

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 - 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** Auxiliary 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
- **Information department:** Regulatory affairs
- **1.4 Emergency telephone number:** International: +01-813-248-0585 (ChemTel Inc.)

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 labeled 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
- **Hazard-determining components of labeling:**
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.

(Contd. on page 2)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 27.07.2020

Version number 1

Revision: 27.07.2020

Trade name: G-CEM ONE - Paste B

(Contd. of page 1)

· 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 characterization: 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:

72869-86-4	Urethane Dimethacrylate (UDMA) Aquatic Chronic 2, H411; Skin Sens. 1B, H317	25-<50%
1830-78-0	2-Hydroxy-1,3 dimethacryloxypropane Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	5-<10%
85590-00-7	methacryloyloxydecyl dihydrogen phosphate Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	2.5-<5%
80-15-9	α,α -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%
1879-09-0	6-tert-butyl-2,4-xylenol Acute Tox. 2, H310; STOT RE 2, H373; Aquatic Chronic 2, H411; Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319	≥ 0.2 -<0.25%

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

(Contd. on page 3)

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

Printing date 27.07.2020

Version number 1

Revision: 27.07.2020

Trade name: G-CEM ONE - Paste B

(Contd. of page 2)

- **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:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire fighting measures that suit the environment.
- **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.
- **6.3 Methods and material for containment and cleaning up:**
Use neutralizing agent.
Absorb liquid components with liquid-binding material.
Dispose of the collected material 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.

EU

(Contd. on page 4)

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

Printing date 27.07.2020

Version number 1

Revision: 27.07.2020

Trade name: **G-CEM ONE - Paste B**

(Contd. of page 3)

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 protection against explosions and fires:** 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 receptacle 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 systems:** No further data; see item 7.
- **8.1 Control parameters**
- **Components 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-xyleneol

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

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

- **8.2 Exposure controls**

- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
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.
- **Breathing equipment:** 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.

- **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.

(Contd. on page 5)

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

Printing date 27.07.2020

Version number 1

Revision: 27.07.2020

Trade name: G-CEM ONE - Paste B

(Contd. of page 4)

· 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
Color:	White
Odor:	Ester-like
Odor threshold:	Not determined.

· pH-value at 20 °C: 1.5

· Change in condition

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

· Flash point: 93 °C

· Flammability (solid, gaseous): Not applicable.

· Ignition temperature: Undetermined.

· Decomposition temperature: Not determined.

· Auto igniting: Product is not selfigniting.

· Danger of explosion: Product does not present an explosion hazard.

· Explosion limits:

Lower:	Not determined.
Upper:	Not determined.

· Vapor pressure: Not determined.

· Density at 20 °C: 1.5 g/cm³

· Relative density: Not determined.

· Vapor density: Not determined.

· Evaporation rate: Not determined.

· Solubility in / Miscibility with

Water: Fully miscible.

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

· Viscosity:

Dynamic:	Not determined.
Kinematic:	Not determined.

· Solvent content:

VOC (EC) 0.0 g/l

(Contd. on page 6)

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

Printing date 27.07.2020

Version number 1

Revision: 27.07.2020

Trade name: **G-CEM ONE - Paste B**

(Contd. of page 5)

- **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 that are relevant for classification:**

72869-86-4 Urethane Dimethacrylate (UDMA)

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

80-15-9 *α,α*-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:**
- **on the skin:**
Causes severe skin burns and eye damage.

- **on the eye:**
Causes serious eye damage.

- **Sensitization:**
May cause an allergic skin reaction.

- **Additional toxicological information:**

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

- **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.

(Contd. on page 7)

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

Printing date 27.07.2020

Version number 1

Revision: 27.07.2020

Trade name: **G-CEM ONE - Paste B**

(Contd. of page 6)

· **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 bodies of water or drainage ditch undiluted or unneutralized.

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 (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 of together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packagings:**

· **Recommendation:** Disposal must be made according to official regulations.

· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

SECTION 14: Transport information

· **14.1 UN-Number**

· **ADR, IMDG, IATA**

UN3082

· **14.2 UN proper shipping name**

· **DOT**

not regulated

· **ADR**

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

· **IMDG**

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

· **IATA**

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

(Contd. on page 8)

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

Printing date 27.07.2020

Version number 1

Revision: 27.07.2020

Trade name: **G-CEM ONE - Paste B**

(Contd. of page 7)

· **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 MARPOL73/78 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

(Contd. on page 9)

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

Printing date 27.07.2020

Version number 1

Revision: 27.07.2020

Trade name: G-CEM ONE - Paste B

(Contd. of page 8)

· **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**

· **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredient is listed.

· **Section 313 (Specific toxic chemical listings):**

80-15-9 | α,α -dimethylbenzyl hydroperoxide

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

· **MAK (German Maximum Workplace Concentration)**

None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **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.

(Contd. on page 10)

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

Printing date 27.07.2020

Version number 1

Revision: 27.07.2020

Trade name: G-CEM ONE - Paste B

(Contd. of page 9)

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

DOT: US Department of Transportation

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

ACGIH: American Conference of Governmental Industrial Hygienists

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

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

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

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)

· *** 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. 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.