6.1 (For reference only, please check.)

IMDG: 6.1 (For reference only, please check.)

IATA: 6.1 (For reference only, please check.)

14.4 Packing group, if applicable

ADR/RID: II (For reference only, please check.)

IMDG: II (For reference only, please check.)

IATA: II (For reference only, please check.)

14.5 Environmental hazards

ADR/RID: No

IMDG: No

IATA: No

14.6 Special precautions for user

no data available

14.7 Transport in bulk according to IMO instruments

no data available

SECTION 15: Regulatory information

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

Chemical name	Common names and synonyms	CAS number	EC number
Cyclophosphamide	Cyclophosphamide	50-18-0	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.

SECTION 16: Other information

Information on revision

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Abbreviations and acronyms

- CAS: Chemical Abstracts Service
- ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
- RID: Regulation concerning the International Carriage of Dangerous Goods by Rail
- IMDG: International Maritime Dangerous Goods
- IATA: International Air Transportation Association
- TWA: Time Weighted Average
- STEL: Short term exposure limit
- LC50: Lethal Concentration 50%
- LD50: Lethal Dose 50%
- EC50: Effective Concentration 50%

References

- IPCS - The International Chemical Safety Cards (ICSC), website: <http://www.ilo.org/dyn/icsc/showcard.home>
- HSDB - Hazardous Substances Data Bank, website: <https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm>
- IARC - International Agency for Research on Cancer, website: <http://www.iarc.fr/>
- eChemPortal - The Global Portal to Information on Chemical Substances by OECD, website: http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en
- CAMEO Chemicals, website: <http://cameochemicals.noaa.gov/search/simple>
- ChemIDplus, website: <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>
- ERG - Emergency Response Guidebook by U.S. Department of Transportation, website: <http://www.phmsa.dot.gov/hazmat/library/erg>
- Germany GESTIS-database on hazard substance, website: <http://www.dguv.de/ifa/gestis/gestis-stoffdatenbank/index-2.jsp>
- ECHA - European Chemicals Agency, website: <https://echa.europa.eu/>

Other Information

CAS No. for monohydrate is 6055-19-2. Depending on the degree of exposure, periodic medical examination is suggested. Do NOT take working clothes home.

Any questions regarding this SDS, Please send your inquiry to sds@xixisys.com

Disclaimer: 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. We as supplier shall not be held liable for any damage resulting from handling or from contact with the above product.