

1 Identification of the substance or mixture and of the supplier

- · Other means of identification
- · 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 Henry Schein Dental

243-249 Bush Road, Rosedale Auckland 0632, NEW ZEALAND

Free Phone: 0800 808 855

· Further information obtainable from: Regulatory affairs

· Emergency telephone number: 0800 764 766 (National Poisons Centre)

2 Hazards identification

· Classification of the substance or mixture

Flammable liquids Category 4 H227 Combustible liquid.

Skin corrosion Category 1A H314 Causes severe skin burns and eye damage.

Serious eye damage Category 1 H318 Causes serious eye damage.

Skin sensitisation Category 1 H317 May cause an allergic skin reaction.

Specific target organ toxicity - repeated exposure

H373 May cause damage to the lung through

Category 2 prolonged or repeated exposure. Route of

exposure: Inhalation.

Hazardous to the aquatic environment chronic Category 2H411 Toxic to aquatic life with long lasting effects.

- · 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









GHS05

GHS07

GHS08

GHS09

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

Urethane Dimethacrylate (UDMA)

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica

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· Hazard statements

Combustible liquid.

Causes severe skin burns and eye damage.

May cause an allergic skin reaction.

May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

Toxic to aquatic life with long lasting effects.

· Precautionary statements

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Do not breathe dusts or mists.

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

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or 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/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:		
CAS: 72869-86-4	Urethane Dimethacrylate (UDMA)	25-<50%
EINECS: 276-957-5	Hazardous to the aquatic environment chronic Category 2, H411; Skin sensitisation Sub-category 1B, H317	
CAS: 1830-78-0	2-Hydroxy-1,3 dimethacryloxypropane	5-<10%
EINECS: 217-388-4	Skin irritation Category 2, H315; Eye irritation Category 2, H319; Specific target organ toxicity - single exposure Category 3, H335	
CAS: 68909-20-6	Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	5-<10%
EINECS: 272-697-1	Specific target organ toxicity - repeated exposure Category 2, H373	
CAS: 85590-00-7	methacryloyloxydecyl dihydrogen phosphate	2.5-<5%
	Skin irritation Category 2, H315; Eye irritation Category 2, H319; Specific target organ toxicity - single exposure Category 3, H335	

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CAS: 80-15-9	α,α -dimethylbenzyl hydroperoxide	0.5-<1%
EINECS: 201-254-7	Organic peroxide Type E, H242; Acute inhalation toxicity Category 3, H331; Specific target organ toxicity - repeated exposure Category 2, H373; Skin corrosion Category 1B, H314; Hazardous to the aquatic environment chronic Category 2, H411; Acute oral toxicity Category 4, H302; Acute dermal toxicity Category 4, H312; Flammable liquids Category 4, H227	
CAS: 1879-09-0	6-tert-butyl-2,4-xylenol	0.2-<0.5%
EINECS: 217-533-1	Acute dermal toxicity Category 2, H310; Specific target organ toxicity - repeated exposure Category 2, H373; Acute oral toxicity Category 4, H302; Skin irritation Category 2, H315; Eye irritation Category 2, H319	
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.

· 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

· 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.

- · Protective equipment: Wear self-contained respiratory protective device.
- · Additional information

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

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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.

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: No special measures required.
- · 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/personal protection

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

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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
Colour: White
Odour: Ester-like
Odour threshold: Not determined.

• pH-value at 20 °C: 1.5

Change in condition

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

· Flash point: 93 °C

Flammability
 Auto-ignition temperature:
 Decomposition temperature:
 Not applicable.
 Undetermined.
 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: 1.5 g/cm³
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.

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· Viscosity:	
· Dynamic:	Not determined.
· Kinematic:	Not determined.
· Solvent content:	
· VOC (EC)	$0.0\mathrm{g/l}$
· 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)-, hydrolysi 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.

11 Toxicological information

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

· 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 -dimethy	lbenzyl 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 Causes severe skin burns and eye damage.
- · Serious eye damage/irritation Causes serious eye damage.
- · 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.

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· STOT-repeated exposure

May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

- · Aspiration hazard Based on available data, the classification criteria are not met.
- · Interactive effects
- Repeated dose toxicity May cause damage to organs through prolonged or repeated exposure.
- · 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:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

Must not reach sewage water or drainage ditch undiluted or unneutralised.

Danger to drinking water if even small quantities leak into the ground.

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.

- · 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
- · NZS, IMDG, IATA

UN3082

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

· New Zealan	· New Zealand Inventory of Chemicals		
72869-86-4	Urethane Dimethacrylate (UDMA)		
60676-86-0	Silica, vitreous		
2530-85-0	3-trimethoxysilylpropyl methacrylate		
1830-78-0	2-Hydroxy-1,3 dimethacryloxypropane		
68909-20-6	Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica		
80-15-9	a,a -dimethylbenzyl hydroperoxide		
6381-92-6	Ethylene diaminetetraacetic acid sodium salt		
1879-09-0	6-tert-butyl-2,4-xylenol		

· HSNO Approval numbers

80-15-9	a,a -dimethylbenzyl hydroperoxide	HSR001368
1879-09-0	6-tert-butyl-2,4-xylenol	HSR003625

• GHS label elements The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms









GHS05

GHS07

GHS08

GHS09

· Signal word Danger

· Hazard-determining components of labelling:

Urethane Dimethacrylate (UDMA)

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica

· Hazard statements

Combustible liquid.

Causes severe skin burns and eye damage.

May cause an allergic skin reaction.

May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

Toxic to aquatic life with long lasting effects.

· Precautionary statements

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not breathe dusts or mists.

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

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IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or 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.
- 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.
- H411 Toxic to aquatic life with long lasting effects.
- · Department issuing SDS: Regulatory affairs
- · Contact: msds@gc.dental
- · 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

Organic peroxide Type E: Organic peroxides - Type E/F

Acute oral toxicity Category 4: Acute toxicity – Category 4

Acute dermal toxicity Category 2: Acute toxicity - Category 2

Acute inhalation toxicity Category 3: Acute toxicity – Category 3

Skin corrosion Category 1A: Skin corrosion/irritation – Category 1A Skin corrosion Category 1B: Skin corrosion/irritation – Category 1B

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

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Serious eye damage Category 1: Serious eye damage/eye irritation – Category 1

Eye irritation Category 2: Serious eye damage/eye irritation – Category 2

Skin sensitisation Category 1: Skin sensitisation - Category 1

Skin sensitisation Sub-category 1B: Skin sensitisation – Category 1B

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

Hazardous to the aquatic environment chronic Category 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.

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