

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

Printing date 14.12.2018

Revision: 14.12.2018

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

- **1.1 Product identifier**
- **Trade name:** SPEIKOCAL with x-ray contrast
- **Article number:** 1055
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Calcium hydroxide for dental use
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
SPEIKO-Dr.Speier GmbH, Walther-Rathenau-Str. 59, 33602 Bielefeld, GERMANY  
Tel. +49/521/770107-0
- **Further information obtainable from:** SPEIKO-Dr.Speier GmbH, info@speiko.de
- **1.4 Emergency telephone number:**  
Giftnotruf Berlin  
Tel. +49/30/30686 700

### SECTION 2: Hazards identification

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



GHS05 corrosion

Eye Dam. 1 H318 Causes serious eye damage.

- **2.2 Label elements** Medical products are exempted from labelling acc. (EC) No 1272/2008 (Article 1 (5) d))
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms** GHS05
- **Signal word** Danger
- **Hazard-determining components of labelling:**  
calcium dihydroxide
- **Hazard statements**  
H318 Causes serious eye damage.
- **Precautionary statements**
  - P101 If medical advice is needed, have product container or label at hand.
  - P102 Keep out of reach of children.
  - P103 Read label before use.
  - P280 Wear eye protection / face protection.
  - P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  - P310 Immediately call a POISON CENTER/doctor.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

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

· **Dangerous components:**

CAS: 1305-62-0	calcium dihydroxide	50.0%
EINECS: 215-137-3	 Eye Dam. 1, H318	

(Contd. on page 2)

**Safety data sheet**  
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Revision: 14.12.2018

Trade name: **SPEIKOCAL with x-ray contrast**

(Contd. of page 1)

CAS: 7727-43-7

barium sulphate, natural

10.0%

EINECS: 231-784-4

substance with a Community workplace exposure limit

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### SECTION 4: First aid measures

#### · 4.1 Description of first aid measures

- **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. Then consult a doctor.
- **After swallowing:** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### SECTION 5: Firefighting measures

#### · 5.1 Extinguishing media

- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **6.4 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.

### SECTION 7: Handling and storage

#### · 7.1 Precautions for safe handling

Prevent formation of dust.

Not required.

- **Information about fire - and explosion protection:** No special measures required.

#### · 7.2 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:** 8 B
- **7.3 Specific end use(s)** No further relevant information available.

### SECTION 8: Exposure controls/personal protection

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

(Contd. on page 3)

GB

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Trade name: **SPEIKOCAL with x-ray contrast**

(Contd. of page 2)

· **8.1 Control parameters**· **Ingredients with limit values that require monitoring at the workplace:****1305-62-0 calcium dihydroxide**

WEL	Short-term value: 4* mg/m <sup>3</sup> Long-term value: 5 1* mg/m <sup>3</sup> *resprable fraction
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**7727-43-7 barium sulphate, natural**

WEL	Long-term value: 10* 4** mg/m <sup>3</sup> *inhalable dust **respirable dust
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· **Additional information:** The lists valid during the making were used as basis.· **8.2 Exposure controls**· **Personal protective equipment:**· **General protective and hygienic measures:**

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes.

· **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· **Protection of hands:**

Protective gloves

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 trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**

Tightly sealed goggles

**SECTION 9: Physical and chemical properties**· **9.1 Information on basic physical and chemical properties**· **General Information**· **Appearance:****Form:** suspension**Colour:** white· **Odour:** Characteristic· **Odour threshold:** Not determined.

(Contd. on page 4)

GB

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Printing date 14.12.2018

Revision: 14.12.2018

Trade name: **SPEIKOCAL with x-ray contrast**

(Contd. of page 3)

· <b>pH-value at 20 °C:</b>	12.5
· <b>Change in condition</b>	
<b>Melting point/freezing point:</b>	Undetermined.
<b>Initial boiling point and boiling range:</b>	Undetermined.
· <b>Flash point:</b>	Not applicable.
· <b>Flammability (solid, gas):</b>	Not determined. Not applicable.
· <b>Decomposition temperature:</b>	Not determined.
· <b>Auto-ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapour pressure:</b>	Not applicable.
· <b>Density:</b>	Not determined.
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.
· <b>Solubility in / Miscibility with water:</b>	slurry slurry
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not applicable.
<b>Kinematic:</b>	Not applicable.
· <b>Solvent content:</b>	
<b>VOC (EC)</b>	0.00 %
<b>Solids content:</b>	60 %
· <b>9.2 Other information</b>	No further relevant information available.

### SECTION 10: Stability and reactivity

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

### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation**  
Causes serious eye damage.

(Contd. on page 5)

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(Contd. of page 4)

- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

### SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

### SECTION 13: Disposal considerations

- **13.1 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.

### SECTION 14: Transport information

- |  |                 |
|--|-----------------|
| · <b>14.5 Environmental hazards:</b>   |                 |
| · <b>Marine pollutant:</b>   | no<br>No        |
| · <b>14.6 Special precautions for user</b>                                       | Not applicable. |
| · <b>Segregation groups</b>  |                 |
| · <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable. |

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

GB

(Contd. on page 6)

**Safety data sheet**  
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(Contd. of page 5)

**SECTION 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**

*H318 Causes serious eye damage.*

**· Abbreviations and acronyms:**

*GHS: Globally Harmonised System of Classification and Labelling of Chemicals*

*EINECS: European Inventory of Existing Commercial Chemical Substances*

*ELINCS: European List of Notified Chemical Substances*

*CAS: Chemical Abstracts Service (division of the American Chemical Society)*

*VOC: Volatile Organic Compounds (USA, EU)*

*PBT: Persistent, Bioaccumulative and Toxic*

*vPvB: very Persistent and very Bioaccumulative*

*Eye Dam. 1: Serious eye damage/eye irritation – Category 1*

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