


Page 1 of 4  Print Date 28.11.2018	<b>Material Safety Data Sheet</b> according to Regulation (EC) No. 1907/2006 (REACH)  Nystatin, mikronisiert, API (mikrobielle Herkunft)	 Revision Date 28.11.2018
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## 1 Identification of the substance/mixture and of the company/undertaking

• **Informations to product No. 4491**

• **Product name:**

**Nystatin, mikronisiert, API (mikrobielle Herkunft)**  
Nystatinum

• **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

• **Hazards identification:** The substance is not classified as dangerous according to European Union legislation.

## 3 Composition / information on ingredients

**CAS-No. Substance name**

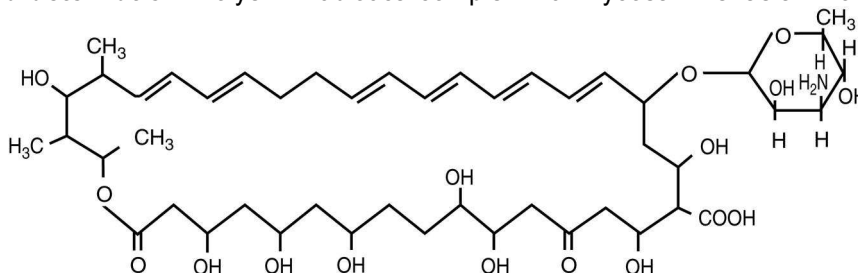
1400-61-9 Nystatin


• **EINECS-No.:** 215-749-0

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

• **INCI-Name:** -

• **Chemical characterization:** Polyen-Antibiotica-complex with mycosamine as amino-sugar.



<p>Page 2 of 4</p> <p>Print Date 28.11.2018</p>	<p><b>Material Safety Data Sheet</b> according to Regulation (EC) No. 1907/2006 (REACH)</p> <p>Nystatin, mikronisiert, API (mikrobielle Herkunft)</p>	 <p>Revision Date 28.11.2018</p>
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#### 4 First aid measures

- **General advices:** No special measures required.
- **after inhalation:** Fresh air, if feeling unwell seek medical advice.
- **after skin contact:** Wash away with plenty of water.
- **after eye contact:** Rinse out with plenty of water with the eyelid wide open.
- **after swallowing:** If feeling unwell continuously seek medical advice.

#### 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, but not flammable. In case of fire dangerous vapours/gases can be generated: Smoke gases.
- **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 dust formation and contact with substance.
- **Environmental protective measures:** Prevent from entering into drains.
- **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:** No special measures required.
- **Storage:**
- **Requirements for storage areas and containers:** Tightly closed. Store at a dry place. At room temperature ( +15°C to +25°C ).

#### 8 Exposure controls / personal protective equipment

- **Personal protective equipment:**
- **General protective and hygiene measures:** The usual precaution measures during handling of chemicals are to observe.
- **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:** yellow – light brown
- **Odour:** nearly odourless

<p>Page 3 of 4</p> <p>Print Date 28.11.2018</p>	<p><b>Material Safety Data Sheet</b> according to Regulation (EC) No. 1907/2006 (REACH)</p> <p>Nystatin, mikronisiert, API (mikrobielle Herkunft)</p>	 <p>Revision Date 28.11.2018</p>
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- **Melting point / melting range:** > 160 °C
- **Boiling point / boiling range:** not determined
- **Density:** not determined
- **Solubility in / Miscibility with**
- **Water:** Not readily soluble
- **pH-range:** not determined

## 10 Stability and reactivity

- **Thermal decomposition / conditions to avoid:**  
Protect from heat and light
- **Materials to avoid:** Strong oxidizers. Water (Hygroscopic).
- **Hazardous reactions:** No hazardous reactions known.
- **Hazardous decomposition products:** Nitrogen oxides, Carbon monoxide (In case of fire)

## 11 Toxicological information

- **Acute toxicity:**  
LD50(oral,Rat): 10000 mg/kg  
LD50(i.p.,Rat): 25 mg/kg  
LD50(oral,Mouse): 8000 mg/kg  
LD50(i.p.,Mouse): 4,4 mg/kg  
LD50(s.c.,Mouse): 120 mg/kg  
LD50(i.v.,Mouse): 3 mg/kg
- **Sensitization:** no sensitizing effect known.
- **Additional toxicological informations:** In case of appropriate handling and usage the product does not cause harmful effects.

## 12 Ecological information


- **Aquatic toxicity:**  
Quantitative data about ecological effects of this product are not available.
- **Water hazard class:** 1 (self classification): 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:**  
Not classified as dangerous in the meaning of transport regulations.

Page 4 of 4  Print Date 28.11.2018	<b>Material Safety Data Sheet</b> according to Regulation (EC) No. 1907/2006 (REACH)  Nystatin, mikronisiert, API (mikrobielle Herkunft)	 Revision Date 28.11.2018
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## 15 Regulatory information

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

The product does not need to be labelled according to GHS-regulations.

· **National regulations (Germany):**

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

· **Storage class TRGS 510:** 11

## 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.