

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 20.10.2015

Version number 1

Revision: 18.09.2015

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

· **1.1 Product identifier**

· **Trade name:** Glass Ionomer Silver Reinforced

· **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** Dental filling material

· **1.3 Details of the supplier of the safety data sheet**

· **Supplier:**

DE Healthcare Ltd.

Unit 9, Kingsthorpe Business Centre,

Studland Road, Kingsthorpe,

Northampton NN2 6NE U.K.

Distributed by/Distribudo por/Distribue par/Vertrieb durch/Distribuito da:

And in the USA/Y en EEUU/Et aux Etats-Unis/Und in USA/ E in USA:

41 Weaver Road

Denver, PA 17517 USA

· **Contact:**

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Emergency :

Chemtrec US: (800) 424-9300

Chemtrec International: 001 703-527-3887

SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**

· **Classification according to Regulation (EC) No 1272/2008**

The product is not classified according to the CLP regulation.

· **2.2 Label elements**

· **Labelling according to Regulation (EC) No 1272/2008**

As a medical device the product is not subject to labelling regulations under 1272/2008/EC.

· **Hazard pictograms** Void

· **Hazard statements** Void

· **Precautionary statements**

Wear protective clothing / eye protection.

Wear protective gloves.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

· **2.3 Other hazards** Use only for intended scope of application

· **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:**

	fluoro-aluminosilicate glass	50-100%
	Eye Irrit. 2, H319	
	polyacrylic acid	10-25%
	Eye Irrit. 2, H319	
CAS: 7440-22-4	silver	5-10%
EINECS: 231-131-3	Aquatic Acute 1, H400; Aquatic Chronic 1, H410	
CAS: 87-69-4	(+)-tartaric acid	2.5-5%
EINECS: 201-766-0	Eye Dam. 1, H318	

SECTION 4: First aid measures

· **4.1 Description of first aid measures**

· **After inhalation:** Seek medical treatment in case of complaints.

· **After skin contact:** Immediately rinse with water.

· **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

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- **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:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **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** For dental use only.
- **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:**
Keep container tightly sealed.
See storage instructions on package
- **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:**

7440-22-4 silver (5-10%)

WEL Long-term value: 0.1 mg/m³

13463-67-7 titanium dioxide (≤ 2.5%)

WEL Long-term value: 10* 4** mg/m³
*total inhalable **respirable

- **Additional information:** The lists valid during the making were used as basis.

· **8.2 Exposure controls**

- **Personal protective equipment:**

- **General protective and hygienic measures:**

The usual precautionary measures are to be adhered to when handling chemicals.

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- Avoid contact with the eyes and skin.
- **Respiratory protection:** Not required.
- **Protection of hands:**



Protective gloves

- **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.

- **Eye protection:** Safety glasses

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

· Form:	Solid
· Colour:	Whitish
· Odour:	Characteristic
· Odour threshold:	Not determined.

- **pH-value:** Not applicable.

- **Change in condition**

· Melting point/Melting range:	Undetermined.
· Boiling point/Boiling range:	Undetermined.

- **Flash point:** Not applicable.

- **Flammability (solid, gaseous):** Not determined.

- **Decomposition temperature:** Not determined.

- **Self-igniting:** Product is not selfigniting.

- **Danger of explosion:** Product does not present an explosion hazard.

- **Density:** Not determined.

- **Relative density** Not determined.

- **Vapour density** Not applicable.

- **Evaporation rate** Not applicable.

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

Insoluble.

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

- **Viscosity:**

· Dynamic:	Not applicable.
· Kinematic:	Not applicable.

· **Solids content:** 100.0 %

- **9.2 Other information** 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.

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- **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**
- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **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
- **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

- | | |
|--|------|
| · 14.1 UN-Number | |
| · ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name | - |
| · ADR, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es) | - |

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· ADR, ADN, IMDG, IATA	
· Class	Void
· 14.4 Packing group	-
· ADR, IMDG, IATA	Void
· 14.5 Environmental hazards:	Not applicable.
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	-

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.**

SECTION 16: Other information

· **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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

Aquatic Acute 1: Hazardous to the aquatic environment - Acute Hazard, Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1

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