

# Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 05.09.2011

Revision: 02.09.2011

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

- **Product identifier**
- **Trade name:** Apernyl mit Acetylsalicylsäure
- **Article number:** 1000 (100 dental sticks), 33759 (samples)
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** Dental drug / Dolor post treatment
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
SPEIKO-Dr.Speier GmbH, POB 7204, 48039 Münster, GERMANY  
Tel. ++49/251/78904-0, Fax ++49/251/78904-22
- **Further information obtainable from:** SPEIKO-Dr.Speier GmbH, info@speiko.de
- **Emergency telephone number:**  
Giftnotruf Berlin  
Tel. +49/30/30686 790 (+49/30/19240)

## 2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS07

Acute Tox. 4 H302 Harmful if swallowed.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**



Xn; Harmful

R22: Harmful if swallowed.

- **Information concerning particular hazards for human and environment:**  
The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- **Classification system:**  
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

- **Label elements**

- **Labelling according to EU guidelines:**  
Observe the general safety regulations when handling chemicals.  
The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials.
- **Code letter and hazard designation of product:**  
Xn Harmful
- **Risk phrases:**  
22 Harmful if swallowed.
- **Safety phrases:**  
36 Wear suitable protective clothing.  
60 This material and its container must be disposed of as hazardous waste.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

GB

(Contd. on page 2)

# Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 05.09.2011

Revision: 02.09.2011



Trade name: *Apernyl mit Acetylsalicylsäure*

(Contd. of page 1)

### 3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 50-78-2 EINECS: 200-064-1	O-acetylsalicylic acid	 Xn R22  Acute Tox. 4, H302	58.2%
CAS: 9005-25-8 EINECS: 232-679-6	Starch	substance with a Community workplace exposure limit	32.2%

- **Additional information:** For the wording of the listed risk phrases refer to section 16.

### 4 First aid measures

- **Description of first aid measures**
- **General information:**  
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** Call for a doctor immediately.
- **Information for doctor:**  
· **Most important symptoms and effects, both acute and delayed** No further relevant information available.  
· **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### 5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**  
Dispose contaminated material as waste according to item 13.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

### 7 Handling and storage

- **Handling:**
- **Precautions for safe handling** No special precautions are necessary if used correctly.
- **Information about fire - and explosion protection:** No special measures required.

(Contd. on page 3)

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 05.09.2011

Revision: 02.09.2011

Trade name: *Apernyl mit Acetylsalicylsäure*

(Contd. of page 2)

- *Conditions for safe storage, including any incompatibilities*
- *Storage:*
- *Requirements to be met by storerooms and receptacles: No special requirements.*
- *Information about storage in one common storage facility: Not required.*
- *Further information about storage conditions: None.*
- *Storage class: 13*
- *Specific end use(s) No further relevant information available.*

### 8 Exposure controls/personal protection

- *Additional information about design of technical facilities: No further data; see item 7.*
- *Control parameters*

· **Ingredients with limit values that require monitoring at the workplace:**

**50-78-2 O-acetylsalicylic acid**

WEL Long-term value: 5 mg/m<sup>3</sup>

**9005-25-8 Starch**

WEL Long-term value: 10\* 4\*\* mg/m<sup>3</sup>  
\*total inhalable \*\*respirable

- *Additional information: The lists valid during the making were used as basis.*
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not required.
- **Protection of hands:**  
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.  
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**  
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material**  
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Not required.

### 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**
  - **Form:** solid, wedge-shaped tablet (dental stick)
  - **Colour:** white
  - **Odour:** Characteristic
  - **Odour threshold:** Not determined.
- **pH-value:** Not applicable.

(Contd. on page 4)

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 05.09.2011

Revision: 02.09.2011

Trade name: *Apernyl mit Acetylsalicylsäure*

(Contd. of page 3)

- |  |  |
|--|--|
| · <b>Change in condition</b><br><i>Melting point/Melting range: Undetermined.</i><br><i>Boiling point/Boiling range: Undetermined.</i> |  |
| · <b>Flash point:</b>  | <i>Not applicable.</i>                               |
| · <b>Ignition temperature:</b>   | <i>not applicable °C</i>                             |
| · <b>Decomposition temperature:</b>  | <i>Not determined.</i>                               |
| · <b>Self-igniting:</b>  | <i>Product is not selfigniting.</i>                  |
| · <b>Danger of explosion:</b>  | <i>Product does not present an explosion hazard.</i> |
| · <b>Density:</b>  | <i>Not determined.</i>                               |
| · <b>Solubility in / Miscibility with water at 20°C:</b>   | <i>2.5 g/l</i>                                       |
| · <b>Solvent content:</b>  |  |
| <b>Organic solvents:</b>   | <i>0.0 %</i>   |
| <b>VOC (EC)</b>  | <i>0 %</i>   |
| · <b>Other information</b>   | <i>No further relevant information available.</i>    |

### 10 Stability and reactivity

- **Reactivity**
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** *No decomposition if used according to specifications.*
- **Possibility of hazardous reactions** *No dangerous reactions known.*
- **Conditions to avoid** *No further relevant information available.*
- **Incompatible materials:** *No further relevant information available.*
- **Hazardous decomposition products:** *No dangerous decomposition products known.*

### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** *No irritant effect.*
- **on the eye:** *No irritating effect.*
- **Sensitization:** *No sensitizing effects known.*
- **Additional toxicological information:**  
*The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:*  
*Harmful*

### 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** *No further relevant information available.*
- **Persistence and degradability** *No further relevant information available.*
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** *No further relevant information available.*
- **Mobility in soil** *No further relevant information available.*

(Contd. on page 5)

GB

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 05.09.2011

Revision: 02.09.2011

Trade name: *Apernyl mit Acetylsalicylsäure*

(Contd. of page 4)

- **Additional ecological information:**
- **General notes:**  
*Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water*  
*Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.*
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*
- **Other adverse effects** *No further relevant information available.*

### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**  
*Must not be disposed together with household garbage. Do not allow product to reach sewage system.*
- **Uncleaned packaging:**
- **Recommendation:** *Disposal must be made according to official regulations.*

### 14 Transport information

- |  |                        |
|--|------------------------|
| · <b>UN-Number</b>   | -                      |
| · <b>UN proper shipping name</b>   | -                      |
| · <b>Transport hazard class(es)</b>  | -                      |
| · <b>Packing group</b>   | -                      |
| · <b>Environmental hazards:</b>  |                        |
| · <b>Marine pollutant:</b>   | <i>No</i>              |
| · <b>Special precautions for user</b>  | <i>Not applicable.</i> |
| · <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | <i>Not applicable.</i> |

### 15 Regulatory information

- **Chemical safety assessment:** *A Chemical Safety Assessment has not been carried out.*

### 16 Other information

*This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.*

- **Relevant phrases**  
*H302 Harmful if swallowed.*  
*R22 Harmful if swallowed.*
- **Abbreviations and acronyms:**  
*GHS: Globally Harmonized System of Classification and Labelling of Chemicals*  
*VOC: Volatile Organic Compounds (USA, EU)*