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Hazardous according to criteria of Australian Safety and Compensation Council.

## 1 Identification

- · Other means of identification
- · Trade name: G-CEM ONE Paste A
- 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

Flammable liquids – Category 4 H227 Combustible liquid. Skin corrosion/irritation – Category 2 H315 Causes skin irritation.

Eye damage/irritation – Category 2A H319 Causes serious eye irritation.

Skin sensitisation – Category 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



GHS07

- · Signal word Warning
- · Hazard-determining components of labelling:

*Urethane Dimethacrylate (UDMA) (10-<25 %)* 

· Hazard statements

Combustible liquid.

Causes skin irritation.

Causes serious eye irritation.

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May cause an allergic skin reaction.

### · Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

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

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

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

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

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:	
1830-78-0	2-Hydroxy-1,3 dimethacryloxypropane	≥10-<20%
	Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A, H319; Specific target organ toxicity (single exposure) – Category 3, H335	
72869-86-4	Urethane Dimethacrylate (UDMA)	10-<25%
	Skin sensitisation – Category 1B, H317	
68909-20-6	Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	5-<10%
	Specific target organ toxicity (repeated exposure) – Category 2, H373	
13463-67-7	titanium dioxide	0.5-<1%
	Carcinogenicity – Category 2, H351	
1879-09-0	6-tert-butyl-2,4-xylenol	0.1-<0.2%
	Acute toxicity - dermal — Category 2, H310; Specific target organ toxicity (repeated exposure) — Category 2, H373; Acute toxicity - oral — Category 4, H302; Skin corrosion/irritation — Category 2, H315; Eye damage/irritation — Category 2A, H319	

<sup>·</sup> Additional information: For the wording of the listed hazard phrases refer to section 16.

# 4 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. Then consult a doctor.

· 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

- · Suitable extinguishing agents: CO2, sand, extinguishing powder. Do not use water.
- · For safety reasons unsuitable extinguishing agents: Water
- · 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.

- · 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.

Do not allow to penetrate the ground/soil.

· Methods and material for containment and cleaning up:

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.

- · Information about fire and explosion protection: Protect against electrostatic charges.
- · 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.

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- · Further information about storage conditions: None.
- · Specific end use(s) No further relevant information available.

## 8 Exposure controls and personal protection

· Appropriate engineering controls No further data; see section 7.

Ingredients with limit values that require monitoring at the workplace:

### 13463-67-7 titanium dioxide

WES Long-term value: 10 mg/m³ inhalable dust

#### · DNELs

## 13463-67-7 titanium dioxide

Inhalative DNEL inhalation 10 mg/m3 (man)

### 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.
- · 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.

· Eye protection:



Tightly sealed goggles

## 9 Physical and Chemical Properties

- · General Information
- · Appearance:
- · Form: Pasty

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

• pH-value at 20 °C (68 °F): 6.5

· Change in condition

Melting point/freezing point:
 Initial boiling point and boiling range:
 Undetermined.
 Flash point:
 Flammability
 Auto-ignition temperature:
 Decomposition temperature:
 Mot determined.
 Not determined.

• **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): 1.9 g/cm³ (15.8555 lbs/gal)

Relative density
 Vapour density
 Evaporation rate
 Not determined.
 Not determined.

· Solubility in / Miscibility with

• water: Insoluble. • Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

Dynamic: Not determined. Kinematic: Not determined.

· Solvent content:

 $\cdot$  VOC (EC) 0.0 g/l

· Other information

• Particle characteristics SiO2: Diameter particle structure = 2.5 - 50 nm (TEM, d50, number-

based)

Diameter agglomerate = 5 - 50 mm (laser diffraction dry module, d50,

volume based)

68909-20-6 Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis

products with silica:

set including amorphous nanoforms; surface-treated nanoforms;

Spheroidal; amorphous forms; amorphous nanoform

· Physical state Fluid

## 10 Stability and Reactivity

- · Reactivity No further relevant information available.
- 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.

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# 11 Toxicological Information

- · Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.

· LD/LC50	· LD/LC50 values relevant for classification:						
72869-86-4 Urethane Dimethacrylate (UDMA)							
Oral	LD50	>5,000 mg/kg (rat female) (OECD 401)					
13463-67-	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	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 eve damage/irritation Causes serious eye irritation.
- · Respiratory or skin sensitisation May cause an allergic skin reaction.
- · 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.
- · Interactive effects
- 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)

- · 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:

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

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

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# 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.

UN-Number		
ADG, IMDG, IATA	not regulated	
UN proper shipping name		
ADG, IMDG, IATA	not regulated	
Transport hazard class(es)		
ADG, ADN, IMDG, IATA		
Class	not regulated	
Packing group		
ADG, IMDG, IATA	not regulated	
Environmental hazards:		
Marine pollutant:	No	
Special precautions for user	Not applicable.	
Transport in bulk according to Annex I	I of Marpol	
and the IBC Code	Not applicable.	

# 15 Regulatory information

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

· Australian Inventory of Industrial Chemicals		
65997-17-3	Glass, oxide, chemicals	
72869-86-4	Urethane Dimethacrylate (UDMA)	
68909-20-6	Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	
2530-85-0	3-trimethoxysilylpropyl methacrylate	
13463-67-7	titanium dioxide	
1309-37-1	Iron(III)oxide	
1317-61-9	triiron tetraoxide	
10373-78-1	Camphorquinone	
20344-49-4	Iron hydroxide oxide	
10287-53-3	ethyl 4-dimethylaminobenzoate	
1879-09-0	6-tert-butyl-2,4-xylenol	

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

75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

### · 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 Warning

### · Hazard-determining components of labelling:

*Urethane Dimethacrylate (UDMA) (10-<25 %)* 

#### · Hazard statements

Combustible liquid.

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

## · Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

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

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

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

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

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.
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

# 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.

H351 Suspected of causing cancer.

H373 May cause damage to organs through prolonged or repeated exposure.

- · Department issuing SDS: Regulatory affairs
- · Contact: msds@gc.dental

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#### · Abbreviations and acronyms:

ADR: Accord relatif au transport international 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

Flammable liquids – Category 4: Flammable liquids – Category 4

Acute toxicity - oral - Category 4: Acute toxicity - Category 4 Acute toxicity - dermal - Category 2: Acute toxicity - Category 2

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

Eye damage/irritation - Category 2A: Serious eye damage/eye irritation - Category 2A

Skin sensitisation – Category 1: Skin sensitisation – Category 1 Skin sensitisation – Category 1B: Skin sensitisation – Category 1B

Carcinogenicity – Category 2: Carcinogenicity – Category 2

Specific target organ toxicity (single exposure) – Category 3: Specific target organ toxicity (single exposure) – Category 3: Specific target organ toxicity (repeated exposure) – Category 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.

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