

MATERIAL SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product name : Cyclosporin A

CAS Number : 59865-13-3

Company : Fujian Kerui Pharmaceutical Co., Ltd.
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2. HAZARDS IDENTIFICATION

Classification of the substance or mixture

According to Regulation (EC) No1272/2008

Acute toxicity, Oral (Category 4)

Carcinogenicity (Category 1B)

Reproductive toxicity (Category 1B)

According to European Directive 67/548/EEC as amended.
May cause cancer. Harmful if swallowed. May impair fertility.

Label elements

Pictogram



Signal word

Danger

Hazard statement(s)

H302

Harmful if swallowed.

H350

May cause cancer.

H360

May damage fertility or the unborn child.

Precautionary statement(s)

P201

Obtain special instructions before use.

P308 + P313

IF exposed or concerned: Get medical advice/attention.

Hazard symbol(s)

T

Toxic

R-phrases(s)

R45

May cause cancer.

R60

May impair fertility.

R22

Also harmful if swallowed.

S-phrases(s)

S53

Avoid exposure - obtain special instructions before use.

S45

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Caution - substance not yet tested completely.

Restricted to professional users.

Other hazards - none

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms : Cyclosporine
Antibiotic S 7481F1

Formula : $C_{62}H_{111}N_{11}O_{12}$

Molecular Weight : 1.202,61 g/mol

| CAS-No. | EC-No. | Index-No. | Classification | Concentration |
|----------------------|--------|-----------|---|---------------|
| Cyclosporin A | | | | |
| 59865-13-3 | - | - | Acute Tox. 4; Carc. 1B; Repr. 1B; H302, H350, H360 T, R45 - R22 - R60 | - |

For the full text of the H-Statements mentioned in this Section, see Section 16.

4. FIRST AID MEASURES

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move person into fresh air. If not breathing give artificial respiration Consult a physician.

In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Special protective equipment for fire-fighters

Wear self contained breathing apparatus for fire fighting if necessary.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions

Use personal protective equipment. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation. Evacuate personnel to safe areas.

Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Keep in suitable, closed containers for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling

Avoid formation of dust and aerosols. Avoid exposure - obtain special instructions before use. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.

Conditions for safe storage

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Personal protective equipment****Respiratory protection**

Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hand protection

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Handle with gloves.

Eye protection

Safety glasses with side-shields conforming to EN166

Skin and body protection

Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Hygiene measures

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES**Appearance**

| | |
|--------|-------|
| Form | solid |
| Colour | white |

Safety data

| | |
|-----------------------|-------------------|
| pH | no data available |
| Melting point | no data available |
| Boiling point | no data available |
| Flash point | no data available |
| Ignition temperature | no data available |
| Lower explosion limit | no data available |
| Upper explosion limit | no data available |
| Water solubility | no data available |

10. STABILITY AND REACTIVITY**Chemical stability**

Stable under recommended storage conditions.

Conditions to avoid

Heat.

Materials to avoid

Alkali metals, Aluminum, Strong oxidizing agents

Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Carbon oxides, nitrogen oxides (NOx)

11. TOXICOLOGICAL INFORMATION**Acute toxicity**

LD50 Oral - rat - 1.480 mg/kg

Remarks: Behavioral: Muscle contraction or spasticity. Diarrhoea Skin and Appendages: Other: Hair.

Skin corrosion/irritation

no data available

Serious eye damage/eye irritation

no data available

Respiratory or skin sensitization

no data available

Germ cell mutagenicity

no data available

Carcinogenicity

Possible human carcinogen

IARC: 1 - Group 1: Carcinogenic to humans (Cyclosporin A)

Reproductive toxicity

Presumed human reproductive toxicant

May cause reproductive disorders.

Specific target organ toxicity - single exposure

no data available

Specific target organ toxicity - repeated exposure

no data available

Aspiration hazard

no data available

Potential health effects**Inhalation**

May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion

Harmful if swallowed.

Skin

May be harmful if absorbed through skin. May cause skin irritation.

Eyes

May cause eye irritation.

Signs and Symptoms of Exposure

Nausea, Vomiting, Tremors, Diarrhoea, elevated blood pressure, To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Additional Information

RTECS: GZ4120000

12. ECOLOGICAL INFORMATION**Toxicity**

no data available

Persistence and degradability

no data available

Bioaccumulative potential

no data available

Mobility in soil

no data available

PBT and vPvB assessment

no data available

Other adverse effects

no data available

13. DISPOSAL CONSIDERATIONS

Product

Observe all federal, state, and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated packaging

Dispose of as unused product.

14. TRANSPORT INFORMATION

ADR/RID

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

15. REGULATORY INFORMATION

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

16. OTHER INFORMATION

Text of H-code(s) and R-phrases mentioned in Section 3

| | |
|------------|---|
| Acute Tox. | Acute toxicity |
| Carc. | Carcinogenicity |
| H302 | Harmful if swallowed. |
| H350 | May cause cancer. |
| H360 | May damage fertility or the unborn child. |
| Repr. | Reproductive toxicity |
| T | Toxic |
| R22 | Harmful if swallowed. |
| R45 | May cause cancer. |
| R60 | May impair fertility. |

Further information

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.