

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.10.2015

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 Express Fill kit
- **1.2 Relevant identified uses of the substance or mixture and uses advised against** Non-dental use.
- **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:**

| | |
|---|--|
| www.dehpbrand.com info@dehpbrand.com Tel. +44 1634 266 056 | 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 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 characterisation: 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 | (+)-tartaric acid | Eye Dam. 1, H318 | 2.5-5% |

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.

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:** No special measures required.
- **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* Not applicable.
- *Eye protection:* Safety glasses

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

| | |
|---------------------------|----------------------|
| · <i>Form:</i> | Solid |
| · <i>Colour:</i> | Beige |
| · <i>Odour:</i> | Weak, characteristic |
| · <i>Odour threshold:</i> | Not determined. |

· *pH-value:* Not applicable.

· Change in condition

| | |
|---------------------------------------|---------------|
| · <i>Melting point/Melting range:</i> | Undetermined. |
| · <i>Boiling point/Boiling range:</i> | 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:

Fully miscible.

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

· Viscosity:

· *Dynamic:* Not applicable.

· *Kinematic:* Not applicable.

· 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.

· 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.

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- **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:** Generally not 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** Smaller quantities can be disposed of with household waste.
- **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

- | | |
|--|-----------------|
| · 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 |
| · 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. |

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· 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

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 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