Safety Data Sheet

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Section 1: Identification

Product Name CYCLOPHOSPHAMIDE USP MONOHYDRATE
Commercial Name Endoxan®, Cyclophophane, Cytophosphane, Cycloblastin, Cyclostin, Cytoxan®, Neosar®, Procytox®, Sendoxan®, Cyc
Product Use Antineoplastic; Immunosuppressant
Restrictions On Use N/A

Product Code 30-4871

Company
PCCA
9901 South Wilcrest
Houston, TX 77099
Phone: 1-800-331-2498
Fax: 1-800-874-5760

In case of emergency contact:
CHEMTREC (24hr) 1-800-424-9300

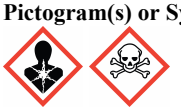
Section 2: Hazard(s) Identification

OSHA Haz Com: CFR 1910.1200 Toxic if Swallowed (Category 3) May Cause Cancer (Category 1B) Suspected of Causing Genetic Defects (Category 2) Suspected of Damaging Fertility or the Unborn Child (Category 2) Toxic to Aquatic Life (Category 2)

Signal Word DANGER

Hazard Statement(s) Toxic if swallowed. Suspected of causing genetic defects. May cause cancer. Suspected of damaging fertility or the unborn child. Toxic to aquatic life.

Pictogram(s) or Symbol(s)



Precautionary Statement(s):

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not eat, drink or smoke when using this product. Avoid release to the environment. Use personal protective equipment as required. Specific treatment (see on this label).

Response Wash thoroughly after handing. IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. IF exposed or concerned: Get medical advice/attention. Rinse mouth.

Storage Store locked up.

Disposal Dispose of contents/container in accordance with local/ regional/national/ international regulations.

Section 3: Composition/Information on Ingredients

Substance/Mixture Cyclophosphamide Monohydrate
Components Cyclophosphamide Monohydrate
% By Weight >=97.0
CAS# 6055-19-2
Molecular Weight Not available.
Chemical Formula C7H15Cl2N2O2P
Synonym(s) N, N-Bis(2-chloroethyl)tetrahydro-2H-I, 3, 2-oxazaphosphorin-2-amine-2-oxide monohydrate; Endoxan®, Cyclophophane, Cytophosphane, Cycloblastin, Cyclostin, Cytoxan®, Neosar®, Procytox®, Sendoxan®, Cyclophosphamide hydrate, Revimmune®

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Cyclophosphamide Monohydrate	6055-19-2	>=97.0		

Section 4: First-Aid Measures

Inhalation If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. May cause irritation. Avoid inhalation! Remove to fresh air.

Skin Contact May cause irritation and is absorbable through intact skin, Avoid all contact! Immediately flush with copious quantities of water.

Eye Contact May cause irritation. Avoid exposure. Flush with copious quantities of water.

Ingestion May cause irritation and toxicity. Avoid ingestion! Flush out mouth with water. This material is well absorbed from the gastrointestinal tract.

Symptoms/Effects

Acute Possible eye, skin, gastrointestinal tract and/or respiratory tract irritation.

Delayed Possible hypersensitization, infertility, severe bladder infection, congestive heart failure, bone-marrow depression, blood disorders and cancer.

Immediate Medical Attention

Medical Attention: Treatment of cyclophosphamide overdose should be symptomatic and supportive and may include the following: 1.Administer charcoal as a slurry. 2.For hypotension with signs of hypovolemia, administer fluid cautiously. 3.Hyperuricemia can be minimized by alkalinization of urine, adequate hydration, and/or administration of allopurinol. 4.Hemorrhagic cystitis can be treated with mesna, hydration and formalin to control bleeding. Hemodialysis may be of benefit. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures.

Section 5: Fire-Fighting Measures

Suitable Extinguishing Media

Water spray, dry chemical, carbon dioxide or foam as appropriate

Unsuitable Extinguishing Media

None known.

Products of Combustion

COx, NOx, POx, HCl, phosphine (PH3) and other noxious gases or vapours in case of incomplete combustion.

Firefighters Special Equipment and Precautions

As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Section 6: Accidental Release Measures

Protective Equipment: Wear suitable protective equipment. Emergency Procedures: Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment. For Emergency Responders: Switch off electrical equipment and any other sources of ignition. Evacuate area. Wear self-contained breathing apparatus, appropriate boots and heavy rubber gloves. Environmental Precautions: Keep away from drains, surface and ground water. Methods and Materials for Containment and Cleaning up: -For Containment: Place spillage and all contaminated cleanup materials in a thick plastic hazardous waste disposal bag or leak-proof container and label it "CAUTION: HAZARDOUS CHEMICAL WASTE". -For Cleaning up: Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Wash spill site with a 0.2N solution of potassium hydroxide in methanol. Alternatively, this material may be destroyed in a hood by mixing with 0.2N potassium hydroxide in methanol for 1 hour.

Section 7: Handling and Storage

Precautions for Safe Handling: Measures to Prevent Fire: The product itself does not burn. Measures to Prevent Aerosol and Dust Generation: If technically possible use local exhaust ventilation. Measures to Pretect the Environment: No special provisions if the product is used appropriately. Conditions for Safe Storage, including any Incompatibilities: Techical Measures and Storage Conditions: Store at 2C to 8C. Packaging Materials: Sealed in 2-ply polyethylene bags, and put in aluminum tin. Storage Class: 6.1D

Section 8: Exposure Controls/Personal Protection

Exposure Limits	OSHA: STEL & TWA=N/A; ACGIH: STEL & TWA=N/A; NIOSH: STEL & TWA=N/A; EU: STEL, TWA, BLV=N/A; OEB =4 Substance/Mixture only to be used by those trained in its safe use.
Engineering Controls	Enclosed processes or local exhaust ventilation.
Personal Protection	First Aid responders should pay attention to self-protection and use the recommended protective clothing (chemical resistant gloves, splash protection). Respiratory Protection: Use a NIOSH approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used. Eye Protection: Wear protective chemical safety goggles. Hand Protection: Chemically compatible. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. This material is extremely potent. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment. Protective Clothing: For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties may be necessary to prevent take-home contamination.

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Section 9: Physical and Chemical Properties

Appearance	White to almost white crystalline powder
Odor	N/A
Odor Threshold	N/A

Melting Point	N/A	**pH**	N/A
Freezing Point	N/A	**Vapor Pressure**	1.15x10^-4 mmHg
Boiling Point/Range	N/A	**Vapor Density**	N/A
Decomposition temperature	N/A	**Viscosity**	N/A
Partition Coefficient: n-octanol/water	N/A	**Evaporation Rate**	N/A
Flash Point	113°F	**Autoignition temperature**	N/A
Flammability	N/A	**Flammability or Explosive Limits:**	
		Lower	N/A
		Upper	N/A

Solubility(ies)	Water soluble
Other	N/A

Section 10: Stability and Reactivity

Reactivity	No reactivity hazards known.
Chemical Stability	Stable under recommended conditions of use.
Hazardous Polymerization	Will not occur.
Conditions to Avoid	Heat. Ignition.
Incompatible Materials	Strong oxidizing agents. Strong acids. Strong bases.
Hazardous Decomposition Products	When heated to decomposition material emits toxic fumes of POx, COx, NOx, phosphine (PH3) and HCl. Emits toxic fumes under fire conditions.

Section 11: Toxicological Information

RTECS RP6157750

Acute Toxicity

p.o.: Rats LD50= 94 mg/kg Mice LD50= 350 mg/kg Dogs LD50= 44 mg/kg i.v.: Mice LD50= 275 mg/kg Guinea pigs LD50= 400 mg/kg Rabbits LD50= 130 mg/kg Dogs LD50= 40 mg/kg i.p.: Rats LD50= 121 mg/kg

Skin Corrosion/Irritation

N/A

Serious Eye Damage/Irritation

N/A

Respiratory or Skin Sensitization

N/A

Germ Cell Mutagenicity

Ames: Positive

Carcinogenicity

NTP: Group 1, IARC: Group 1, OSHA: Repr. Tox., ACGIH: Not Listed, NOISH: Not Listed

Reproductive Toxicity

Human: May impair fertility in men and women. Cyclophosphamide may impair fertility in males and females and parental use prior to conception has been associated with fetal abnormalities. Use by pregnant women may cause fetal harm, especially in the first trimester. This material has been shown to be teratogenic at very low doses in animals. Breastfeeding: Cyclophosphamide is present in breast milk. Neutropenia, thrombocytopenia, low hemoglobin, and diarrhea have been reported in infants breast fed by women treated with cyclophosphamide. Because of the potential for serious adverse reactions in nursing infants from cyclophosphamide, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Routes of Entry

N/A

Symptoms Related to Exposure

Hypersensitivity to material, bone marrow depression, blood disorders, chickenpox, herpes zoster, infection, previous cytotoxic drug therapy or radiation therapy, impaired kidney or liver function and tumor cell infiltration of bone marrow.

Potential Health Effects

Information on the Likely Routes of Exposure: Inhalation, ingestion. Possible hypersensitization, infertility, severe bladder infection, congestive heart failure, bone-marrow depression, blood disorders and cancer.

Target Organ(s) Bone marrow; Heart; Bladder; Kidneys; Blood: GI; Testes; Ovary; Uterus/Cervix.

Section 12: Ecological Information

Ecotoxicity

Natural Pollution Sources: Synthesized product Acute (Short-term) Toxicity: LC50 (Fish-96h): EC50= 70 mg/L, ChV= 200 mg/L EC50 (Daphnies-48h): EC50= 8.168 mg/L; EC50> 987 mg/L, Daphnia magna, NOEC= 56 mg/L, Daphnia magna IC50 (Algae-72h): IC50> 100 mg/L EC50= 11 mg/L

Persistance and Degradability

Persistence: Cyclophosphamide exhibited only poor degradability in the Zahn-Wellens test and the sewage treatment plant simulation test. Cyclophosphamide was not biodegraded at a concentration of 5 mg/L in the Closed Bottle Test in 28 days ("not readily biodegradable"). t1/2= 38 days in water; t1/2= 75 days in soil Degradability: N/A

Bioaccumulative Potential

Kow: Log Kow = 0.6 BCF: 3.2

Mobility in Soil

Known or Predicted Distribution to Environmental Compartments: Air = < 0.01% Water = 17.5% Soil = 82.3% Sediment = < 0.5% Surface Tension: 44.3 dyne/cm Koc: Koc : 94.23 L/kg; Log Koc: 1.974 Leaching and Mobility: This estimated Koc value suggests that Cyclophosphamide is expected to be mobile in soil.

Other Adverse Effects

N/A

Section 13: Disposal Considerations

Waste Disposal

Product/Packaging Disposal: Product residue: Deliver to the Environmental service of the factory or to any specialized and approved disposal service. Incineration in accordance with laws. Uncleaned packaging: Deliver to the Environmental service of the factory or to any specialized and approved disposal service. Incineration in accordance with laws. Dispose in accordance with all applicable regulations. This material and its container must be disposed of in a safe manner.

Disposal of Container

Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner.

Other Considerations

N/A

Section 14: Transport Information

DOT Classification

Organophosphorous compound, solid, toxic, 6.1 III n.o.s.

Section 15: Regulatory Information

Regulations

TSCA: Exempt OSHA: None of the chemicals in this product are considered highly hazardous by OSHA. SARA: SARA Section 302 Extremely Hazardous Substance: Not Listed. SARA Section 302/304 Emergency Planning and Notification: None. SARA Section 311/312 Hazard Categories: Acute Health Hazard; Chronic Health Hazard. SARA Section 313 Toxic Chemicals-Supplier Notification Required: None. EPA: -CERCLA: Listed -California: P65: Cancer; Developmental, female, male

Other

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

Section 16: Other Information

This information was prepared on November 24, 2009 and last updated on March 6, 2014. This version was amended according to Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Fifth revised edition, United Nations, New York and Geneva, 2013, and Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP). The information and recommendations contained herein are based upon tests believed to be reliable. However, PCCA does not guarantee the accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage maybe required. PCCA assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.