

**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:** SPEIKO EDTA-Gel
- **Article number:** 1053
- **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** Aufbereitung von Wurzelkanälen
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
SPEIKO-Dr.Speier GmbH, Walther-Rathenau-Str. 59, D-33602 Bielefeld  
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**



GHS07

Eye Irrit. 2 H319 Causes serious eye irritation.

- **2.2 Label elements**  
Medizinprodukte sind nicht kennzeichnungspflichtig im Sinne Chemikaliengesetz (ChemG §2 (1) 2a) und (EG) Nr. 1272/2008 (Artikel 1 (5) d))
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms** GHS07
- **Signal word** Warning
- **Hazard statements**  
H319 Causes serious eye irritation.
- **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.
  - P264 Wash thoroughly after handling.
  - 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.
  - P337+P313 If eye irritation persists: Get medical advice/attention.
- **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: 60-00-4	edetic acid	 Eye Irrit. 2, H319	15.0%
EINECS: 200-449-4			

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- **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.
- **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** No special precautions are necessary if used correctly.
- **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:** 12
- **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.
- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.

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- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:** 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.

### SECTION 9: Physical and chemical properties

#### · 9.1 Information on basic physical and chemical properties

##### · General Information

##### · Appearance:

<b>Form:</b>	Gel
<b>Colour:</b>	white
<b>Odour:</b>	Characteristic
<b>Odour threshold:</b>	Not determined.

· **pH-value at 20 °C:** 9.5

##### · Change in condition

<b>Melting point/freezing point:</b>	~0 °C
<b>Initial boiling point and boiling range:</b>	Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gas):** Not determined.  
Not applicable.

· **Decomposition temperature:** Not determined.

· **Auto-ignition temperature:** Product is not selfigniting.

· **Explosive properties:** Product does not present an explosion hazard.

##### · Explosion limits:

<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.

· **Vapour pressure:** 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.

· **Solubility in / Miscibility with water:**

Soluble.

· **Partition coefficient: n-octanol/water:** Not determined.

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· <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>	
	100.0 %
· <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 irritation.  
Reizwirkung
- **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 2 (German Regulation) (Self-assessment): hazardous for water  
Do not allow product to reach ground water, water course or sewage system.  
Danger to drinking water if even small quantities leak into the ground.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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- **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.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

### SECTION 14: Transport information

- |   |                 |
|---|-----------------|
| · <b>14.1 UN-Number</b><br>· <b>ADR, ADN, IMDG, IATA</b>                                    | Void            |
| · <b>14.2 UN proper shipping name</b><br>· <b>ADR, ADN, IMDG, IATA</b>                      | Void            |
| · <b>14.3 Transport hazard class(es)</b><br>· <b>ADR, ADN, IMDG, IATA</b><br>· <b>Class</b> | Void            |
| · <b>14.4 Packing group</b><br>· <b>ADR, IMDG, IATA</b>                                     | Void            |
| · <b>14.5 Environmental hazards:</b><br>· <b>Marine pollutant:</b>                          | No              |
| · <b>14.6 Special precautions for user</b>  | Not applicable. |
| · <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>            | Not applicable. |
| · <b>UN "Model Regulation":</b>   | Void            |

### 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.

### 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**  
H319 Causes serious eye irritation.
- **Abbreviations and acronyms:**  
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)  
IMDG: International Maritime Code for Dangerous Goods  
IATA: International Air Transport Association  
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

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**Trade name: SPEIKO EDTA-Gel**

vPvB: very Persistent and very Bioaccumulative  
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

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