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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 Paste B
- *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. 4 H227 Combustible liquid.

Skin Corr. 1A 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.

· 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



· Signal word Danger

• *Hazard-determining components of labelling:* Urethane Dimethacrylate (UDMA) α,α -dimethylbenzyl hydroperoxide

6-tert-butyl-2,4-xylenol

• *Hazard statements* Combustible liquid. Causes severe skin burns and eye damage.

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May cause an allergic skin reaction.
Precautionary statements
Keep away from flames and 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).
Take off contaminated clothing and wash it before reuse.
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 d	components:	
72869-86-4	Urethane Dimethacrylate (UDMA)	25-<50%
	Skin Sens. 1, H317	
1830-78-0	2-Hydroxy-1,3 dimethacryloxypropane	5-<10%
	Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	
85590-00-7	methacryloyloxydecyl dihydrogen phosphate	2.5-<5%
	Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	
80-15-9	α,α -dimethylbenzyl hydroperoxide	0.5-<1%
	Self-react. C, H242; Org. Perox. E, H242; Acute Tox. 3, H331; STOT RE 2, H373; Skin Corr. 1B, H314; Acute Tox. 4, H302; Acute Tox. 4, H312; Flam. Liq. 4, H227	
1879-09-0	6-tert-butyl-2,4-xylenol	≥0.2-<0.25%
	Acute Tox. 2, H310; Acute Tox. 3, H331; STOT RE 2, H373; Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2A, H319	
4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4	aformation. For the wording of the listed harard phrases refer to section 16	-

• 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.

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• 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.*

• Information for doctor:

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

• *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.	
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:	
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.	
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See Section 13 for disposal information.

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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.
- Information about fire and explosion protection: No special measures required.
- · 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.
- · 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:
- 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/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.

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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

Colour:WhOdour:EstOdour threshold:NopH-value at 20 °C (68 °F):1.5Change in condition Melting point/freezing point:UnInitial boiling point and boiling range:UnFlash point:93Flammability (solid, gas):No	ndetermined. ndetermined. 3 °C (199.4 °F)
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Flash point:93Flammability (solid, gas):No	3 °C (199.4 °F)
Flammability (solid, gas): No	
• • • • • •	1. 11
T • • • • • • • • • • • • • • • • • • •	ot applicable.
Ignition temperature: Un	ndetermined.
Decomposition temperature: No	ot determined.
Auto-ignition temperature:Pro	roduct is not selfigniting.
Explosive properties: Pro	roduct does not present an explosion hazard.
Explosion limits:	
	ot determined.
Upper: No.	ot determined.
Vapour pressure: No	ot determined.
Density at 20 °C (68 °F): 1.5	5 g/cm ³ (12.5175 lbs/gal)
• • • •	ot determined.
	ot determined.
	ot determined.
Solubility in / Miscibility with	
water: Fu	ılly miscible.
Partition coefficient: n-octanol/water: No	ot determined.
Viscosity:	
2,5100000	ot determined. ot determined.

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Solvent content:
 VOC (EC)
 Other information

0.0 g/l 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:

72869-86-4 Urethane Dimethacrylate (UDMA)

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

80-15-9 a,a -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 Strong caustic effect on skin and mucous membranes.

· Serious eye damage/irritation

Strong caustic effect.

Strong irritant with the danger of severe eye injury.

• Respiratory or skin sensitisation Sensitisation possible through skin contact.

· Additional toxicological information: Corrosive

· Repeated dose toxicity No further relevant information available.

• CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)

No further relevant information available.

12 Ecological Information

· Toxicity

• Aquatic toxicity: 72869-86-4 Urethane Dimethacrylate (UDMA)

EC50/48h (static) >1.2 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.
- 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.

- · 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	
· UN-Number · ADG, IMDG, IATA	UN3082
· UN proper shipping name · ADG	3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE
·IMDG	LIQUID, N.O.S. (Urethane Dimethacrylate (UDMA)) ENVIRONMENTALLY HAZARDOUS SUBSTANCE LIQUID, N.O.S. (Urethane Dimethacrylate (UDMA), α,α
·IATA	dimethylbenzyl hydroperoxide), MARINE POLLUTANT ENVIRONMENTALLY HAZARDOUS SUBSTANCE LIQUID, N.O.S. (Urethane Dimethacrylate (UDMA))
· Transport hazard class(es)	
· ADG	
- Class	9 (M6) Miscellaneous dangerous substances and articles.
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Label	9
IMDG, IATA	
Class Label	9 Miscellaneous dangerous substances and articles. 9
Packing group ADG, IMDG, IATA	111
Environmental hazards: Marine pollutant: Special marking (ADG): Special marking (IATA):	No Symbol (fish and tree) Symbol (fish and tree) Symbol (fish and tree)
Special precautions for user Hazard identification number (Kemler code): EMS Number: Stowage Category	Warning: Miscellaneous dangerous substances and articles 90 F-A,S-F A
Transport in bulk according to Annex II of Mar and the IBC Code	pol Not applicable.
Transport/Additional information:	
ADG Limited quantities (LQ) Excepted quantities (EQ) Transport category Tunnel restriction code	5L Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml 3 -
IMDG Limited quantities (LQ) Excepted quantities (EQ)	5L Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
UN "Model Regulation":	UN 3082 ENVIRONMENTALLY HAZARDOU SUBSTANCE, LIQUID, N.O.S. (URETHAN DIMETHACRYLATE (UDMA)), 9, III

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture

- · Australian Inventory of Chemical Substances
- 60676-86-0 Silica, vitreous

72869-86-4 Urethane Dimethacrylate (UDMA)

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2530-85-0 3	-trimethoxysilylpropy	vl methacrylate
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80-15-9 α, α -dimethylbenzyl hydroperoxide

6381-92-6 Ethylene diaminetetraacetic acid sodium salt

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

· Standard for the Uniform Scheduling of Medicines and Poisons

None of the ingredients is listed.

· 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*



· Signal word Danger

· Hazard-determining components of labelling: Urethane Dimethacrylate (UDMA) α, α -dimethylbenzyl hydroperoxide 6-tert-butyl-2,4-xylenol · Hazard statements Combustible liquid. Causes severe skin burns and eye damage. May cause an allergic skin reaction. · Precautionary statements Keep away from flames and 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). Take off contaminated clothing and wash it before reuse. 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 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
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

• *Relevant phrases* H227 Combustible liquid. H242 Heating may cause a fire.

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(Contd. of page 9) 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.
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)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Flam. Liq. 4: Flammable liquids – Category 4
Self-react. C: Self-reactive substances and mixtures – Type C/D
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. 2: Acute toxicity - definition – Category 2 Acute Tox. 3: Acute toxicity - inhalation – Category 3
Skin Corr. 1A: Skin corrosion/irritation – Category 1A
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. 2A: Serious eye damage/eye irritation – Category 2A
Skin Sens. 1: Skin sensitisation – Category 1 STOT SE 2: Sensitisation – training (circle surgerys) – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3 STOT RE 2: Specific target organ toxicity (repeated exposure) – 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:
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or suggestions are made without any guarantee, representation or warranty, express or implied, on our part.

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