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-Labelling Elements:

![GHS symbols]

· 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**
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.
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.
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:
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

- **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.