



Safety Data Sheet

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

Cyclosporine (A) USP

55-3196

Section 1: Identification

Product Name Cyclosporine (A) USP
Commercial Name Cyclosporine
Product Use Not available.
Restrictions On Use Not available.
Product Code 55-3196
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: Carcinogenicity: Category 1A Reproductive toxicity, effects on or via lactation Acute Toxicity, oral: Category 4
CFR 1910.1200

Signal Word DANGER

Hazard Statement(s) May cause cancer. May cause harm to breast-fed children. Harmful if swallowed. Restricted to professional users.

Pictogram(s) or Symbol(s)



Precautionary Statement(s):

Prevention

P260 Do not breathe dust/ fume/ gas/ mist/ vapours/spray. P201 Obtain special instructions before use. P263 Avoid contact during pregnancy and while nursing. P280 Wear protective gloves/ protective clothing / eye protection / face protection. P264 Wash thoroughly with water for at least 15 minutes after use.

Response

P308+P313 IF exposed or concerned: Get medical advice / attention.

Storage

Not available

Disposal

Not available.

Section 3: Composition/Information on Ingredients

Substance/Mixture Substances
Components Cyclosporin (A) USP
% By Weight 100
CAS# 59865-13-3
Molecular Weight 1202.61 g/mole
Chemical Formula C62-H111-N11-O12
Synonym(s) Cyclosporin A

Mixtures	CAS#	% by Weight	TLV/PEL	LC50/LD50
Name				
Cyclosporine	59865-13-3	100	Not available.	ORAL (LD50): Acute: 1480 mg/kg [Rat]. 2329 mg/kg [Mouse]. 10000 mg/kg [Rabbit].

Section 4: First-Aid Measures

Inhalation	Remove to open air. If the subject stops breathing, administer artificial respiration. Get medical advice/attention immediately
Skin Contact	Remove contaminated clothing. Rinse skin with a shower immediately. Get medical advice/attention immediately. Wash contaminated clothing before using it again.
Eye Contact	Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.
Ingestion	Get medical advice/attention immediately. Do not induce vomiting. Do not administer anything not explicitly authorised by a doctor.

Symptoms/Effects**Acute** Not available.**Delayed** Not available.**Immediate Medical Attention**

Not available.

Section 5: Fire-Fighting Measures**Suitable Extinguishing Media**

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray

Unsuitable Extinguishing Media

Not available.

Products of Combustion

Do not breathe combustion products. The product is combustible and, when the powder is released into the air in sufficient concentrations and in the presence of a source of ignition, it can create explosive mixtures with air. Fires may start or get worse by leakage of the solid product from the container, when it reaches high temperatures or through contact with sources of ignition.

Firefighters Special Equipment and Precautions

GENERAL INFORMATION: Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations. SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS: Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Eliminate sources of ignition (cigarettes, flames, sparks, etc.) from the air in which the leak occurred. If there are no contraindications, spray solid products with water to prevent the formation of dust. Use breathing equipment if fumes or powders are released into the air. Block the leakage if there is no hazard. Do not handle damaged containers or leaked product before donning appropriate protective gear. Send away individuals who are not suitably equipped. For information on risks for the environmental and health, respiratory tract protection, ventilation and personal protection equipment, refer to the other sections of this sheet. Environmental precautions: The product must not penetrate the sewers, surface water, ground water and neighbouring areas. Methods and material for containment and cleaning up: Use spark-proof mechanical equipment to collect the leaked solid product and place in plastic containers. Eliminate any residues and clean surfaces using methanol, avoiding any dispersion: washing liquids must be sent to the incinerator. Air the leakage area well. Contaminated material must be disposed of in compliance with the instructions set forth in point 13

Section 7: Handling and Storage

Precautions for safe handling: Avoid electric charge build-up. Do not smoke. Do not spray onto flames or incandescent bodies. Use in facilities fitted with suitable collection systems, in dedicated systems and under closed circuit conditions. Wear protective gloves. Use airtight safety goggles. Conditions for safe storage, including any incompatibilities: Store in a ventilated place, in well-sealed containers, out of direct sunlight, light and moisture, at room temperature and away from all sources of combustion. Do not use metal containers. Storage class TRGS 510 (Germany): 6.1C

Section 8: Exposure Controls/Personal Protection**Exposure Limits** Not available.



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Engineering Controls

Not available

Personal Protection

Use of adequate technical measures should always take priority over personal protective equipment. Respect general rules of hygiene such as: storing work overalls separately from normal clothes; not smoking, eating and/or drinking outside the designated areas; washing hands before eating or smoking. Occupational exposure control Work with adequate localised aspiration systems. Hand protection: Wear chemical protection gloves, in compliance with applicable EN standards. Eye protection: Wear airtight goggles, in compliance with applicable EN standards. Skin protection: Wear chemical protection overalls, in compliance with applicable EN standards. Breathing protection: Wear facemask with P3 dust filter, in compliance with applicable EN standards. ENVIRONMENTAL EXPOSURE CONTROLS: The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards

Section 9: Physical and Chemical Properties

Appearance	White crystalline solid		
Odor	Odorless		
Odor Threshold	Not available.		
Melting Point	148-151°C	pH	Not available.
Freezing Point	Not available.	Vapor Pressure	Not applicable.
Boiling Point/Range	Not available.	Vapor Density	Not available.
Decomposition temperature	Not available.	Viscosity	Not available
Partition Coefficient: n-octanol/water	Not available.	Evaporation Rate	Not available.
Flash Point	Not available.	Autoignition temperature	Not available.
Flammability	Not available.	Flammability or Explosive Limits:	
		Lower	Not available.
		Upper	Not available.
Solubility(ies)	Slightly soluble in water at 20°C. Soluble in methanol, ethanol, acetone, ethyl ether and dichloromethane. Slightly soluble in saturated hydrocarbons. Insoluble in hexane.		
Other	Minimum ignition temperature (MI) > 500°C Minimum ignition energy (MIE) (mjoules) 1,6-2,1 LEL (g/m3) 30-60		

Section 10: Stability and Reactivity

Reactivity	There are no particular risks of reaction with other substances in normal conditions of use
Chemical Stability	The product is stable in normal conditions of use and storage.
Hazardous Polymerization	No hazardous reactions are foreseeable in normal conditions of use and storage.
Conditions to Avoid	Avoid overheating, electrostatic discharge and all sources of combustion. Take all usual precautions for chemical products.
Incompatible Materials	Do not use metal containers. Exothermic reactions are possible on contact with strong oxidising or reducing agents, acids or bases.
Hazardous Decomposition Products	In the event of thermal decomposition or fire, may release gases and fumes that are potentially harmful to health such as carbon oxides and nitrogen oxides.

Section 11: Toxicological Information
RTECS GZ4120000

Acute Toxicity

Acute toxicity, category 4. Harmful if swallowed. Animal from RTECS mouse p.os mg/kg 2329 (LD50) i.p. mg/kg nd (TDLo) i.v. mg/kg 96 (LD50) s.c. µg/kg nd (LD50) rat p.os mg/kg 1480 (LD50) i.p. mg/kg 147 (LD50) i.v. mg/kg 24 (LD50) s.c. mg/kg 286 (LD50).

Skin Corrosion/Irritation

Does not meet the classification criteria for this hazard class

Serious Eye Damage/Irritation

Does not meet the classification criteria for this hazard class

Respiratory or Skin Sensitization

Does not meet the classification criteria for this hazard class

Germ Cell Mutagenicity

Does not meet the classification criteria for this hazard class

Carcinogenicity

May cause cancer

Reproductive Toxicity

May cause harm to breast-fed children

Routes of Entry

Not available.

Symptoms Related to Exposure

Not available.

Potential Health Effects

Not available.

Target Organ(s)

Does not meet the classification criteria for this hazard class

Section 12: Ecological Information**Ecotoxicity**

Not available.

Persistence and Degradability

Not available.

Bioaccumulative Potential

Not available.

Mobility in Soil

Not available.

Other Adverse Effects

Not available.

Section 13: Disposal Considerations**Waste Disposal**

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations. Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

Disposal of Container

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

Other Considerations

Not available.

Section 14: Transport Information**DOT Classification**

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

Section 15: Regulatory Information**Regulations**

Seveso Category - Directive 2012/18/EC: Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006 None Substances in Candidate List (Art. 59 REACH) On the basis of available data, the product does not contain any SVHC in percentage greater than 0,1%. Substances subject to authorisation (Annex XIV REACH) None Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012: None Substances subject to the Rotterdam Convention: None Substances subject to the Stockholm Convention: None Healthcare controls Workers exposed to this health-dangerous chemical agent must undergo sanitary checks carried out in compliance with 2004/37/EC directive. German regulation on the classification of substances hazardous to water (AwSV, vom 18. April 2017) Self assessment based on Annex 3 15.2. Chemical safety assessment A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.



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Other

WHMIS CLASS D-2A: Material causing other toxic (Canada) effects (VERY TOXIC).;DSCL (EEC) R36/37- Irritating to eyes and respiratory system. R45- May cause cancer. R48/22- Harmful: danger of serious damage to health by prolonged exposure if swallowed. R62- Possible risk of impaired fertility. R63- Possible risk of harm to the unborn child.;Gloves.;Lab coat.;Dust respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate.;Splash goggles.

Section 16: Other Information

The above information is believed to be correct based on our present knowledge.