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## 1 Identification of the substance/mixture and of the company/undertaking

- **Informations to product No. 5180**
- **Product name:**

### **Ciclosporin, API** Ciclosporinum

- **Supplier of the Product / responsible Company:**

Caesar & Loretz GmbH  
Herderstr. 31  
40721 Hilden  
Tel.: 02103/4994-0  
Fax: 02103/32360  
e-mail: info@caelo.de

- **Emergency telephone:**

Giftinformationszentrum Mainz  
Langenbeckstr. 1, 55131 Mainz  
Tel.: 06131/19240

- **Relevant identified uses of the substance or mixture and uses advised against:**

No further relevant information available.

- **Application of the substance / mixture:**

Ingredient for pharmaceutical drugs or active pharmaceutical ingredient.

## 2 Hazards identification

- **GHS-Labeling Elements:**



- **Signal word:** Danger

- **H-Phrases:**

H302 Harmful if swallowed.  
H350 May cause cancer  
H360 May damage fertility or the unborn child


- **P-Phrases:**

P202 Do not handle until all safety precautions have been read and understood  
P281 Use personal protective equipment as required  
P301 IF SWALLOWED:  
P310 Immediately call a POISON CENTER or doctor/physician

**Acute Tox. 4**

**Carc. 1B**

**Repr. 1B**

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### 3 Composition / information on ingredients

• **Chemical characterization:**

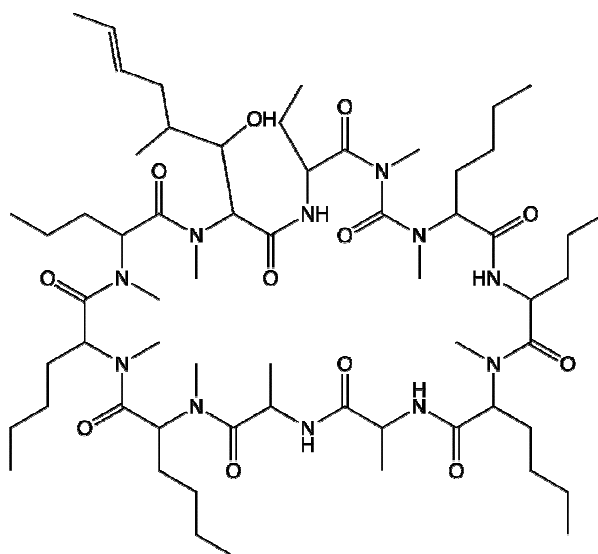
**CAS-No. Substance name**

59865-13-3 Ciclosporin

• **EINECS-Nr.:** 611-907-1

• **REACH Reg. No.:** (pre-registered)

• **INCI-Name:** -




### 4 First aid measures

- **after inhalation:** Bring the person out of the contaminated area to fresh air, Seek medical help immediately. Show product-label or this MSDS.
- **after skin contact:** Take off contaminated clothes and shoes, wash immediately with plenty of water and soap.
- **after eye contact:** Rinse out with plenty of water with the eyelid wide open. Call in ophthalmologist.
- **after swallowing:** Drink plenty of water. Induce vomiting. Seek medical advice immediately.

### 5 Fire-fighting measures

- **Suitable extinguishing media:** All regular extinguishing media can be used. Select fire fighting measures suitable to surrounding environment.
- **Specific hazards during fire fighting:** Combustible. In case of fire dangerous vapours/gases can be generated: Smoke gases.
- **Special protective equipment for fire-fighters:** Suitable protective clothes and respiratory protection.
- **Additional information:** Prevent fire extinguishing water from contaminating surface water, the ground water system or soil. Residues must be deposited according to local regulations.

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## 6 Accidental release measures

- **Personal protective measures:** Wear protective equipment.
- **Environmental protective measures:** Prevent from entering into surface water, the ground water system or soil.
- **Methods for cleaning:** Take up dry. Disposal according to Chapter 13 of this MSDS. Clean up with water.

## 7 Handling and storage

- **Handling:**
- **Advice on safe handling:** Wear protective equipment (S. Punkt 8).
- **Storage:**
- **Requirements for storage areas and containers:** Tightly closed. Store at a dry place. Store at ambient temperature ( + 15 – 25°C ). Protect from light.
- **Advices on common storage:** Not required.

## 8 Exposure controls / personal protective equipment


- **Personal protective equipment:**
- **General protective and hygiene measures:**  
Keep away from food, beverages and animal food.  
Wash hands before breaks and after work.
- **Respiratory protection:** Dust protection mask
- **Hand protection:** Protection gloves of latex or rubber.
- **Eye protection:** Safety glasses.

## 9 Physical and chemical properties

- **Form:** Crystalline powder
- **Colour:** white
- **Odour:** odourless
- **Melting point / melting range:** 148 - 151 °C
- **Boiling point / boiling range:** not determined
- **Solubility in / Miscibility with**
- **Water** not determined.
- **pH-range:** not determined.
- **Molar Mass:** 1202,6

## 10 Stability and reactivity

- **Hazardous decomposition products:**  
At high temperatures irritant or harmful vapours are released.

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## 11 Toxicological information

- **Acute toxicity:**

- **LD/LD50-data relevant for hazard classification:**

LD50: (oral, rat): 1480 mg/kg

LD50: (i.p., rat): 147 mg/kg

LD50: (i.v., rat): 24 mg/kg

LD50: (s.c., rat): 286 mg/kg

LD50: (oral, mouse): 2329 mg/kg

LD50: (i.v., mouse): 96 mg/kg

- **Primary irritating effect:**

- **on skin:** Slightly irritant

- **on eyes:** Slightly irritant

- **Additional toxicological informations:**

Immunosuppressivum. Cancerogene effect: Class. 1 (proved as human cancerogene) according to IARC, 1

## 12 Ecological information

- **Aquatic toxicity:**

Quantitative data about ecological effects of this product are not available.

- **General advices:** Prevent from leaking into ground water, environment waters or drainage.

- **Water hazard class:** 2 (self classification): hazardous for water.

## 13 Disposal considerations

- **Product:**

- **Recommendation:** Disposal according to local regulations as pharmaceutical waste.

- **Empty contaminated packaging:**

- **Recommendation:** Disposal according to the local regulations.

## 14 Transport informations

- **Land transport according to ADR:**

Not classified as dangerous in the meaning of transport regulations.

## 15 Regulatory information

- **Labelling according to actual legislation (GHS, Globally Harmonized System of Classification and Labelling of Chemicals):**

The product is classified and labelled according to GHS-regulations.


- **Hazard symbols:** GHS07, GHS08

- **Signal word:** Danger

- **H-Phrases:**

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H360 May damage fertility or the unborn child

• **P-Phrases:**

P202 Do not handle until all safety precautions have been read and understood

P281 Use personal protective equipment as required

P301 IF SWALLOWED:

P310 Immediately call a POISON CENTER or doctor/physician

• **National regulations (Germany):**

• **Water hazard class:** see chapter 12

• **Storage class TRGS 510:** 6.1C

## 16 Other Information

The information provided in this MSDS is correct to the best of our knowledge at the date of edition.

• **Reason for last revision:** Adjustment to regulation (EC) 1907/2006 (REACH) and GHS-labelling system.