


<p>Page 1 of 5</p> <p>Print Date 22.11.2018</p>	<p>Material Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)</p> <p>Theophyllin, API</p>	 <p>Revision Date 22.11.2018</p>
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1 Identification of the substance/mixture and of the company/undertaking

· **Informations to product No. 2690**

· **Product name:**

Theophyllin, API Theophyllinum

· **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:**

H301 Toxic if swallowed.

· **P-Phrases:**

P301 IF SWALLOWED:

P310 Immediately call a POISON CENTER or doctor/physician.

3 Composition / information on ingredients

CAS-No. Substance name


58-55-9 Theophyllin

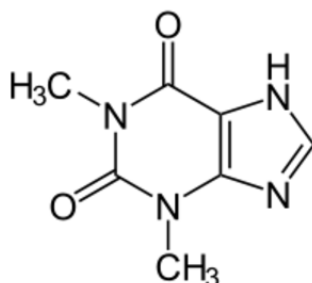
· **EINECS-No.:** 200-385-7

· **REACH Reg. No.:** 01-2119450688-27-0000

· **INCI-Name:** -

· **Chemical characterization:**

<p>Page 2 of 5</p> <p>Print Date 22.11.2018</p>	<p>Material Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)</p> <p>Theophyllin, API</p>	 <p>Revision Date 22.11.2018</p>
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4 First aid measures

- **after inhalation:** Fresh air. Seek medical advice.
- **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.
- **after swallowing:** 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: Nitrogen oxides.
- **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:** Avoid contact with substance.
- **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:** No special requirements.
- **Advice on safe handling:** Ensure good ventilation/exhaustion at the workplace. Handling corresponding to laboratory safety guidelines.
- **Informations to fire or explosion protection:** No special measures required.
- **Storage:**
- **Requirements for storage areas and containers:** Tightly closed. Store at a dry place.
- **Advices on common storage:** Not required.

<p>Page 3 of 5</p> <p>Print Date 22.11.2018</p>	<p>Material Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)</p> <p>Theophyllin, API</p>	 <p>Revision Date 22.11.2018</p>
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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 rubber or latex
- **Eye protection:** Safety glasses

9 Physical and chemical properties

- **Form:** solid
- **Colour:** white
- **Odour:** odourless
- **Melting point / melting range:** 270 - 274 °C
- **Boiling point / boiling range:** not determined
- **Flammability (solid, vapours):** The product is not flammable.
- **Decomposition temperature:** > 273 °C
- **Density:** Bulk density: 280 kg/cbm
- **Solubility in / Miscibility with**
- **Water:** (20 °C) 5,5 g/l.
- **pH-value:** (8,3 g/l) 4,0 – 6,0

10 Stability and reactivity


- **Thermal decomposition / conditions to avoid:** Avoid strong heating.
- **Hazardous reactions:** No hazardous reactions known.
- **Hazardous decomposition products:** None.

11 Toxicological information

- **Acute toxicity:**
LD50 oral, Rat: 272 mg/kg (BASF-Test)
LC50 Rat (inhal.): > 6,7 mg/l 4 h (BASF-Test) test material: aerosol.
LD50 Rat (dermal): > 2.000 mg/kg (BASF-Test)
- **Primary irritant effect:**
- **on skin:** No irritant effect.
- **on eye:** No irritant effect.
- **Additional informations:** Not mutagenous, cancerogen or reproduction toxic.

12 Ecological information

- **Aquatic toxicity:**
Fish toxicity: LC50 (96 h) 100 mg/l, Leuciscus idus (DIN 38412 Teil 15, static)
Aquatic invertebrates: EC50 (48 h) 178 mg/l, Daphnia magna (Guideline 79/831/EWG, static)
Water plants: EC50 (72 h) > 100 mg/l (growth rate), Scenedesmus subspicatus (OECD-guideline 201, static)

<p>Page 4 of 5</p> <p>Print Date 22.11.2018</p>	<p>Material Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)</p> <p>Theophyllin, API</p>	 <p>Revision Date 22.11.2018</p>
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Microorganisms/effect on activated sludge: EC20 (180 min) ca. 900 mg/l, (OECD-Richtlinie 209, aerob)

EC10 (17 h) 1.390 mg/l, Pseudomonas putida (DIN 38412 Teil 8, aquatic)

Persistence and biodegradability

Evaluation biodegradability and elimination (H₂O):

Readily biodegradable (according to OECD-criteria).

Bioaccumulation potential

• **log p(O/W):** (23 °C) -0,008

Due to the distribution coefficient n-octanol/water (log Pow) a bioaccumulation is not likely.

• **Water hazard class:** 1 (VwVwS, Annex 3): slightly 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:**
- **Proper shipping name:** Toxic solids, organic, n.o.s. (Theophylline)
- **Class:** 6.1
- **UN-number:** 2811
- **Packing group:** III
- **Classification code:** T2
- **Limited quantities (Table 3.4.6. ADR):** 5 kg
- **Hazard classification number:** 60
- **Special provisions (Chapter 3.3 ADR):** 274, 614
- **Additional informations for sea transport IMDG:**
- **EMS-No.:** F-A, S-A
- **Properties:** -

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:** GHS06

• **Signal word:** Danger

• **H-Phrases:**

H301 Toxic if swallowed.

• **P-Phrases:**


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

Page 5 of 5 Print Date 22.11.2018	Material Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH) Theophyllin, API	 Revision Date 22.11.2018
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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.