

Safety Data Sheet according to WHS Regulations

Printing date 27.07.2020

Version number 1



Revision: 27.07.2020

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- **Product identifier**
- **Trade name: G-CEM ONE - Adhesive Enhancing Primer**
- **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
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
GC Australasia Dental Pty Ltd
1753 Botany Road
Banksmeadow, NSW 2019
Tel: +61 2 9301 8200
- **Further information obtainable from:** Regulatory affairs
- **Emergency telephone number:** 24 hours Emergency: 13 11 26.

2 Hazard(s) Identification

- **Classification of the substance or mixture**
Flam. Liq. 3 H226 Flammable liquid and vapour.
Skin Corr. 1A H314 Causes severe skin burns and eye damage.
Eye Dam. 1 H318 Causes serious eye damage.
- **Label elements**
- **GHS label elements** The product is classified and labelled according to the Globally Harmonised System (GHS).
- **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**
Flammable liquid and vapour.
Causes severe skin burns and eye damage.
- **Precautionary statements**
Keep away from heat/sparks/open flames/hot surfaces. No smoking.
Do not breathe dusts or mists.
Wear protective gloves/protective clothing/eye protection/face protection.
IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

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IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing.

Immediately call a POISON CENTER/doctor.

Specific treatment (see on this label).

Store locked up.

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

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

3 Composition and Information on Ingredients

- **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:**

64-17-5	ethyl alcohol Flam. Liq. 2, H225; Eye Irrit. 2A, H319	25-<50%
1830-78-0	2-Hydroxy-1,3 dimethacryloxypropane Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	≥10-<20%
85590-00-7	methacryloyloxydecyl dihydrogen phosphate Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	5-<10%
3153-26-2	oxobis(pentane-2,4-dionato-O,O')vanadium Acute Tox. 3, H301; Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	0.2-<0.5%

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

4 First Aid Measures

- **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.

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- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire Fighting Measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, 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
- **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.
- **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.

6 Accidental Release Measures

- **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.
- **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.
- **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.
- **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.

7 Handling and Storage

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

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- **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.
- **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.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**

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

64-17-5 ethyl alcohol

WES Long-term value: 1880 mg/m³, 1000 ppm

· **DNELs**

128-37-0 Butylated hydroxytoluene

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

Inhalative DNEL inhalation 3.5 mg/m³ (man)

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

- **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.

· **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:



Tightly sealed goggles

9 Physical and Chemical Properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

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

· pH-value at 20 °C (68 °F): 1.5

· Change in condition

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

· Flash point: 30 °C (86 °F)

· 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 (68 °F): 0.98 g/cm³ (8.1781 lbs/gal)

· Relative density: Not determined.

· Vapour 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:

· Organic solvents:	31.0 %
· Water:	30.0 %
· VOC (EC)	430.3 g/l

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· **Other information** No further relevant information available.

10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity**

· **LD/LC50 values 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:**
- **Skin corrosion/irritation** Strong caustic effect on skin and mucous membranes.
- **Serious eye damage/irritation**
Strong caustic effect.
Strong irritant with the danger of severe eye injury.
- **Additional toxicological information:**
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
Irritant
Corrosive
- **Repeated dose toxicity** No further relevant information available.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
No further relevant information available.

12 Ecological Information

- **Toxicity**

· **Aquatic toxicity:**

128-37-0 Butylated hydroxytoluene

EC50/48h (static)	0.48 mg/l (daphnia magna) (OECD 202)
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- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.

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- **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.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **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.

14 Transport information

- | | |
|---|--|
| <ul style="list-style-type: none"> · UN-Number · ADG, IMDG, IATA | <p style="text-align: center;">UNI993</p> |
| <ul style="list-style-type: none"> · UN proper shipping name · ADG · IMDG, IATA | <p style="text-align: center;">1993 FLAMMABLE LIQUID, N.O.S. (ETHANOL SOLUTION)
 FLAMMABLE LIQUID, N.O.S. (ETHANOL SOLUTION)</p> |
| <ul style="list-style-type: none"> · Transport hazard class(es) · ADG | <div style="text-align: center;">  </div> |
| <ul style="list-style-type: none"> · Class · Label | <p style="text-align: center;">3 (F1) Flammable liquids.
 3</p> |

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· **IMDG, IATA**

· **Class** 3 Flammable liquids.
 · **Label** 3

· **Packing group**
 · **ADG, IMDG, IATA** III

· **Environmental hazards:**
 · **Marine pollutant:** No

· **Special precautions for user** Warning: Flammable liquids.
 · **Hazard identification number (Kemler code):** 30
 · **EMS Number:** F-E, S-E
 · **Stowage Category** A

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

· **Transport/Additional information:**

· **ADG**
 · **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

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**· **Australian Inventory of Chemical Substances**

64-17-5	ethyl alcohol
7732-18-5	Water
128-37-0	Butylated hydroxytoluene
3153-26-2	oxobis(pentane-2,4-dionato-O,O')vanadium

· **Standard for the Uniform Scheduling of Medicines and Poisons**

None of the ingredients is listed.

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· **Australia: Priority Existing Chemicals**

None of the ingredients is listed.

- **GHS label elements** The product is classified and labelled according to the Globally Harmonised System (GHS).
 · **Hazard pictograms**



GHS02 GHS05

- **Signal word** *Danger*
- **Hazard statements**
Flammable liquid and vapour.
Causes severe skin burns and eye damage.
- **Precautionary statements**
Keep away from heat/sparks/open flames/hot surfaces. No smoking.
Do not breathe dusts or mists.
Wear protective gloves/protective clothing/eye protection/face protection.
IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Immediately call a POISON CENTER/doctor.
Specific treatment (see on this label).
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.
- **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
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

- **Relevant phrases**
H225 Highly flammable liquid and vapour.
H301 Toxic if swallowed.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
- **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
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)

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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

Acute Tox. 3: Acute toxicity - oral – Category 3

Skin Corr. 1A: Skin corrosion/irritation – Category 1A

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

STOT SE 3: Specific target organ toxicity (single exposure) – 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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