

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 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

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. 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. Aquatic Acute 3 H402 Harmful to aquatic life.

Aquatic Chronic 3 H412 Harmful 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





GHS02

GHS05

- · Signal word Danger
- · Hazard statements

Flammable liquid and vapour.

Causes severe skin burns and eye damage.

Harmful to aquatic life with long lasting effects.

· Precautionary statements

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

Do not breathe dusts or mists.

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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.

- · 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: 64-17-5	ethyl alcohol	25-<50%		
EINECS: 200-578-6	Flam. Liq. 2, H225; Eye Irrit. 2A, H319			
CAS: 1830-78-0	2-Hydroxy-1,3 dimethacryloxypropane	≥10-<20%		
EINECS: 217-388-4	Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335			
CAS: 85590-00-7	methacryloyloxydecyl dihydrogen phosphate	5-<10%		
	Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335			
CAS: 128-37-0	Butylated hydroxytoluene	1-<2.5%		
EINECS: 204-881-4	Aquatic Acute 1, H400; Aquatic Chronic 1, H410			
CAS: 3153-26-2	oxobis(pentane-2,4-dionato-O,O')vanadium	0.2-<0.5%		
EINECS: 221-590-8	Acute Tox. 3, H301; Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335			

[·] 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.

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· 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 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.

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Prevent formation of aerosols.

Avoid contact with the eyes and skin.

· 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/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 (New Zealand) 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	inhalati	on	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.

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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

9 Physical	and	chemic	al pro	nerties
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· 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: 1.5

· Change in condition

· Flash point:

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

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.

Fully miscible.

30 °C

· Explosion limits:

Lower:Not determined.Upper:Not determined.

• Vapour pressure: Not determined.
 • Density at 20 °C: 0.98 g/cm³

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

Solubility in / Miscibility with

· Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

Dynamic: Not determined. **Kinematic:** Not determined.

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· Solvent content:

 Organic solvents:
 31.0 %

 Water:
 30.0 %

 VOC (EC)
 430.3 g/l

• 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 value	s relevant for	classification:
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<i>64-17-5</i>	ethyl	al	col	hol
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	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)

- 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 (carcinogenity, 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.
- · Ecotoxical 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	
· UN-Number	

· ADR, IMDG, IATA UN1993

· UN proper shipping name
· ADR

1993 FLAMMABLE LIQUID, N.O.S. (ETHANOL SOLUTION)

• IMDG, IATA FLAMMABLE LIQUID, N.O.S. (ETHANOL SOLUTION)

· Transport hazard class(es)

 $\cdot ADR$



Class 3 (F1) Flammable liquids.

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Label	3
· IMDG, IATA	
Class	3 Flammable liquids.
Label	3
Packing group ADR, IMDG, IATA	III
Environmental hazards:	
Marine pollutant:	No
Special precautions for user	Warning: Flammable liquids.
Hazard identification number (Kemler code):	30
EMS Number:	<i>F-E,<u>S-E</u></i>
Stowage Category	A
Transport in bulk according to Annex II of Mar	
and the IBC Code	Not applicable.
Transport/Additional information:	
ADR	
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	Maximum nei quantity per outer packaging: 1000 mt 3
Transport category 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. (ETHANO.
Č	SOLUTION), 3, III

15 Regulatory information

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

· New Zealan	· New Zealand Inventory of Chemicals			
64-17-5	ethyl alcohol			
7732-18-5	Water			
70293-55-9	2-[(2-methyl-1-oxoallyl)oxy]ethyl 1,3-dihydro-1,3-dioxoisobenzofuran-5-carboxylate			
1830-78-0	2-Hydroxy-1,3 dimethacryloxypropane			
128-37-0	Butylated hydroxytoluene			
3153-26-2	oxobis(pentane-2,4-dionato-O,O')vanadium			

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	· HSNO Approval numbers		
	64-17-5	ethyl alcohol	HSR001144
	128-37-0	Butylated hydroxytoluene	HSR002784
	3153-26-2	oxobis(pentane-2,4-dionato-O,O')vanadium	HSR005754

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





GHS05

GHS02

- · Signal word Danger
- Hazard statements

Flammable liquid and vapour.

Causes severe skin burns and eye damage.

Harmful to aquatic life with long lasting effects.

· 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.

H400 Very toxic to aquatic life.

H410 Very 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)

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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. 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

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Acute 3: Hazardous to the aquatic environment - acute aquatic hazard - Category 3

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard - Category 1

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – 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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