

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** 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.
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 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**
 
GHS02 GHS05
- **Signal word** Danger
- **Hazard statements**
H226 Flammable liquid and vapour.
H314 Causes severe skin burns and eye damage.
H412 Harmful to aquatic life with long lasting effects.

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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 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:

64-17-5	ethyl alcohol Flam. Liq. 2, H225	25-<50%
1830-78-0	2-Hydroxy-1,3 dimethacryloxypropane Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	≥10-<20%
85590-00-7	methacryloyloxydecyl dihydrogen phosphate Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	5-<10%
128-37-0	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.

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.

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- **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:**
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.
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 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.

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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 protection against explosions and fires:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
Do not spray on 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 receptacle 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 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**

128-37-0 Butylated hydroxytoluene

Dermal	DNEL dermal	0.5 mg/kg bw/day (man)
Inhalative	DNEL inhalation	3.5 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

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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:**

· Form:	Liquid
· Color:	According to product specification
· Odor:	Alcohol-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:** 30 °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:	0.98 g/cm ³
· 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.

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- **Viscosity:**
 - Dynamic:** Not determined.
 - Kinematic:** Not determined.
- **Solvent content:**
 - Organic solvents:** 31.0 %
 - Water:** 30.0 %
 - VOC (EC)** 430.3 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 that are relevant for classification:

64-17-5 ethyl alcohol

Oral	LD50	7,060 mg/kg (rat (f+m))
Inhalative	LC50/4 h	20,000 mg/l (rat (f+m))

128-37-0 Butylated hydroxytoluene

Oral	LD50	>6,000 mg/kg (rat (f+m)) (OECD 401)
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- **Primary irritant effect:**
- **on the skin:**
Causes severe skin burns and eye damage.
- **on the eye:**
Causes serious eye damage.
- **Sensitization:** Based on available data, the classification criteria are not met.
- **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.

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

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 (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**

UN1993

· **14.2 UN proper shipping name**· **DOT**

Flammable liquids, n.o.s. (Ethanol)

· **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
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 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
- Sara

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

None of the ingredient is listed.

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

3153-26-2 oxobis(pentane-2,4-dionato-O,O')vanadium

- **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:**

64-17-5 ethyl alcohol

- **Carcinogenic categories**

- **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

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

64-17-5 ethyl alcohol

A3

128-37-0 Butylated hydroxytoluene

A4

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

64-17-5 ethyl alcohol

5

128-37-0 Butylated hydroxytoluene

4

- **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 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.

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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

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

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)

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

This version replaces all previous versions.

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