

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

Printing date 05.02.2024

Version number 2 (replaces version 1)

Revision: 05.02.2024

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

- **1.1 Product identifier**
- **Trade name: G-CEM Try-In Paste**
- **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** Auxillary for dental technology
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
GC EUROPE N.V.  
Interleuvenlaan 33  
B-3001 Leuven  
Tel. +32/(0)16/74.10.00  
Fax +32/(0)16/40.26.84  
msds@gc.dental
- **Further information obtainable from:** Regulatory affairs
- **1.4 Emergency telephone number:**  
National poison center for United Kingdom of Great Britain and Northern Ireland:  
Belfast: +44 28 90 63 2032  
Birmingham: +44 121 507 4123  
Edinburgh: +44 131 242 1383  
Newcastle Upon Tyne: +44 191 2606182/+44 191 2606180  
Penarth: +44 292 071 55 54

**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 GB CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Exemptions**  
The product, regulated as an invasive medical device by the Regulation (EC) 2017/745, is exempted from labelling requirements for substances and mixtures (according to the provision of the Art 1.5).
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Additional information:**  
Contains Urethane Dimethacrylate (UDMA). May produce an allergic reaction.  
Safety data sheet available on request.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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### SECTION 3: Composition/information on ingredients

#### · 3.2 Mixtures

#### · Description:

Only substances required to be mentioned according to Annex II of regulation 1907/2006 are listed. Information on the other substances that may be present can be obtained upon request.

#### · Dangerous components:

CAS: 56-81-5 EINECS: 200-289-5	glycerol substance with a Community workplace exposure limit	90-<100%
CAS: 7631-86-9 EINECS: 231-545-4	silicon dioxide Nanoform: set including amorphous nanoforms non-surface-treated nanoforms Shape: Spheroidal Structure: amorphous forms Crystallinity: amorphous nanoform	5-<10%
CAS: 1344-28-1 EINECS: 215-691-6	aluminium oxide Nanoform: non-surface-treated nanoforms Shape: Spheroidal Structure: crystalline forms Crystallinity: crystalline nanoform	1-<2.5%
CAS: 13463-67-7 EINECS: 236-675-5 Index number: 022-006-00-2	titanium dioxide Carc. 2, H351 substance with a Community workplace exposure limit	0.5-<1%
CAS: 68611-44-9 EINECS: 271-893-4	Silane, dichlorodimethyl-, reaction products with silica Nanoform: set including amorphous nanoforms surface-treated nanoforms Shape: Spheroidal Structure: amorphous forms Crystallinity: amorphous nanoform	0.2-<0.5%
CAS: 72869-86-4 EINECS: 276-957-5	Urethane Dimethacrylate (UDMA) Aquatic Chronic 2, H411; Skin Sens. 1B, H317	≥0.25-<0.5%

· **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:** If symptoms persist consult doctor.

#### · After inhalation:

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist. Take affected persons into fresh air and keep quiet.

· **After skin contact:** If skin irritation continues, consult a doctor.

#### · After eye contact:

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

#### · After swallowing:

Rinse out mouth and then drink plenty of water.

If symptoms persist consult doctor.

· **4.2 Most important symptoms and effects, both acute and delayed** Allergic reactions

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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:**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.  
Use fire extinguishing methods suitable to surrounding conditions.
- **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.  
No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.
- **Additional information**  
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Remove persons from danger area.  
Wear protective clothing.
- **6.2 Environmental precautions:**  
Do not allow product to reach sewage system or any water course.  
Do not allow to penetrate the ground/soil.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb liquid components with liquid-binding material.  
Dispose of the material collected according to regulations.
- **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:** Store only in unopened original receptacles.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:** None.
- **7.3 Specific end use(s)** No further relevant information available.

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### SECTION 8: Exposure controls/personal protection

#### · 8.1 Control parameters

##### · Ingredients with limit values that require monitoring at the workplace:

##### 56-81-5 glycerol

WEL Long-term value: 10 mg/m<sup>3</sup>

##### 13463-67-7 titanium dioxide

WEL Long-term value: 10\* 4\*\* mg/m<sup>3</sup>  
\*total inhalable \*\*respirable

##### · DNELs

##### 13463-67-7 titanium dioxide

Inhalative DNEL inhalation 10 mg/m<sup>3</sup> (man)

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

#### · 8.2 Exposure controls

· **Appropriate engineering controls** No further data; see section 7.

· **Individual protection measures, such as personal protective equipment**

· **General protective and hygienic measures:**

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

Wash hands before breaks and at the end of work.

· **Respiratory protection:** Suitable respiratory protective device recommended.

· **Hand protection** 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.

· **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

### SECTION 9: Physical and chemical properties

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

##### · General Information

· **Physical state**

Fluid

· **Colour:**

Yellow

· **Odour:**

Alcohol-like

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

Undetermined.

· **Boiling point or initial boiling point and boiling range** 290 °C

· **Flammability**

Not applicable.

· **Lower and upper explosion limit**

· **Lower:**

0.9 Vol %

· **Upper:**

0.0 Vol %

· **Flash point:**

160 °C

· **Auto-ignition temperature:**

Undetermined.

· **Decomposition temperature:**

Not determined.

· **pH**

Not determined.

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<ul style="list-style-type: none"> <li>· <b>Viscosity:</b></li> <li>· <b>Kinematic viscosity</b></li> <li>· <b>Dynamic:</b></li> <li>· <b>Solubility</b></li> <li>· <b>water:</b></li> <li>· <b>Partition coefficient n-octanol/water (log value)</b></li> <li>· <b>Vapour pressure:</b></li> <li>· <b>Density and/or relative density</b></li> <li>· <b>Density at 20 °C:</b></li> <li>· <b>Relative density</b></li> <li>· <b>Vapour density</b></li> <li>· <b>Particle characteristics</b></li> </ul>	<p>Not determined.</p> <p>Not determined.</p> <p>Insoluble.</p> <p>Not determined.</p> <p>Not determined.</p> <p>1.3 g/cm<sup>3</sup></p> <p>Not determined.</p> <p>Not determined.</p> <p>SiO<sub>2</sub>: Diameter particle structure = 2.5 - 50 nm (TEM, d50, number-based) Diameter agglomerate = 5 - 50 nm (laser diffraction dry module, d50, volume based) Al<sub>2</sub>O<sub>3</sub>: Diameter particle structure = 2 - 100 nm (d50, number-based) 7631-86-9 silicon dioxide: set including amorphous nanoforms non-surface-treated nanoforms Shape: Spheroidal Structure: amorphous forms Crystallinity: amorphous nanoform</p> <p>1344-28-1 aluminium oxide: non-surface-treated nanoforms Shape: Spheroidal Structure: crystalline forms Crystallinity: crystalline nanoform</p> <p>68611-44-9 Silane, dichlorodimethyl-, reaction products with silica: set including amorphous nanoforms surface-treated nanoforms Shape: Spheroidal Structure: amorphous forms Crystallinity: amorphous nanoform</p>
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<ul style="list-style-type: none"> <li>· <b>9.2 Other information</b></li> <li>· <b>Appearance:</b></li> <li>· <b>Form:</b></li> <li>· <b>Important information on protection of health and environment, and on safety.</b></li> <li>· <b>Ignition temperature:</b></li> <li>· <b>Explosive properties:</b></li> <li>· <b>Solvent content:</b></li> <li>· <b>Organic solvents:</b></li> <li>· <b>VOC (EC)</b></li> <li>· <b>Change in condition</b></li> <li>· <b>Evaporation rate</b></li> </ul>	<p>Pasty</p> <p>Product is not selfigniting.</p> <p>Product does not present an explosion hazard.</p> <p>90.0 %</p> <p>0.0 g/l</p> <p>Not determined.</p>
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<ul style="list-style-type: none"> <li>· <b>Information with regard to physical hazard classes</b></li> <li>· <b>Explosives</b></li> </ul>	<p>Void</p>
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· <b>Flammable gases</b>	Void
· <b>Aerosols</b>	Void
· <b>Oxidising gases</b>	Void
· <b>Gases under pressure</b>	Void
· <b>Flammable liquids</b>	Void
· <b>Flammable solids</b>	Void
· <b>Self-reactive substances and mixtures</b>	Void
· <b>Pyrophoric liquids</b>	Void
· <b>Pyrophoric solids</b>	Void
· <b>Self-heating substances and mixtures</b>	Void
· <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** Based on available data, the classification criteria are not met.

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

**7631-86-9 silicon dioxide**

Oral	LD50	10,000 mg/kg (rat (f+m))
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**13463-67-7 titanium dioxide**

Oral	LD50	>5,000 mg/kg (mouse) (OECD 420)
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Inhalative	LC50/4 h	>6.82 mg/l (rat male)
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**72869-86-4 Urethane Dimethacrylate (UDMA)**

Oral	LD50	>5,000 mg/kg (rat female) (OECD 401)
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- **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.
- **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.

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- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**
- **Repeated dose toxicity** No further relevant information available.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**  
No further relevant information available.
- **11.2 Information on other hazards**

· <b>Endocrine disrupting properties</b>
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None of the ingredients is listed.
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### SECTION 12: Ecological information

- **12.1 Toxicity**

· <b>Aquatic toxicity:</b>
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72869-86-4 Urethane Dimethacrylate (UDMA)
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EC50/48h (static) >1.2 mg/l (daphnia magna) (OECD 202)
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- **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.
- **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:**  
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.

### 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>  |               |
| · <b>ADR, ADN, IMDG, IATA</b>         | not regulated |
| · <b>14.2 UN proper shipping name</b> |               |
| · <b>ADR, ADN, IMDG, IATA</b>         | not regulated |

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- |   |                 |
|---|-----------------|
| · <b>14.3 Transport hazard class(es)</b>                              |                 |
| · <b>ADR, ADN, IMDG, IATA</b>   |                 |
| · <b>Class</b>  | not regulated   |
| · <b>14.4 Packing group</b>   |                 |
| · <b>ADR, IMDG, IATA</b>  | not regulated   |
| · <b>14.5 Environmental hazards:</b>                                  |                 |
| · <b>Marine pollutant:</b>  | No              |
| · <b>14.6 Special precautions for user</b>                            | Not applicable. |
| · <b>14.7 Maritime transport in bulk according to IMO instruments</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>                                       | not regulated   |

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Poisons Act**

- **Regulated explosives precursors**

None of the ingredients is listed.

- **Regulated poisons**

None of the ingredients is listed.

- **Reportable explosives precursors**

None of the ingredients is listed.

- **Reportable poisons**

None of the ingredients is listed.

- **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

- **Relevant phrases**

H317 May cause an allergic skin reaction.

H351 Suspected of causing cancer.

H411 Toxic to aquatic life with long lasting effects.

- **Classification according to Regulation (EC) No 1272/2008** Calculation method

- **Department issuing SDS:** Regulatory affairs

- **Contact:** msds@gc.dental

- **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

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CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

DNEL: Derived No-Effect Level (UK REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Skin Sens. 1B: Skin sensitisation – Category 1B

Carc. 2: Carcinogenicity – Category 2

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

· **Sources**

• ECHA (<http://echa.europa.eu/>)

• EnviChem ([www.echemportal.org](http://www.echemportal.org))

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

*This version replaces all previous versions.*

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