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

- · 1.1 Product identifier
- · Trade name: Glass Ionomer Luting Cement

· 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 luting cement

· 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.

41 Weaver Road Denver, PA 17517 USA

• Contact: <u>www.dehpbrand.com</u> info@dehpbrand.com Tel. +44 1634 266 056

Emergency : Chemtrec US: (800) 424-9300 Chemtrec International: 001 703-527-3887

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:

SECTION 2: Hazards identification

 \cdot 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 gloves / eye protection.

Wear protective clothing.

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 characterization: Mixtures

• Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous components:

| | fluoro-aluminosilicate glass | Eye Irrit. 2, H319 | 50-100% | |
|-----------------------------------|------------------------------|--------------------|---------|--|
| | polyacrylic acid | Eye Irrit. 2, H319 | 10-25% | |
| CAS: 87-69-4 EINECS: 201-766-0 | | Eye Dam. 1, H318 | 5-10% | |

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.
- After swallowing: If symptoms persist consult doctor.

· 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.

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• **4.3 Indication of any immediate medical attention and special treatment needed** *No further relevant information available.* (Contd. of page 1)

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:
- 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
- · Personal protective equipment:
- *General protective and hygienic measures: The usual precautionary measures are to be adhered to when handling chemicals.*
- Avoid contact with the eyes and skin. • **Respiratory protection:** Not required.
- Protection of hands:



Protective gloves

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· Material of gloves

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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 a | and chemical properties | |
|--------------------------------------|-----------------------------------------------|--|
| General Information | | |
| Appearance: Form: | C - 1: 1 | |
| Form: Colour: | Solid White | |
| · Odour: | | |
| · Oaour: · Odour threshold: | Characteristic | |
| · Oaour threshola: | 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: | Soluble. | |
| Partition coefficient (n-octanol/wat | er): 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

· 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.

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SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity:
- Primary irritant effect:
- on the skin: No irritant effect.
- \cdot on the eye: No irritating effect.
- Sensitization: No sensitizing effects known.
- \cdot Additional toxicological information:

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

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

| • 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) | - | |
| · ADR, ADN, IMDG, IATA | | |
| · Class | Void | |
| · 14.4 Packing group | - | |
| · ADR, IMDG, IATA | Void | |
| · 14.5 Environmental hazards: | Not applicable. | |
| · Marine pollutant: | No | |

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· 14.6 Special precautions for user

• 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

Not applicable.

· UN "Model Regulation":

SECTION 15: Regulatory information

• 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture No further relevant information available.

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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.

· 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 Harmonized 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)

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

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

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