

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

Printing date 27.07.2020

Version number 1

Revision: 27.07.2020

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

- **1.1 Product identifier**
  - **Trade name: G-CEM ONE - Adhesive Enhancing Primer**
- **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**

Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device.

Flam. Liq. 3      H226 Flammable liquid and vapour.  
Skin Corr. 1      H314 Causes severe skin burns and eye damage.  
Eye Dam. 1      H318 Causes serious eye damage.  
Aquatic Chronic 3      H412 Harmful to aquatic life with long lasting effects.
- **2.2 Label elements**
  - **Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labelled according to the CLP regulation.
  - **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**  
  
GHS02    GHS05
- **Signal word** Danger

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- **Hazard statements**

H226 Flammable liquid and vapour.  
 H314 Causes severe skin burns and eye damage.  
 H412 Harmful to aquatic life with long lasting effects.

- **Precautionary statements**

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
 P260 Do not breathe dusts or mists.  
 P280 Wear protective gloves/protective clothing/eye protection/face protection.  
 P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].  
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
 P310 Immediately call a POISON CENTER/doctor.  
 P321 Specific treatment (see on this label).  
 P405 Store locked up.  
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **2.3 Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: 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: 64-17-5 EINECS: 200-578-6 Index number: 603-002-00-5	ethyl alcohol Flam. Liq. 2, H225	25-<50%
CAS: 1830-78-0 EINECS: 217-388-4	2-Hydroxy-1,3 dimethacryloxypropane Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	≥10-<20%
CAS: 85590-00-7	methacryloyloxydecyl dihydrogen phosphate Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	5-<10%
CAS: 128-37-0 EINECS: 204-881-4	Butylated hydroxytoluene Aquatic Acute 1, H400; Aquatic Chronic 1, H410	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.  
 If symptoms persist consult doctor.

- **After inhalation:**

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

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*Take affected persons into fresh air and keep quiet.*

· **After skin contact:**

*Immediately wash with water and soap and rinse thoroughly.*

*Seek medical treatment.*

*If skin irritation continues, consult a doctor.*

· **After eye contact:**

*Protect unharmed eye.*

*Rinse opened eye for several minutes under running water.*

*Call a doctor immediately.*

· **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** *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.*

*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.*

*Keep away from ignition sources.*

*Avoid contact with the eyes and skin.*

*Wear protective clothing.*

· **6.2 Environmental precautions:**

*Do not allow product to reach sewage system or any water course.*

*Inform respective authorities in case of seepage into water course or sewage system.*

*Do not allow to penetrate the ground/soil.*

*In case of seepage into the ground inform responsible authorities.*

· **6.3 Methods and material for containment and cleaning up:**

*Ensure adequate ventilation.*

*Use neutralising agent.*

*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.*

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See Section 13 for disposal information.

### SECTION 7: Handling and storage

· **7.1 Precautions for safe handling**

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

Avoid contact with the eyes and skin.

· **Information about fire - and explosion protection:**

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

Do not spray onto a naked flame or any incandescent material.

· **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:**

Keep container tightly sealed.

Protect from heat and direct sunlight.

Store in a cool place.

· **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:**

64-17-5 ethyl alcohol

WEL Long-term value: 1920 mg/m<sup>3</sup>, 1000 ppm

· **DNELs**

128-37-0 Butylated hydroxytoluene

Dermal DNEL dermal 0.5 mg/kg bw/day (man)

Inhalative DNEL inhalation 3.5 mg/m<sup>3</sup> (man)

· **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.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

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

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· **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.

· **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 protection:**

Tightly sealed goggles

### SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**· **General Information**· **Appearance:**

· <b>Form:</b>	Liquid
· <b>Colour:</b>	According to product specification
· <b>Odour:</b>	Alcohol-like
· <b>Odour threshold:</b>	Not determined.

· **pH-value at 20 °C:** 1.5· **Change in condition**

· <b>Melting point/freezing point:</b>	Undetermined.
· <b>Initial boiling point and boiling range:</b>	Undetermined.

· **Flash point:** 30 °C· **Flammability (solid, gas):** Not applicable.· **Ignition temperature:** Undetermined.· **Decomposition temperature:** Not determined.· **Auto-ignition temperature:** Product is not selfigniting.· **Explosive properties:** Product does not present an explosion hazard.· **Explosion limits:**

· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.

· **Vapour pressure:** Not determined.· **Density at 20 °C:** 0.98 g/cm<sup>3</sup>· **Relative density** Not determined.· **Vapour density** Not determined.

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· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with water:</b>	Fully miscible.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not determined.
<b>Kinematic:</b>	Not determined.
· <b>Solvent content:</b>	
<b>Organic solvents:</b>	31.0 %
<b>Water:</b>	30.0 %
<b>VOC (EC)</b>	430.3 g/l
· <b>9.2 Other information</b>	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** Based on available data, the classification criteria are not met.

· <b>LD/LC50 values relevant for classification:</b>		
<b>64-17-5 ethyl alcohol</b>		
Oral	LD50	7,060 mg/kg (rat (f+m))
Inhalative	LC50/4 h	20,000 mg/l (rat (f+m))
<b>128-37-0 Butylated hydroxytoluene</b>		
Oral	LD50	>6,000 mg/kg (rat (f+m)) (OECD 401)

- **Primary irritant effect:**
- **Skin corrosion/irritation**  
Causes severe skin burns and eye damage.
- **Serious eye damage/irritation**  
Causes serious eye damage.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Repeated dose toxicity** No further relevant information available.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**  
No further relevant information available.
- **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.

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- **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:

##### 128-37-0 Butylated hydroxytoluene

EC50/48h (static) 0.48 mg/l (daphnia magna) (OECD 202)

#### · 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.

#### · Ecotoxicological effects:

· **Remark:** Harmful to fish

#### · Additional ecological information:

##### · General notes:

Must not reach sewage water or drainage ditch undiluted or unneutralised.

Harmful to aquatic organisms

Rinse off of bigger amounts into drains or the aquatic environment may lead to decreased pH-values. A low pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably increased, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

#### · 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.

### SECTION 14: Transport information

#### · 14.1 UN-Number

· **ADR, IMDG, IATA**

UN1993

#### · 14.2 UN proper shipping name

· **ADR**

1993 FLAMMABLE LIQUID, N.O.S. (ETHANOL SOLUTION)

· **IMDG, IATA**

FLAMMABLE LIQUID, N.O.S. (ETHANOL SOLUTION)

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## · 14.3 Transport hazard class(es)

## · ADR



· Class 3 (F1) Flammable liquids.  
· Label 3

## · IMDG, IATA



· Class 3 Flammable liquids.  
· Label 3

## · 14.4 Packing group

· ADR, IMDG, IATA III

## · 14.5 Environmental hazards:

· Marine pollutant: No

## · 14.6 Special precautions for user

Warning: Flammable liquids.

· Hazard identification number (Kemler code): 30

· EMS Number: F-E,S-E

· Stowage Category A

## · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable.

## · Transport/Additional information:

## · ADR

· Limited quantities (LQ) 5L

· Excepted quantities (EQ) Code: E1

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 1000 ml

· Transport category 3

· Tunnel restriction code D/E

## · IMDG

· Limited quantities (LQ) 5L

· Excepted quantities (EQ) Code: E1

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 1000 ml

## · UN "Model Regulation":

UN 1993 FLAMMABLE LIQUID, N.O.S. (ETHANOL SOLUTION), 3, III

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### 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.
- **Seveso category P5c FLAMMABLE LIQUIDS**
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5.000 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50.000 t
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

- **Relevant phrases**  
H225 Highly flammable liquid and vapour.  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H335 May cause respiratory irritation.  
H400 Very toxic to aquatic life.  
H410 Very 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 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)  
VOC: Volatile Organic Compounds (USA, EU)  
DNEL: Derived No-Effect Level (REACH)  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
Flam. Liq. 2: Flammable liquids – Category 2  
Flam. Liq. 3: Flammable liquids – Category 3  
Skin Corr. 1: Skin corrosion/irritation – Category 1  
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  
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1  
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1  
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3
- **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.  
Disclaimer:  
The information contained herein is believed to be true and accurate. However, all statements, recommendations or suggestions are made without any guarantee, representation or warranty, express or implied, on our part.

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*Therefore, no warranty is made or to be implied that the information set out in this document is accurate or complete, and we accordingly exclude all liability in connection with the use of this information or the products referred to herein. All such risks are assumed by the purchaser/user. The information contained herein is also subject to change without notice. For the avoidance of doubt, however, nothing in this document excludes or limits our liability for death or personal injury caused by our negligence or for fraudulent misrepresentation.*

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

- **1.1 Product identifier**
- **Trade name: G-CEM ONE - Paste A**
- **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**  
Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device.
  - Skin Irrit. 2            H315 Causes skin irritation.
  - Eye Irrit. 2            H319 Causes serious eye irritation.
  - Skin Sens. 1            H317 May cause an allergic skin reaction.
  - Aquatic Chronic 3    H412 Harmful to aquatic life with long lasting effects.
- 
- **2.2 Label elements**
  - **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.
  - **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**



GHS07

- **Signal word** Warning

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- **Hazard-determining components of labelling:**

Urethane Dimethacrylate (UDMA)

- **Hazard statements**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

- **Precautionary statements**

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves / eye protection / face protection.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **2.3 Other hazards**

- **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: 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: 1830-78-0 EINECS: 217-388-4	2-Hydroxy-1,3 dimethacryloxypropane Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	≥10-<20%
CAS: 72869-86-4 EINECS: 276-957-5	Urethane Dimethacrylate (UDMA) Aquatic Chronic 2, H411; Skin Sens. 1B, H317	10-<25%
CAS: 13463-67-7 EINECS: 236-675-5	titanium dioxide substance with a Community workplace exposure limit	0.5-<1%
CAS: 1879-09-0 EINECS: 217-533-1	6-tert-butyl-2,4-xlenol Acute Tox. 2, H310; STOT RE 2, H373; Aquatic Chronic 2, H411; Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319	0.1-<0.2%
CAS: 75980-60-8 EINECS: 278-355-8 Index number: 015-203-00-X	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Repr. 2, H361f	0.1-<0.2%

· **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.

If symptoms persist consult doctor.

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- **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:**  
Immediately wash with water and soap and rinse thoroughly.  
Seek medical treatment.  
If skin irritation continues, consult a doctor.
- **After eye contact:**  
Protect unharmed eye.  
Rinse opened eye for several minutes under running water. Then 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
- **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.  
Avoid contact with the eyes and skin.  
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.

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### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**  
Ensure good ventilation/exhaustion at the workplace.  
Prevent formation of aerosols.  
Avoid contact with the eyes and skin.
- **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.

### 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:**

**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)
------------	-----------------	----------------------------

**1879-09-0 6-tert-butyl-2,4-xyleneol**

Inhalative	DNEL inhalation	0.14 mg/m <sup>3</sup> (man)
------------	-----------------	------------------------------

- **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.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

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

- **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.

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- **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 protection:**



Tightly sealed goggles

### SECTION 9: Physical and chemical properties

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

- **General Information**

- **Appearance:**

Form:	Pasty
Colour:	Light yellow
Odour:	Ester-like
Odour threshold:	Not determined.

- **pH-value at 20 °C:** 6.5

- **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.

- **Flash point:** 93 °C

- **Flammability (solid, gas):** Not applicable.

- **Ignition temperature:** Undetermined.

- **Decomposition temperature:** Not determined.

- **Auto-ignition temperature:** Product is not selfigniting.

- **Explosive properties:** Product does not present an explosion hazard.

- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.

- **Vapour pressure:** Not determined.

- **Density at 20 °C:** 1.9 g/cm<sup>3</sup>

- **Relative density** Not determined.

- **Vapour density** Not determined.

- **Evaporation rate** Not determined.

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

Insoluble.

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

- **Viscosity:**

Dynamic:	Not determined.
Kinematic:	Not determined.

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- **Solvent content:**  
VOC (EC) 0.0 g/l
- **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** Based on available data, the classification criteria are not met.

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

**72869-86-4 Urethane Dimethacrylate (UDMA)**

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

**13463-67-7 titanium dioxide**

Oral	LD50	>5,000 mg/kg (mouse) (OECD 420)
------	------	---------------------------------

Inhalative	LC50/4 h	>6.82 mg/l (rat male)
------------	----------	-----------------------

**1879-09-0 6-tert-butyl-2,4-xylenol**

Oral	LD50	910 mg/kg (rat (f+m)) (OECD 401)
------	------	----------------------------------

Dermal	LD50	<200 mg/kg (rabbit) (OECD 402)
--------	------	--------------------------------

- **Primary irritant effect:**
- **Skin corrosion/irritation**  
Causes skin irritation.
- **Serious eye damage/irritation**  
Causes serious eye irritation.
- **Respiratory or skin sensitisation**  
May cause an allergic skin reaction.
- **Repeated dose toxicity** No further relevant information available.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**  
No further relevant information available.
- **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.

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### SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**

**72869-86-4 Urethane Dimethacrylate (UDMA)**

EC50/48h (static) >1.2 mg/l (daphnia magna) (OECD 202)

· **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.

### SECTION 14: Transport information

· **14.1 UN-Number**

· **ADR, IMDG, IATA** not regulated

· **14.2 UN proper shipping name**

· **ADR, IMDG, IATA** not regulated

· **14.3 Transport hazard class(es)**

· **ADR, ADN, IMDG, IATA**

· **Class** not regulated

· **14.4 Packing group**

· **ADR, IMDG, IATA** not regulated

· **14.5 Environmental hazards:**

· **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":** not regulated

### 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.
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

- **Relevant phrases**
  - H302 Harmful if swallowed.
  - H310 Fatal in contact with skin.
  - H315 Causes skin irritation.
  - H317 May cause an allergic skin reaction.
  - H319 Causes serious eye irritation.
  - H335 May cause respiratory irritation.
  - H361f Suspected of damaging fertility.
  - H373 May cause damage to organs through prolonged or repeated exposure.
  - 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 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)
  - VOC: Volatile Organic Compounds (USA, EU)
  - DNEL: Derived No-Effect Level (REACH)
  - LC50: Lethal concentration, 50 percent
  - LD50: Lethal dose, 50 percent
  - PBT: Persistent, Bioaccumulative and Toxic
  - vPvB: very Persistent and very Bioaccumulative
  - Acute Tox. 4: Acute toxicity - oral – Category 4
  - Acute Tox. 2: Acute toxicity - dermal – Category 2
  - Skin Irrit. 2: Skin corrosion/irritation – Category 2
  - Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
  - Skin Sens. 1: Skin sensitisation – Category 1
  - Skin Sens. 1B: Skin sensitisation – Category 1B
  - Repr. 2: Reproductive toxicity – Category 2
  - STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
  - STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2
  - Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
  - Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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

- **1.1 Product identifier**
- **Trade name: G-CEM ONE - Paste B**
- **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**  
Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device.  
Skin Corr. 1            H314 Causes severe skin burns and eye damage.  
Eye Dam. 1            H318 Causes serious eye damage.  
Skin Sens. 1           H317 May cause an allergic skin reaction.  
Aquatic Chronic 2    H411 Toxic to aquatic life with long lasting effects.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.
- **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**



GHS05    GHS07    GHS09

- **Signal word** Danger

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**· Hazard-determining components of labelling:**

Urethane Dimethacrylate (UDMA)

**· Hazard statements**

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H411 Toxic to aquatic life with long lasting effects.

**· Precautionary statements**

P260 Do not breathe dusts or mists.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor.

P321 Specific treatment (see on this label).

P362+P364 Take off contaminated clothing and wash it before reuse.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

**· 2.3 Other hazards****· Results of PBT and vPvB assessment****· PBT:** Not applicable.**· vPvB:** Not applicable.**SECTION 3: Composition/information on ingredients****· 3.2 Chemical characterisation: 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: 72869-86-4 EINECS: 276-957-5	Urethane Dimethacrylate (UDMA) Aquatic Chronic 2, H411; Skin Sens. 1B, H317	25-<50%
CAS: 1830-78-0 EINECS: 217-388-4	2-Hydroxy-1,3 dimethacryloxypropane Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	5-<10%
CAS: 85590-00-7	methacryloyloxydecyl dihydrogen phosphate Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	2.5-<5%
CAS: 80-15-9 EINECS: 201-254-7 Index number: 617-002-00-8	$\alpha,\alpha$ -dimethylbenzyl hydroperoxide Org. Perox. E, H242; Acute Tox. 3, H331; STOT RE 2, H373; Skin Corr. 1B, H314; Aquatic Chronic 2, H411; Acute Tox. 4, H302; Acute Tox. 4, H312	0.5-<1%
CAS: 1879-09-0 EINECS: 217-533-1	6-tert-butyl-2,4-xyleneol Acute Tox. 2, H310; STOT RE 2, H373; Aquatic Chronic 2, H411; Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319	$\geq 0.2$ -<0.25%

**· Additional information:** For the wording of the listed hazard phrases refer to section 16.

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### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:**  
Immediately remove any clothing soiled by the product.  
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:**  
Immediately wash with water and soap and rinse thoroughly.  
Seek medical treatment.  
If skin irritation continues, consult a doctor.
- **After eye contact:**  
Protect unharmed eye.  
Rinse opened eye for several minutes under running water.  
Call a doctor immediately.
- **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
- **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.  
Avoid contact with the eyes and skin.  
Wear protective clothing.
- **6.2 Environmental precautions:**  
Do not allow product to reach sewage system or any water course.  
Inform respective authorities in case of seepage into water course or sewage system.  
Do not allow to penetrate the ground/soil.  
In case of seepage into the ground inform responsible authorities.

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· **6.3 Methods and material for containment and cleaning up:**

Use neutralising agent.

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**

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

Avoid contact with the eyes and skin.

· **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:** Keep container tightly sealed.

· **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.

· **DNELs**

**1879-09-0 6-tert-butyl-2,4-xylenol**

Inhalative	DNEL inhalation	0.14 mg/m <sup>3</sup> (man)
------------	-----------------	------------------------------

· **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.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

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

· **Protection of hands:**



Protective gloves

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- **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 protection:**



Tightly sealed goggles

## SECTION 9: Physical and chemical properties

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

- **General Information**

- **Appearance:**

· <b>Form:</b>	Pasty
· <b>Colour:</b>	White
· <b>Odour:</b>	Ester-like
· <b>Odour threshold:</b>	Not determined.

- **pH-value at 20 °C:** 1.5

- **Change in condition**

· <b>Melting point/freezing point:</b>	Undetermined.
· <b>Initial boiling point and boiling range:</b>	Undetermined.

- **Flash point:** 93 °C

- **Flammability (solid, gas):** Not applicable.

- **Ignition temperature:** Undetermined.

- **Decomposition temperature:** Not determined.

- **Auto-ignition temperature:** Product is not selfigniting.

- **Explosive properties:** Product does not present an explosion hazard.

- **Explosion limits:**

· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.

- **Vapour pressure:** Not determined.

· <b>Density at 20 °C:</b>	1.5 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.

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

Fully miscible.

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

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- |                                |  |
|--------------------------------|--|
| · <b>Viscosity:</b>            |  |
| <b>Dynamic:</b>                | Not determined.                            |
| <b>Kinematic:</b>              | Not determined.                            |
| · <b>Solvent content:</b>      |  |
| <b>VOC (EC)</b>                | 0.0 g/l                                    |
| · <b>9.2 Other information</b> | 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** Based on available data, the classification criteria are not met.

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

**72869-86-4 Urethane Dimethacrylate (UDMA)**

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

**80-15-9  $\alpha,\alpha$ -dimethylbenzyl hydroperoxide**

Oral	LD50	382 mg/kg (rat (f+m))
------	------	-----------------------

Dermal	LD50	500 mg/kg (rat (f+m))
--------	------	-----------------------

Inhalative	LC50/4 h	220 mg/l (rat (f+m))
------------	----------	----------------------

**1879-09-0 6-tert-butyl-2,4-xylenol**

Oral	LD50	910 mg/kg (rat (f+m)) (OECD 401)
------	------	----------------------------------

Dermal	LD50	<200 mg/kg (rabbit) (OECD 402)
--------	------	--------------------------------

- **Primary irritant effect:**
- **Skin corrosion/irritation**  
Causes severe skin burns and eye damage.
- **Serious eye damage/irritation**  
Causes serious eye damage.
- **Respiratory or skin sensitisation**  
May cause an allergic skin reaction.
- **Repeated dose toxicity** No further relevant information available.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**  
No further relevant information available.
- **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.

### SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**

**72869-86-4 Urethane Dimethacrylate (UDMA)**

EC50/48h (static) >1.2 mg/l (daphnia magna) (OECD 202)

· **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:**

Must not reach sewage water or drainage ditch undiluted or unneutralised.

Rinse off of bigger amounts into drains or the aquatic environment may lead to decreased pH-values. A low pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably increased, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

· **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.

### SECTION 14: Transport information

· **14.1 UN-Number**

· **ADR, IMDG, IATA**

UN3082

· **14.2 UN proper shipping name**

· **ADR**

3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Urethane Dimethacrylate (UDMA))

· **IMDG**

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Urethane Dimethacrylate (UDMA),  $\alpha,\alpha$ -dimethylbenzyl hydroperoxide), MARINE POLLUTANT

· **IATA**

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Urethane Dimethacrylate (UDMA))

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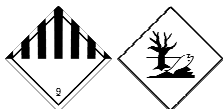
## · 14.3 Transport hazard class(es)

## · ADR



· Class 9 (M6) Miscellaneous dangerous substances and articles.  
· Label 9

## · IMDG, IATA



· Class 9 Miscellaneous dangerous substances and articles.  
· Label 9

## · 14.4 Packing group

· ADR, IMDG, IATA III

## · 14.5 Environmental hazards:

· Marine pollutant: No  
Symbol (fish and tree)  
· Special marking (ADR): Symbol (fish and tree)  
· Special marking (IATA): Symbol (fish and tree)

· 14.6 Special precautions for user Warning: Miscellaneous dangerous substances and articles.  
· Hazard identification number (Kemler code): 90  
· EMS Number: F-A,S-F  
· Stowage Category A

· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code Not applicable.

## · Transport/Additional information:

· ADR  
· Limited quantities (LQ) 5L  
· Excepted quantities (EQ) Code: E1  
Maximum net quantity per inner packaging: 30 ml  
Maximum net quantity per outer packaging: 1000 ml  
· Transport category 3  
· Tunnel restriction code -

· IMDG  
· Limited quantities (LQ) 5L  
· Excepted quantities (EQ) Code: E1  
Maximum net quantity per inner packaging: 30 ml  
Maximum net quantity per outer packaging: 1000 ml

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· **UN "Model Regulation":** UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (URETHANE DIMETHACRYLATE (UDMA)), 9, III

### 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.
- **Seveso category E2** Hazardous to the Aquatic Environment
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 200 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 t
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

- **Relevant phrases**  
H242 Heating may cause a fire.  
H302 Harmful if swallowed.  
H310 Fatal in contact with skin.  
H312 Harmful in contact with skin.  
H314 Causes severe skin burns and eye damage.  
H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.  
H331 Toxic if inhaled.  
H335 May cause respiratory irritation.  
H373 May cause damage to organs through prolonged or repeated exposure.  
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 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)  
VOC: Volatile Organic Compounds (USA, EU)  
DNEL: Derived No-Effect Level (REACH)  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
Org. Perox. E: Organic peroxides – Type E/F  
Acute Tox. 4: Acute toxicity - oral – Category 4  
Acute Tox. 2: Acute toxicity - dermal – Category 2  
Acute Tox. 3: Acute toxicity - inhalation – Category 3

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*Skin Corr. 1: Skin corrosion/irritation – Category 1**Skin Corr. 1B: Skin corrosion/irritation – Category 1B**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**Skin Sens. 1: Skin sensitisation – Category 1**Skin Sens. 1B: Skin sensitisation – Category 1B**STOT SE 3: Specific target organ toxicity (single exposure) – Category 3**STOT RE 2: Specific target organ toxicity (repeated exposure) – 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.***Disclaimer:**

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

· **1.1 Product identifier**

· **Trade name:** GC Initial LiSi Block

· **CAS Number:**

66402-68-4

· **EC number:**

266-340-9

· **1.2 Relevant identified uses of the substance or mixture and uses advised against**

· **Sector of Use**

SU22 Professional uses: Public domain (administration, education, entertainment, services, craftsmen)

· **Product category** PC0 Other

· **Process category**

PROC24 High (mechanical) energy work-up of substances bound in /on materials and/or articles

· **Environmental release category** ERC12a Processing of articles at industrial sites with low release

· **Article category** AC4 Stone, plaster, cement, glass and ceramic articles

· **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 substance is not classified, according to the 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

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

**SECTION 3: Composition/information on ingredients**

- **3.1 Chemical characterisation: Substances**
- **CAS No. Description**  
66402-68-4 Ceramic material
- **Identification number(s)**
- **EC number:** 266-340-9

**SECTION 4: First aid measures**

- **4.1 Description of first aid measures**
- **General information:**  
No special measures required.  
If symptoms persist consult doctor.
- **After inhalation:** Take affected persons into fresh air and keep quiet.
- **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:**  
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** 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.  
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.

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- **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:**  
Pick up mechanically.  
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**  
Prevent formation of dust.  
Any unavoidable deposit of dust must be regularly removed.
- **Information about fire - and explosion protection:** Dust can combine with air to form an explosive mixture.
- **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.

### 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:** Not required.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Engineering controls** Always ensure that the extraction unit on your milling machine is in good working order.
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
The usual precautionary measures are to be adhered to when handling chemicals.  
Do not inhale dust / smoke / mist.  
Wash hands before breaks and at the end of work.
- **Respiratory protection:** Suitable respiratory protective device recommended.
- **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.  
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.

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· Eye protection: Safety glasses

### SECTION 9: Physical and chemical properties

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

##### · General Information

##### · Appearance:

· Form:	Solid mass
· Colour:	According to product specification
· Odour:	Odourless
· Odour threshold:	Not determined.

· pH-value: Not applicable.

##### · Change in condition

· Melting point/freezing point:	Undetermined.
· Initial boiling point and boiling range:	Undetermined.

· Flash point: Not applicable.

· Flammability (solid, gas): Product is not flammable.

· Ignition temperature: Undetermined.

· Decomposition temperature: Not determined.

· Auto-ignition temperature: Not determined.

· Explosive properties: Product does not present an explosion hazard.

##### · Explosion limits:

· Lower:	Not determined.
· Upper:	Not determined.

· Vapour pressure: Not applicable.

· Density at 20 °C:	2.5 g/cm <sup>3</sup>
· 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.

· 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.

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- **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** Based on available data, the classification criteria are not met.
- **LD/LC50 values relevant for classification:** No further relevant information available.
- **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.
- **Repeated dose toxicity** No further relevant information available.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**  
No further relevant information available.
- **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  
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.  
Contact waste processors for recycling information.

- **European waste catalogue**

18 00 00	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE)
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18 01 00	wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 04	wastes whose collection and disposal is not subject to special requirements in order to prevent infection (for example dressings, plaster casts, linen, disposable clothing, diapers)

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

· <b>14.1 UN-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
· <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 Transport in bulk according to Annex II of Marpol and the IBC Code</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**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I Substance is not listed.**
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

- **Classification according to Regulation (EC) No 1272/2008 Calculation method**
- **Department issuing SDS:** Regulatory affairs
- **Contact:** msds@gc.dental
- **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  
CAS: Chemical Abstracts Service (division of the American Chemical Society)  
LC50: Lethal concentration, 50 percent

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*LD50: Lethal dose, 50 percent**PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative***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.***Disclaimer:**

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