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Safety Data Sheet in accordance with HSNO

Printing date 27.07.2020

Version number 1

Revision: 27.07.2020

1 Identification of the substance or mixture and of the supplier

· 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 Henry Schein Dental 23 William Pickering Drive, Albany Auckland 0632, NEW ZEALAND

PO Box 101140, NSMC Auckland 0745, 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

Flam. Liq. 4 H227 Combustible liquid.

Acute Tox. 5 H333 May be harmful if inhaled.

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. May be harmful if inhaled.

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(Contd. of page 1) 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. • 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 compone 	ents:	
CAS: 72869-86-4	Urethane Dimethacrylate (UDMA)	25-<50%
EINECS: 276-957-5	Skin Sens. 1, H317	
CAS: 1830-78-0	2-Hydroxy-1,3 dimethacryloxypropane	5-<10%
EINECS: 217-388-4	Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	
CAS: 85590-00-7	methacryloyloxydecyl dihydrogen phosphate	2.5-<5%
	Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	
CAS: 80-15-9	α,α -dimethylbenzyl hydroperoxide	0.5-<1%
EINECS: 201-254-7	Self-react. C, H242; Org. Perox. E, H242; Acute Tox. 3, H331; STOT RE 2, H373; Skin Corr. 1B, H314; Aquatic Chronic 2, H411; Acute Tox. 4, H302; Acute Tox. 4, H312; Flam. Liq. 4, H227	
CAS: 1879-09-0	6-tert-butyl-2,4-xylenol	≥0.2-<0.25%
EINECS: 217-533-1	<i>Acute Tox. 2, H310; Acute Tox. 3, H331; STOT RE 2, H373; Aquatic Chronic 2, H411; Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2A, H319; Aquatic Acute 2, H401</i>	
· Additional informat	ion. For the wording of the listed hazard phrases refer to section 16	

 \cdot 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.*

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• 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

- · 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.

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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.

· 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/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

Information on basic physical and chen	ical properties	
General Information		
Appearance:		
Form:	Pasty	
Colour:	White	
Odour: Odour threshold:	Ester-like 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 (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:	1.5 g/cm ³	
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.	

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• Solvent content: VOC (EC)

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• 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 eve 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 pHvalue 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.

· UN-Number	
ADR, IMDG, IATA	UN3082
· UN proper shipping name	
ADR	3082 ENVIRONMENTALLY HAZARDOUS SUBSTANC
	LIQUID, N.O.S. (Urethane Dimethacrylate (UDMA))
·IMDG	ENVIRONMENTALLY HAZARDOUS SUBSTANC
	LIQUID, N.O.S. (Urethane Dimethacrylate (UDMA), α,α dimethylbenzyl hydroperoxide), MARINE POLLUTANT
· IATA	ENVIRONMENTALLY HAZARDOUS SUBSTANC.
	LIQUID, N.O.S. (Urethane Dimethacrylate (UDMA))
Transport hazard class(es)	
ADR	
· 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 ADR, IMDG, IATA	111
Environmental hazards:	
Marine pollutant:	No
	Symbol (fish and tree)
Special marking (ADR):	Symbol (fish and tree)
Special marking (IATA):	Symbol (fish and tree)
Special precautions for user	Warning: Miscellaneous dangerous substances and articles
Hazard identification number (Kemler code):	90
EMS Number:	F-A,S-F
Stowage Category	A
Transport in bulk according to Annex II of Mar	pol
and the IBC Code	Not applicable.
Transport/Additional information:	
ADR	
Limited quantities (LQ)	5L
Excepted quantities (EQ)	Code: El
	Maximum net quantity per inner packaging: 30 ml
_	Maximum net quantity per outer packaging: 1000 ml
Transport category	3
Tunnel restriction code	-
IMDG	
Limited quantities (LQ)	5L
Excepted quantities (EQ)	Code: El
	Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
UN "Model Regulation":	UN 3082 ENVIRONMENTALLY HAZARDOU
or mouti negutitor .	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 Zealand Inventory of Chemicals
- 60676-86-0 Silica, vitreous

72869-86-4 Urethane Dimethacrylate (UDMA)

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1830-78-0 2-Hydroxy-1,3 dimethacryloxypropane	
2530-85-0 3-trimethoxysilylpropyl methacrylate	
80-15-9 α,α -dimethylbenzyl hydroperoxide	
6381-92-6 Ethylene diaminetetraacetic acid sodium salt	
1879-09-0 6-tert-butyl-2,4-xylenol	
HSNO Approval numbers	LICDAALAC
80-15-9 α,α -dimethylbenzyl hydroperoxide	HSR00136
1879-09-0 6-tert-butyl-2,4-xylenol	HSR00362
• GHS label elements The product is classified and labelled according to the Globally Har • Hazard pictograms	monised System (0115)
GHS05 GHS07 • 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.	
May be harmful if inhaled.	
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 ski	n with water/shower
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, i	
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 re	egulations.
· Directive 2012/18/EU	
• Named dangerous substances - ANNEX I None of the ingredients is listed.	
• Seveso category E2 Hazardous to the Aquatic Environment	
\cdot Qualifying quantity (tonnes) for the application of lower-tier requirements 200 t	
$\cdot \tilde{\mathbf{Q}}$ ualifying quantity (tonnes) for the application of upper-tier requirements 500 t	
Qualifying quantity (tonnes) for the application of apper-iter requirements 500 i	

16 Other information

• **Relevant phrases** H227 Combustible liquid.

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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.
H401 Toxic to aquatic life.
H411 Toxic to aquatic life with long lasting effects.
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. 3: Acute toxicity - inhalation – Category 3
Acute Tox. 5: Acute toxicity - inhalation – Category 5 Acute Tox. 5: Acute toxicity - inhalation – Category 5
Skin Corr. 1A: Skin corrosion/irritation – Category 1A
Skin Corr. 1B: Skin corrosion/irritation – Category 1B
Skin Irrit. 2: Skin corrosion/irritation – Category 2
<i>Eye Dam. 1: Serious eye damage/eye irritation – Category 1</i> <i>Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A</i>
Skin Sens. 1: Skin sensitisation – Category 1
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2
Aquatic Acute 2: Hazardous to the aquatic environment - acute aquatic hazard – Category 2
Aquatic Chronic 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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