

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

Printing date 16.12.2022

Version number 7 (replaces version 6)

Revision: 16.12.2022

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

- **1.1 Product identifier**
- **Trade name:** *AquaCem*
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture** *glass-ionomer cement*
- **Uses advised against** *No further relevant information available.*
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
*Dentsply DeTrey GmbH*  
*De-Trey-Str. 1*  
*D-78467 Konstanz*  
*GERMANY*  
*Tel.: +49-(0)7531-583-0*  
*Fax: +49-(0)7531-583-104*  
*email: KonstanzDEU.info-sdb@dentsplysirona.com*
- **Further information obtainable from:** *Research and Development*
- **1.4 Emergency telephone number:** *+49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00)*

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
*Skin Irrit. 2 H315 Causes skin irritation.*  
*Eye Irrit. 2 H319 Causes serious eye irritation.*  
*STOT SE 3 H335 May cause respiratory irritation.*
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
*The product is classified and labelled according to the GB CLP regulation.*
- **Hazard pictograms**



GHS07

- **Signal word** *Warning*
- **Hazard-determining components of labelling:**  
*Poly acrylic acid*
- **Hazard statements**  
*H315 Causes skin irritation.*  
*H319 Causes serious eye irritation.*  
*H335 May cause respiratory irritation.*
- **Precautionary statements**  
*P261 Avoid breathing dust/fume/gas/mist/vapours/spray.*  
*P280 Wear protective gloves / eye protection / face protection.*  
*P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.*  
*P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.*  
*P405 Store locked up.*  
*P501 Dispose of contents/container in accordance with local/regional/national/international regulations.*
- **Additional information:**  
*As this product is a medical device in the meaning of Directive 93/42/EEC and regulation (EC) 2017/745 and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according to regulation (EC) 1272/2008.*

(Contd. on page 2)

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

Printing date 16.12.2022

Version number 7 (replaces version 6)

Revision: 16.12.2022

**Trade name: AquaCem**

(Contd. of page 1)

- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

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

- **Dangerous components:**

|                                   |   |              |
|-----------------------------------|---|--------------|
| CAS: 9003-01-4                    | Poly acrylic acid<br>Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335 | ≥ 20 – ≤ 25% |
| CAS: 87-69-4<br>EINECS: 201-766-0 | (+)-tartaric acid<br>Eye Dam. 1, H318   | ≥ 1 – ≤ 2.5% |

- **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**
- **General information** Immediately remove any clothing soiled by the product.
- **After inhalation** Supply fresh air; consult doctor in case of complaints.
- **After skin contact** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact**  
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing**  
If symptoms persist consult doctor.  
Rinse out mouth and then drink plenty of water.
- **Information for doctor** No further relevant information available.
- **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**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **For safety reasons unsuitable extinguishing agents** Water with full jet.
- **5.2 Special hazards arising from the substance or mixture**  
Formation of toxic gases is possible during heating or in case of fire.
- **5.3 Advice for firefighters**
- **Protective equipment:** Self-contained respiratory protective device.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Avoid formation of dust.  
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Dispose contaminated material as waste according to item 13.  
Ensure adequate ventilation.  
Pick up mechanically.

(Contd. on page 3)

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

Printing date 16.12.2022

Version number 7 (replaces version 6)

Revision: 16.12.2022

**Trade name: AquaCem**

(Contd. of page 2)

- **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** Observe normal care for working with chemicals.
- **Information about fire - and explosion protection:** No special measures required.
- **Handling** Product is intended for dental use only.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
- Keep receptacle tightly sealed.
- Protect from humidity and water.
- **7.3 Specific end use(s)** No further relevant information available.

### SECTION 8: Exposure controls/personal protection

- **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.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see item 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures**
- Keep away from foodstuffs, beverages and feed.
- Immediately remove all soiled and contaminated clothing
- Wash hands before breaks and at the end of work.
- Avoid contact with the eyes and skin.
- **Respiratory protection:** Not necessary if room is well-ventilated.
- **Hand protection**



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 through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye/face protection** Safety glasses

(Contd. on page 4)

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

Printing date 16.12.2022

Version number 7 (replaces version 6)

Revision: 16.12.2022

Trade name: AquaCem

(Contd. of page 3)

· **Body protection:** Protective work clothing.

### **SECTION 9: Physical and chemical properties**

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

##### · General Information

|  |                  |
|--|------------------|
| · Physical state   | Solid.           |
| · Colour:  | Yellowish        |
| · Odour:   | Product specific |
| · Odour threshold:   | Not determined.  |
| · Melting point/freezing point:                            | undetermined     |
| · Boiling point or initial boiling point and boiling range | Undetermined.    |
| · Flammability   | Not determined.  |
| · Lower and upper explosion limit                          |                  |
| · Lower:   | Not determined.  |
| · Upper:   | Not determined.  |
| · Flash point:   | Not applicable   |
| · Ignition temperature:                                    | Not applicable   |
| · Decomposition temperature:                               | Not determined.  |
| · pH   | Not applicable.  |
| · Viscosity:   |                  |
| · Kinematic viscosity                                      | Not applicable.  |
| · dynamic:   | Not applicable.  |
| · Solubility   |                  |
| · Water:   | Insoluble        |
| · Partition coefficient n-octanol/water (log value)        | Not determined.  |
| · Vapour pressure:   | Not applicable.  |
| · Density and/or relative density                          |                  |
| · Density:   | Not determined   |
| · Relative density   | Not determined.  |
| · Vapour density   | Not applicable.  |

#### · 9.2 Other information

|   |   |
|---|---|
| · Appearance:   |   |
| · Form:   | Powder  |
| · Important information on protection of health and environment, and on safety. |   |
| · Auto-ignition temperature:  | Product is not selfigniting.                  |
| · Explosive properties:   | Product does not present an explosion hazard. |
| · Solvent content:  |   |
| · Solids content:   | 100.0 %                                       |
| · Change in condition   |   |
| · Evaporation rate  | Not applicable.                               |

#### · Information with regard to physical hazard classes

|   |      |
|---|------|
| · Explosives                            | Void |
| · Flammable gases                       | Void |
| · Aerosols                              | Void |
| · Oxidising gases                       | Void |
| · Gases under pressure                  | Void |
| · Flammable liquids                     | Void |
| · Flammable solids                      | Void |
| · Self-reactive substances and mixtures | Void |
| · Pyrophoric liquids                    | Void |
| · Pyrophoric solids                     | Void |
| · Self-heating substances and mixtures  | Void |

(Contd. on page 5)

GB

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

Printing date 16.12.2022

Version number 7 (replaces version 6)

Revision: 16.12.2022

**Trade name: AquaCem**

(Contd. of page 4)

- |  |      |
|--|------|
| · <b>Substances and mixtures, which emit flammable gases in contact with water</b> | Void |
| · <b>Oxidising liquids</b>   | Void |
| · <b>Oxidising solids</b>  | Void |
| · <b>Organic peroxides</b>   | Void |
| · <b>Corrosive to metals</b>   | Void |
| · <b>Desensitised explosives</b>   | Void |

### 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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity**

- **LD/LC50 values relevant for classification:**

**CAS: 9003-01-4 Poly acrylic acid**

|      |      |                   |
|------|------|-------------------|
| Oral | LD50 | 2,500 mg/kg (rat) |
|------|------|-------------------|

**CAS: 87-69-4 (+)-tartaric acid**

|      |      |                     |
|------|------|---------------------|
| Oral | LD50 | > 2,000 mg/kg (rat) |
|------|------|---------------------|

- **Skin corrosion/irritation** Causes skin irritation.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **STOT-single exposure** May cause respiratory irritation.
- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

None of the ingredients is listed.

### SECTION 12: Ecological information

- **12.1 Toxicity**

- **Aquatic toxicity:**

**CAS: 9003-01-4 Poly acrylic acid**

|          |  |
|----------|--|
| LC50/96h | 168 – 280 mg/l (daphnia magna)               |
|          | 580 – 2,000 mg/l (Fish acute toxicity study) |

**CAS: 87-69-4 (+)-tartaric acid**

|          |  |
|----------|--|
| LC50/96h | > 100 mg/l (Fish acute toxicity study) |
| EC50/48h | 93 mg/L (daphnia magna)                |

- **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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

(Contd. on page 6)

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

Printing date 16.12.2022

Version number 7 (replaces version 6)

Revision: 16.12.2022

**Trade name: AquaCem**

(Contd. of page 5)

- **12.6 Endocrine disrupting properties**  
*The product does not contain substances with endocrine disrupting properties.*
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:**  
*Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.*

**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>14.1 UN number or ID number</b><br>· <b>ADR, IMDG, IATA</b>                            | <i>Void</i>            |
| · <b>14.2 UN proper shipping name</b><br>· <b>ADR, IMDG, IATA</b>                           | <i>Void</i>            |
| · <b>14.3 Transport hazard class(es)</b><br>· <b>ADR, ADN, IMDG, IATA</b><br>· <b>Class</b> | <i>Void</i>            |
| · <b>14.4 Packing group</b><br>· <b>ADR, IMDG, IATA</b>                                     | <i>Void</i>            |
| · <b>14.5 Environmental hazards:</b>  | <i>Not applicable.</i> |
| · <b>14.6 Special precautions for user</b>  | <i>Not applicable.</i> |
| · <b>14.7 Maritime transport in bulk according to IMO instruments</b>                       | <i>Not applicable.</i> |
| · <b>UN "Model Regulation":</b>   | <i>Void</i>            |

**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **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.*

*The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.*

(Contd. on page 7)

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

Printing date 16.12.2022

Version number 7 (replaces version 6)

Revision: 16.12.2022

**Trade name: AquaCem**

(Contd. of page 6)

For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

- **Relevant phrases**

- H315 Causes skin irritation.

- H318 Causes serious eye damage.

- H319 Causes serious eye irritation.

- H335 May cause respiratory irritation.

- **Department issuing SDS: Research & Development**

- **Contact: HotLine for urgent technical support: +49-7531-583-350**

- **Abbreviations and acronyms:**

- ADR: Accord relatif au transport international 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)

- LC50: Lethal concentration, 50 percent

- LD50: Lethal dose, 50 percent

- PBT: Persistent, Bioaccumulative and Toxic

- vPvB: very Persistent and very Bioaccumulative

- Skin Irrit. 2: Skin corrosion/irritation – Category 2

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

- Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

- STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

- **\* Data compared to the previous version altered.**

GB