

SAFETY DATA SHEETS

This SDS packet was issued with item:

071424860

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

071313790

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

071313758

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 10/17/2019

Version US-EN-Rev 2



Reviewed on 10/17/2019

1 Identification

- **Product identifier**
- **Trade name:** G-Multi PRIMER
- **Relevant identified uses of the substance or mixture and uses advised against**
Dental material
The product is intended for professional use.
To avoid risks for humans and environment obtain instructions.
- **Application of the substance / the mixture** Auxiliary for dental technology
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
GC America Inc.
3737 W. 127th Street
Alsip, IL 60803
USA

SDS.gcamerica@gc.dental
- **Information department:** Regulatory Affairs
- **Emergency telephone number:**
During normal opening times (Monday–Friday 8:00 AM–5:00 PM Central Time): +1 (708) 597-0900
Transportation (CHEMTREC®) Emergency Telephone No. +1 (800) 424-9300

2 Hazard(s) identification

- **Classification of the substance or mixture**
Flam. Liq. 2 H225 Highly flammable liquid and vapor.
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **Additional information:**
The information provided is in regards to the toxicity and hazard rating(s) of the individual component(s) in the formulation. The associated risk(s) depends on the route(s) of exposure. The hazard rating system is based entirely on the existence of the risk(s) and does not take into account the likelihood of reduced risk(s) through proper usage and handling.
- **Label elements**
- **GHS label elements**
Exempt from labeling – medical devices and drugs do not require labeling according to HCS 2012.
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**
 
- **Signal word** Danger
- **Hazard-determining components of labeling:**
dimethacrylate component**
- **Hazard statements**
Highly flammable liquid and vapor.
May cause an allergic skin reaction.

(Contd. on page 2)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 10/17/2019

Version US-EN-Rev 2

Reviewed on 10/17/2019

Trade name: G-Multi PRIMER

(Contd. of page 1)

- **Precautionary statements**

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
 Contaminated work clothing must not be allowed out of the workplace.
 Wear protective gloves/protective clothing/eye protection/face protection.
 If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
 Store in a well-ventilated place. Keep cool.
 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Hazard not otherwise classified (HNOC):** None known.

- **Additional information:**

2 % of the mixture consists of component(s) of unknown toxicity.

- **Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**

- **Description:** Mixture of the substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 64-17-5	ethyl alcohol	75 – < 100%
	phosphoric acid ester monomer**	1 – < 2.5%
	dimethacrylate component**	1 – < 2.5%

- **Additional information:**

If a substance is marked with **, then substance is a trade secret. This is allowed under OSHA's Hazard Communication Standard (HCS) as a trade secret and under GHS as Confidential Business Information (CBI).

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; consult doctor in case of complaints.

In case of unconsciousness place patient stably in side position for transportation.

- **After skin contact:**

Immediately wash with water and soap and rinse thoroughly.

Seek medical treatment.

- **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, 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

(Contd. on page 3)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 10/17/2019

Version US-EN-Rev 2

Reviewed on 10/17/2019

Trade name: G-Multi PRIMER

(Contd. of page 2)

- **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, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Use fire fighting measures that suit the environment.
- **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.
Do not allow to penetrate the ground/soil.
- **Methods and material for containment and cleaning up:**
Ensure adequate ventilation.
Absorb liquid components with liquid-binding material.
Dispose of the collected material 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.
- **Protective Action Criteria for Chemicals**
Protective Action Criterion (PAC); Protective Action Criteria (PACs); Lower Explosive Limit (LEL)
* indicates the PAC value is between 10% and up to 50% of the LEL (10% LEL ≤ PAC < 50% LEL).
** indicates the PAC value is between 50% and up to 100% of the LEL (50% LEL ≤ PAC < 100% LEL).
*** indicates the PAC value is at 100% or more of the LEL (PAC ≥ LEL).
excerpt from Introduction to PAC Table 2 – PAC Rev. 29 – May 2016

- **PAC-1:**

CAS: 64-17-5	ethyl alcohol	1,800 ppm
	silane**	71 mg/m ³
	dimethacrylate component**	33 mg/m ³

- **PAC-2:**

CAS: 64-17-5	ethyl alcohol	3300* ppm
	silane**	780 mg/m ³

(Contd. on page 4)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 10/17/2019

Version US-EN-Rev 2

Reviewed on 10/17/2019

Trade name: G-Multi PRIMER

(Contd. of page 3)

	dimethacrylate component**	360 mg/m ³
· PAC-3:		
CAS: 64-17-5	ethyl alcohol	15000* ppm
	silane**	4,700 mg/m ³
	dimethacrylate component**	2,100 mg/m ³

7 Handling and storage

· Handling:

· Precautions for safe handling

Observe instructions for use.
 Ensure good ventilation/exhaustion at the workplace.
 Prevent formation of aerosols.
 Avoid contact with the eyes and skin.

Use caution when opening. The product is a highly flammable liquid and vapor; keep away from heat, hot surfaces, sparks, flames and other ignitions sources. Use with adequate ventilation. Do not ingest or breathe vapor. Personal Protective Equipment (PPE) such as gloves and safety eyewear are always to be worn. Check bottle with liquid before using. Make sure that upon removal of cap, the bottle opening has no obstructions. Some bottles may contain an insert (as a seal). The insert must be in the cap and not obstructing opening.

In case of contact, flush eyes with water for at least 15 minutes. Get prompt medical attention. If overcome by vapor, move to fresh air. If breathing is difficult, administer oxygen and seek medical attention. If swallowed, dilute by giving water to drink and seek medical attention. In case of contact with skin wash thoroughly with soap and water. Store securely. Store in a well ventilated place. Keep cool. Dispose of all waste according to local regulations.

· Information about protection against explosions and fires:

Keep ignition sources away - Do not smoke.
 Protect from heat.
 Protect against electrostatic charges.
 Do not spray on a naked flame or any incandescent material.

· Conditions for safe storage, including any incompatibilities

· Storage:

· Requirements to be met by storerooms and receptacles:

Store in a cool location.
 Store only in unopened original receptacles.

· Information about storage in one common storage facility: Store away from foodstuffs.

· Further information about storage conditions:

Observe instructions for use / storage.
 Keep receptacle tightly sealed.
 Store in cool, dry conditions in well sealed receptacles.
 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 systems: No further data; see item 7.

(Contd. on page 5)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 10/17/2019

Version US-EN-Rev 2

Reviewed on 10/17/2019

Trade name: G-Multi PRIMER

(Contd. of page 4)

- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.
At this time, the other constituents have no known exposure limits.

CAS: 64-17-5 ethyl alcohol

PEL	Long-term value: 1900 mg/m ³ , 1000 ppm
REL	Long-term value: 1900 mg/m ³ , 1000 ppm
TLV	Short-term value: 1880 mg/m ³ , 1000 ppm

- **Regulatory information**

PEL: Guide to Occupational Exposure Values (OSHA PELs)

REL: Guide to Occupational Exposure Values (NIOSH RELs)

TLV: Guide to Occupational Exposure Values (ACGIH)

- **Additional information:** The lists that were valid during the creation were used as basis.

- **Exposure controls**

- **Personal protective equipment:**

- **General protective and hygienic measures:**

The usual precautionary measures for handling chemicals should be followed.
Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Immediately remove all soiled and contaminated clothing.

- **Breathing equipment:**



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:**



Safety glasses

US
(Contd. on page 6)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 10/17/2019

Version US-EN-Rev 2

Reviewed on 10/17/2019

Trade name: G-Multi PRIMER

(Contd. of page 5)

9 Physical and chemical properties

- Information on basic physical and chemical properties

- General Information

- Appearance:

Form:	Liquid
Color:	Colorless
Odor:	Alcohol-like
Odor threshold:	Not determined.

- pH-value: Not determined.

- Change in condition

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	78 °C (172.4 °F)

- Flash point: 13 °C (55.4 °F)

- Flammability (solid, gaseous): Not applicable.

- Ignition temperature: Undetermined.

- Decomposition temperature: Not determined.

- Auto igniting: Product is not self-igniting.

- Danger of explosion: Product is not explosive. However, formation of explosive air/vapor mixtures are possible.

- Explosion limits:

Lower:	3.5 Vol %
Upper:	15 Vol %

- Vapor pressure: Not determined.

- Density at 20 °C (68 °F): 0.8 g/cm³ (6.68 lbs/gal)

- Relative density: Not determined.

- Vapor density: Not determined.

- Evaporation rate: Not determined.

- Solubility in / Miscibility with

Water:	Soluble.
--------	----------

- Partition coefficient (n-octanol/water): Not determined.

- Viscosity:

Dynamic:	Not determined.
Kinematic:	Not determined.

- Solvent content:

Organic solvents:	92.0 %
VOC content:	92.02 %

Solids content:	0.0 %
-----------------	-------

- Other information: No further relevant information available.

10 Stability and reactivity

- Reactivity: No further relevant information available.

(Contd. on page 7)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 10/17/2019

Version US-EN-Rev 2

Reviewed on 10/17/2019

Trade name: G-Multi PRIMER

(Contd. of page 6)

- **Chemical stability** Stable at ambient temperature.
- **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:**
Carbon dioxide
Carbon monoxide

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **LD/LC50 values that are relevant for classification:** No further relevant information available.
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**
- **Carcinogenic categories**

· IARC (International Agency for Research on Cancer)	
ethyl alcohol	1

· NTP (National Toxicology Program)	
None of the ingredients is listed.	

· OSHA-Ca (Occupational Safety & Health Administration)	
None of the ingredients is listed.	

- **Carcinogenic categories' legend:**

IARC Group 1: The agent is carcinogenic to humans.

IARC Group 2A: The agent is probably carcinogenic to humans.

IARC Group 2B: The agent is possibly carcinogenic to humans.

IARC Group 3: The agent is not classifiable as to its carcinogenicity to humans.

IARC Group 4: The agent is probably not carcinogenic to humans.

NTP K: Known to be human carcinogen.

NTP R: Reasonably anticipated to be human carcinogen.

- **Additional carcinogenic information:**

The substance, ethyl alcohol, also known as ethanol, is listed by IARC as a Group 1 carcinogen but in alcoholic beverage consumption. IARC Volume 100E (2012) "Personal Habits and Indoor Combustions" stated in its monograph "Consumption of Alcoholic Beverages" the following evaluation: "Ethanol in alcoholic beverages is carcinogenic to humans (Group 1)." GC products are not consumable alcoholic beverages.

- **Repeated dose toxicity.** No further relevant information available.

- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**

No further relevant information available.

US

(Contd. on page 8)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 10/17/2019

Version US-EN-Rev 2

Reviewed on 10/17/2019

Trade name: G-Multi PRIMER

(Contd. of page 7)


12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior 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 1 (German regulation, AwSV) (Self-assessment): slightly hazardous to water
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.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Dispose of contents / container in accordance with local / regional / national / international regulations.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

- | | |
|---|--|
| <ul style="list-style-type: none"> · UN-Number · DOT, ADR, IMDG, IATA | <p>UN1170</p> |
| <ul style="list-style-type: none"> · UN proper shipping name · DOT · ADR · IMDG, IATA | <p>Ethanol solutions
1170 ETHANOL SOLUTION
ETHANOL SOLUTION</p> |
| <ul style="list-style-type: none"> · Transport hazard class(es) · DOT | <div style="text-align: center;">  </div> |
| <ul style="list-style-type: none"> · Class | <p>3 Flammable liquids</p> |

(Contd. on page 9)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200



Printing date 10/17/2019

Version US-EN-Rev 2

Reviewed on 10/17/2019

Trade name: G-Multi PRIMER

(Contd. of page 8)

· Label	3
· ADR	
	
· Class	3 (F1) Flammable liquids
· Label	3
· IMDG, IATA	
	
· Class	3 Flammable liquids
· Label	3
· Packing group	
· DOT, ADR, IMDG, IATA	II
· Environmental hazards:	Not applicable.
· Special precautions for user	Warning: Flammable liquids
· Danger code (Kemler):	30
· EMS Number:	F-E, S-D
· Stowage Category	A
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR	
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· IMDG	
· Limited quantities (LQ)	1L
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 1170 ETHANOL SOLUTION, 3, II

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
- SARA (Superfund Amendments and Reauthorization Act)

· Section 355 (extremely hazardous substances):

None of the ingredients is listed.

(Contd. on page 10)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 10/17/2019

Version US-EN-Rev 2

Reviewed on 10/17/2019

Trade name: G-Multi PRIMER

(Contd. of page 9)

· Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

· TSCA (Toxic Substances Control Act):

ethyl alcohol	ACTIVE
silane**	ACTIVE
dimethacrylate component**	ACTIVE
methacrylate**	ACTIVE

· Hazardous Air Pollutants

None of the ingredients is listed.

· Proposition 65**· Chemicals known to cause cancer:**

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

The substance ethyl alcohol, also known as ethanol, is on California's Proposition 65 list of "Chemicals Known to the State To Cause Cancer or Reproductive Toxicity" as a developmental toxicant but as "ethyl alcohol in alcoholic beverages." GC products are not consumable alcoholic beverages.

ethyl alcohol

· Carcinogenic categories**· EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· EPA carcinogenic categories' legend:

EPA weight-of-evidence (WoE): official codes and categories from EPA's 1986 guidelines and unofficial, derived codes from EPA's standard hazard descriptors from 1996, 1999, and 2005 guidelines
 A: human carcinogen (1986)

B1: probable human carcinogen – based on limited evidence of carcinogenicity in humans (1986)

B2: probable human carcinogen – based on sufficient evidence of carcinogenicity in animals (1986)

C: possible human carcinogen (1986)

D: not classifiable as to human carcinogenicity (1986)

E: evidence of non-carcinogenicity for humans (1986)

CaH: carcinogenic to humans

CBD: carcinogenic potential cannot be determined

I: data are inadequate for an assessment of human carcinogenic potential

II: inadequate information to assess carcinogenic potential

K/L: known/likely human carcinogen

L: likely to be carcinogenic to humans

NL: not likely to be carcinogenic to humans

S: suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential

SC: suggestive evidence of carcinogenic potential

· TLV (Threshold Limit Value established by ACGIH)

ethyl alcohol A3

· ACGIH carcinogenic categories' legend:

A1: confirmed human carcinogen

A2: suspected human carcinogen

A3: confirmed animal carcinogen with unknown relevance to humans

(Contd. on page 11)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 10/17/2019

Version US-EN-Rev 2

Reviewed on 10/17/2019

Trade name: G-Multi PRIMER

(Contd. of page 10)

A4: not classifiable as a human carcinogen

A5: not suspected as a human carcinogen

NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

- **GHS label elements**

Exempt from labeling – medical devices and drugs do not require labeling according to HCS 2012.

The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**



- **Signal word** Danger

- **Hazard-determining components of labeling:**

dimethacrylate component**

- **Hazard statements**

Highly flammable liquid and vapor.

May cause an allergic skin reaction.

- **Precautionary statements**

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

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

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

If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

Store in a well-ventilated place. Keep cool.

Dispose of contents/container in accordance with local/regional/national/international regulations.

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

16 Other information

- **Department issuing SDS:** Regulatory Affairs

- **Contact:**

Regulatory Affairs

Telephone No. +1 (708) 597-0900

SDS.gcamerica@gc.dental

- **Date of preparation / last revision** 10/17/2019 / 1

- **Abbreviations and acronyms:**

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

HCS: Hazard Communication Standard (USA)

MSDS: Material Safety Data Sheet

SDS: Safety Data Sheet

ECHA: European Chemicals Agency

OSHA: Occupational Safety and Health Administration (USA)

PAC: Protective Action Criterion (USA)

PACs: Protective Action Criteria (USA)

HNOC: Hazard Not Otherwise Classified (USA)

LEL: Lower Explosive Limit

UEL: Upper Explosive Limit

OSHA-Ca: Occupational Safety and Health Administration – Carcinogens or potential carcinogens regulated (USA)

NIOSH-Ca: National Institute for Occupational Safety and Health – Carcinogen List (USA)

NIOSH: National Institute for Occupational Safety and Health (USA)

TSCA: Toxic Substances Control Act (USA)

AwSV: Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (Ordinance on facilities for handling substances that are hazardous to water) (Germany)

(Contd. on page 12)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 10/17/2019

Version US-EN-Rev 2

Reviewed on 10/17/2019

Trade name: G-Multi PRIMER

(Contd. of page 11)

NOEC: No Observed Effect Concentration

ADR: Accord européen relatif au transport international des marchandises dangereuses par route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG Code: International Maritime Dangerous Goods Code

DOT: Department of Transportation (USA)

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Flam. Liq. 2: Flammable liquids – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

Sources

- Manufacturers' MSDSs/SDSs
- OSHA (<https://www.osha.gov/dts/chemicalsampling/toc/chmcas.html>)
- TOXNET (<http://toxnet.nlm.nih.gov/>)
- ECHA (<http://echa.europa.eu/>)
- EnviChem (www.echemportal.org)

Notes:

CAS Registry Number® is a Registered Trademark of the American Chemical Society.

CHEMTREC® is a registered service mark of the American Chemistry Council, Inc.

- *** Data compared to the previous version altered.** This version replaces all previous versions.

Disclaimer:

The information contained herein is believed to be true and accurate. However, all statements, recommendations or suggestions are made without any guarantee, representation or warranty, express or implied, on our part. Therefore, no warranty is made or to be implied that the information set out in this document is accurate or complete, and we accordingly exclude all liability in connection with the use of this information or the products referred to herein. All such risks are assumed by the purchaser/user. The information contained herein is also subject to change without notice. For the avoidance of doubt, however, nothing in this document excludes or limits our liability for death or personal injury caused by our negligence or for fraudulent misrepresentation.

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/07/2021

Version US-EN-Rev 1

Reviewed on 02/07/2021

1 Identification

- **Product identifier**

- **Trade name:** G-CEM ONE™ (Paste B)

- **Relevant identified uses of the substance or mixture and uses advised against**

Dental material

The product is intended for professional use.

To avoid risks for humans and environment obtain instructions.

- **Application of the substance / the mixture** Dental cement

- **Details of the supplier of the safety data sheet**

- **Manufacturer/Supplier:**

GC America Inc.

3737 W. 127th Street

Alsip, IL 60803

USA

SDS.gcamerica@gc.dental

- **Information department:** Regulatory Affairs

- **Emergency telephone number:**

During normal opening times (Monday–Friday 8:00 AM–5:00 PM Central Time): +1 (708) 597-0900

Transportation (CHEMTREC®) Emergency Telephone No. +1 (800) 424-9300

2 Hazard(s) identification

- **Classification of the substance or mixture**

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2A H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure.

- **Additional information:**

The information provided is in regards to the toxicity and hazard rating(s) of the individual component(s) in the formulation. The associated risk(s) depends on the route(s) of exposure. The hazard rating system is based entirely on the existence of the risk(s) and does not take into account the likelihood of reduced risk(s) through proper usage and handling.

Avoid use of this product in patients with known allergies to methacrylate monomer or methacrylate polymer.

- **Label elements**

- **GHS label elements**

Exempt from labeling – medical devices and drugs do not require labeling according to HCS 2012.

The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**



- **Signal word** Warning

(Contd. on page 2)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/07/2021

Version US-EN-Rev 1

Reviewed on 02/07/2021

Trade name: G-CEM ONE™ (Paste B)

(Contd. of page 1)

- **Hazard-determining components of labeling:**

urethane dimethacrylate (UDMA)

initiator**

- **Hazard statements**

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

May cause damage to organs through prolonged or repeated exposure.

- **Precautionary statements**

Do not breathe dust/fume/gas/mist/vapors/spray.

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

Wear protective gloves / 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.

Wash contaminated clothing before reuse.

Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Hazard(s) not otherwise classified (HNOC):** None known.

- **Additional information:**

17.5 % of the mixture consists of component(s) of unknown toxicity.

- **Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**

- **Description:** Mixture of the substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 72869-86-4	urethane dimethacrylate (UDMA)	25 – < 50%
	dimethacrylate**	5 – < 10%
	phosphoric acid ester monomer**	2.5 – < 5%
	initiator**	1 – < 2.5%
	stabilizer**	0.2 – < 0.5%

- **Additional information:**

Concentrations of dangerous components are expressed in percent by weight (% w/w).

If a substance is marked with **, then substance is a trade secret. This is allowed under OSHA's Hazard Communication Standard (HCS) as a trade secret and under GHS as Confidential Business Information (CBI).

4 First-aid measures

- **Description of first aid measures**

- **General information:**

Immediately remove any clothing soiled by the product.

If symptoms persist consult doctor.

(Contd. on page 3)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/07/2021

Version US-EN-Rev 1

Reviewed on 02/07/2021

Trade name: G-CEM ONE™ (Paste B)

(Contd. of page 2)

- **After inhalation:**
Supply fresh air; consult doctor in case of complaints.
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:**
Immediately wash with water and soap and rinse thoroughly.
Seek medical treatment.
- **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

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire fighting measures that suit the environment.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **Special hazards arising from the substance or mixture**
In case of fire, the following can be released:
Carbon monoxide (CO)
Nitrogen oxides (NO_x)
Carbon dioxide
- **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:**
Absorb liquid components with liquid-binding material.
Dispose of the collected material according to regulations.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.

(Contd. on page 4)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/07/2021

Version US-EN-Rev 1

Reviewed on 02/07/2021

Trade name: G-CEM ONE™ (Paste B)

(Contd. of page 3)

See Section 13 for disposal information.

- **Protective Action Criteria for Chemicals**

Protective Action Criterion (PAC); Protective Action Criteria (PACs); Lower Explosive Limit (LEL)

* indicates the PAC value is between 10% and up to 50% of the LEL ($10\% \text{ LEL} \leq \text{PAC} < 50\% \text{ LEL}$).** indicates the PAC value is between 50% and up to 100% of the LEL ($50\% \text{ LEL} \leq \text{PAC} < 100\% \text{ LEL}$).*** indicates the PAC value is at 100% or more of the LEL ($\text{PAC} \geq \text{LEL}$).

excerpt from Introduction to PAC Table 2 – PAC Rev. 29 – May 2016

- **PAC-1:**

CAS: 72869-86-4	urethane dimethacrylate (UDMA)	120 mg/m ³
	silane**	71 mg/m ³
	initiator**	0.15 ppm
CAS: 6381-92-6	ethylene diaminetetraacetic acid sodium salt	30 mg/m ³

- **PAC-2:**

CAS: 72869-86-4	urethane dimethacrylate (UDMA)	1,300 mg/m ³
	silane**	780 mg/m ³
	initiator**	1.6 ppm
CAS: 6381-92-6	ethylene diaminetetraacetic acid sodium salt	330 mg/m ³

- **PAC-3:**

CAS: 72869-86-4	urethane dimethacrylate (UDMA)	7,900 mg/m ³
	silane**	4,700 mg/m ³
	initiator**	9.7 ppm
CAS: 6381-92-6	ethylene diaminetetraacetic acid sodium salt	2,000 mg/m ³

7 Handling and storage

- **Handling:**

- **Precautions for safe handling**

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

Observe instructions for use.

Avoid contact with the eyes and skin.

- **Information about protection against explosions and fires:** 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:**

Observe instructions for use / storage.

Keep receptacle tightly sealed.

- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.

(Contd. on page 5)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/07/2021

Version US-EN-Rev 1

Reviewed on 02/07/2021

Trade name: G-CEM ONE™ (Paste B)

(Contd. of page 4)

- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.
At this time, the other constituents have no known exposure limits.

initiator**

WHEEL	Long-term value: 6 mg/m ³ , 1 ppm
Skin	

- **Regulatory information WHEEL:** Guide to Occupational Exposure Values (AIHA WHEELs)
- **Additional information:** The lists that were valid during the creation were used as basis.

- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
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.
- **Breathing equipment:**



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:**



Safety glasses

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**
Form: Pasty

(Contd. on page 6)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/07/2021

Version US-EN-Rev 1

Reviewed on 02/07/2021

Trade name: G-CEM ONE™ (Paste B)

(Contd. of page 5)

· Color:	According to product specification
· Odor:	Characteristic
· Odor threshold:	Not determined.
· pH-value:	Not determined.
· Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	283 °C (541.4 °F)
· Flash point:	> 100 °C (> 212 °F)
· Flammability (solid, gaseous):	Not applicable.
· Ignition temperature:	Undetermined.
· Decomposition temperature:	Not determined.
· Auto igniting:	Product is not self-igniting.
· Danger of explosion:	Not determined.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapor pressure:	Not determined.
· Density:	Not determined.
· Relative density	Not determined.
· Vapor density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with Water:	Insoluble.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
VOC content:	0.00 %
Solids content:	48.7 %
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability** Stable at ambient temperature.
- **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.

(Contd. on page 7)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/07/2021

Version US-EN-Rev 1

Reviewed on 02/07/2021

Trade name: G-CEM ONE™ (Paste B)

(Contd. of page 6)

- **Hazardous decomposition products:**
Carbon dioxide
Carbon monoxide

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

- **LD/LC50 values that are relevant for classification:**

stabilizer**

Oral	LD50	530 mg/kg (mouse) 910 mg/kg (rat male) (OECD 401)
Dermal	LD50	50 mg/kg (rabbit) (OECD 402)

- **Primary irritant effect:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** Irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Symptoms related to the physical, chemical and toxicological characteristics:** Allergic reactions
- **Subacute to chronic toxicity:** No further relevant information available.
- **Numerical measures of toxicity:**
ATEmix (Oral) is 31 534 mg/kg bodyweight.
ATEmix (Dermal) is 12 230 mg/kg bodyweight.
ATEmix (Inhalation) is 18 161 mg/l (for vapors).
ATEmix is the acute toxicity estimate of the mixture.
- **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

silica, vitreous

3

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

- **Carcinogenic categories' legend:**

IARC Group 1: The agent is carcinogenic to humans.
 IARC Group 2A: The agent is probably carcinogenic to humans.
 IARC Group 2B: The agent is possibly carcinogenic to humans.
 IARC Group 3: The agent is not classifiable as to its carcinogenicity to humans.
 IARC Group 4: The agent is probably not carcinogenic to humans.
 NTP K: Known to be human carcinogen.
 NTP R: Reasonably anticipated to be human carcinogen.

- **Additional carcinogenic information:**

- **Repeated dose toxicity.** May cause damage to organs through prolonged or repeated exposure.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** No further relevant information available.
- **Carcinogenicity** No further relevant information available.

(Contd. on page 8)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/07/2021

Version US-EN-Rev 1

Reviewed on 02/07/2021

Trade name: G-CEM ONE™ (Paste B)

(Contd. of page 7)

- **Reproductive toxicity** No further relevant information available.
- **Specific target organ toxicity - single exposure** No further relevant information available.
- **Specific target organ toxicity - repeated exposure** No further relevant information available.
- **Aspiration hazard** No further relevant information available.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior 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, AwSV) (Self-assessment): clearly hazardous to 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:**
Dispose of contents / container in accordance with local / regional / national / international regulations.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|---------------------------------------|-----------------|
| · UN-Number | |
| · DOT, ADR, IMDG, IATA | Not regulated. |
| · UN proper shipping name | |
| · DOT, ADR, IMDG, IATA | Not regulated. |
| · Transport hazard class(es) | |
| · DOT, ADR, ADN, IMDG, IATA | |
| · Class | Not regulated. |
| · Packing group | |
| · DOT, ADR, IMDG, IATA | Not regulated. |
| · Environmental hazards: | Not applicable. |
| · Special precautions for user | Not applicable. |

(Contd. on page 9)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/07/2021

Version US-EN-Rev 1

Reviewed on 02/07/2021

Trade name: G-CEM ONE™ (Paste B)

(Contd. of page 8)

- | | |
|--|-----------------|
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | Not regulated. |

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
- SARA (Superfund Amendments and Reauthorization Act)

· Section 355 (extremely hazardous substances):

None of the ingredients is listed.

· Section 313 (Specific toxic chemical listings):

initiator**

· TSCA (Toxic Substances Control Act):

silica, vitreous	ACTIVE
urethane dimethacrylate (UDMA)	ACTIVE
dimethacrylate**	ACTIVE
surface-treated silica**	ACTIVE
silane**	ACTIVE
initiator**	ACTIVE
stabilizer**	ACTIVE

· Additional information:

If a substance is marked with **, then substance is a trade secret. This is allowed under OSHA's Hazard Communication Standard (HCS) as a trade secret and under GHS as Confidential Business Information (CBI).

· Hazardous Air Pollutants

None of the ingredients is listed.

· Proposition 65

· Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Carcinogenic categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

· EPA carcinogenic categories' legend:

EPA weight-of-evidence (WoE): official codes and categories from EPA's 1986 guidelines and unofficial, derived codes from EPA's standard hazard descriptors from 1996, 1999, and 2005 guidelines
 A: human carcinogen (1986)
 B1: probable human carcinogen – based on limited evidence of carcinogenicity in humans (1986)

(Contd. on page 10)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/07/2021

Version US-EN-Rev 1

Reviewed on 02/07/2021

Trade name: G-CEM ONE™ (Paste B)

(Contd. of page 9)

B2: probable human carcinogen – based on sufficient evidence of carcinogenicity in animals (1986)
 C: possible human carcinogen (1986)
 D: not classifiable as to human carcinogenicity (1986)
 E: evidence of non-carcinogenicity for humans (1986)
 CaH: carcinogenic to humans
 CBD: carcinogenic potential cannot be determined
 I: data are inadequate for an assessment of human carcinogenic potential
 II: inadequate information to assess carcinogenic potential
 K/L: known/likely human carcinogen
 L: likely to be carcinogenic to humans
 NL: not likely to be carcinogenic to humans
 S: suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential
 SC: suggestive evidence of carcinogenic potential

TLV (Threshold Limit Value)

None of the ingredients is listed.

ACGIH carcinogenic categories' legend:

A1: confirmed human carcinogen
 A2: suspected human carcinogen
 A3: confirmed animal carcinogen with unknown relevance to humans
 A4: not classifiable as a human carcinogen
 A5: not suspected as a human carcinogen

NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

GHS label elements

Exempt from labeling – medical devices and drugs do not require labeling according to HCS 2012.
 The product is classified and labeled according to the Globally Harmonized System (GHS).

Hazard pictograms

Signal word Warning

Hazard-determining components of labeling:

urethane dimethacrylate (UDMA)
initiator**

Hazard statements

Causes skin irritation.
 Causes serious eye irritation.
 May cause an allergic skin reaction.
 May cause damage to organs through prolonged or repeated exposure.

Precautionary statements

Do not breathe dust/fume/gas/mist/vapors/spray.
 Contaminated work clothing must not be allowed out of the workplace.
 Wear protective gloves / 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.
 Wash contaminated clothing before reuse.
 Dispose of contents/container in accordance with local/regional/national/international regulations.

(Contd. on page 11)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/07/2021

Version US-EN-Rev 1

Reviewed on 02/07/2021

Trade name: G-CEM ONE™ (Paste B)

(Contd. of page 10)

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

16 Other information

- **Department issuing SDS:** Regulatory Affairs
- **Contact:**
Regulatory Affairs
Telephone No. +1 (708) 597-0900
SDS.gcamerica@gc.dental
- **Date of preparation / last revision** 02/07/2021 / -
- **Abbreviations and acronyms:**
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
HCS: Hazard Communication Standard (USA)
MSDS: Material Safety Data Sheet
SDS: Safety Data Sheet
ADN: Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ECHA: European Chemicals Agency
OSHA: Occupational Safety and Health Administration (USA)
PAC: Protective Action Criterion (USA)
PACs: Protective Action Criteria (USA)
HNOC: Hazard Not Otherwise Classified (USA)
LEL: Lower Explosive Limit
UEL: Upper Explosive Limit
OSHA-Ca: Occupational Safety and Health Administration – Carcinogens or potential carcinogens regulated (USA)
NIOSH-Ca: National Institute for Occupational Safety and Health – Carcinogen List (USA)
NIOSH: National Institute for Occupational Safety and Health (USA)
TSCA: Toxic Substances Control Act (USA)
AwSV: Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (Ordinance on facilities for handling substances that are hazardous to water) (Germany)
NOEC: No Observed Effect Concentration
ADR: Accord européen relatif au transport international des marchandises dangereuses par route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
OECD: Organization for Economic Cooperation and Development
IMDG Code: International Maritime Dangerous Goods Code
DOT: Department of Transportation (USA)
IATA: International Air Transport Association
CAS: Chemical Abstracts Service (division of the American Chemical Society)
VOC: Volatile Organic Compounds (USA, EU)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
Skin Sens. 1: Skin sensitisation – Category 1
STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2
- **Sources**
 - Manufacturers' MSDSs/SDSs
 - OSHA (<https://www.osha.gov/dts/chemicalsampling/toc/chmcas.html>)
 - PubChem (<https://pubchem.ncbi.nlm.nih.gov/>)
 - ECHA (<http://echa.europa.eu/>)
 - EnviChem (www.echemportal.org)
- **Notes:**
CAS Registry Number® is a Registered Trademark of the American Chemical Society.
CHEMTREC® is a registered service mark of the American Chemistry Council, Inc.

(Contd. on page 12)

Safety Data Sheet
acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/07/2021

Version US-EN-Rev 1

Reviewed on 02/07/2021

Trade name: G-CEM ONE™ (Paste B)

(Contd. of page 11)

Disclaimer:

The information contained herein is believed to be true and accurate. However, all statements, recommendations or suggestions are made without any guarantee, representation or warranty, express or implied, on our part. Therefore, no warranty is made or to be implied that the information set out in this document is accurate or complete, and we accordingly exclude all liability in connection with the use of this information or the products referred to herein. All such risks are assumed by the purchaser/user. The information contained herein is also subject to change without notice. For the avoidance of doubt, however, nothing in this document excludes or limits our liability for death or personal injury caused by our negligence or for fraudulent misrepresentation.

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/07/2021

Version US-EN-Rev 1

Reviewed on 02/07/2021


1 Identification

- **Product identifier**
- **Trade name:** G-CEM ONE™ (Paste A, Shades: A2, AO3, BO1, Translucent, and White opaque)
- **Relevant identified uses of the substance or mixture and uses advised against**
Dental material
The product is intended for professional use.
To avoid risks for humans and environment obtain instructions.
- **Application of the substance / the mixture** Dental cement
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
GC America Inc.
3737 W. 127th Street
Alsip, IL 60803
USA

SDS.gcamerica@gc.dental
- **Information department:** Regulatory Affairs
- **Emergency telephone number:**
During normal opening times (Monday–Friday 8:00 AM–5:00 PM Central Time): +1 (708) 597-0900
Transportation (CHEMTREC®) Emergency Telephone No. +1 (800) 424-9300

2 Hazard(s) identification

- **Classification of the substance or mixture**
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2A H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
Repr. 1B H360 May damage fertility or the unborn child.
- **Additional information:**
The information provided is in regards to the toxicity and hazard rating(s) of the individual component(s) in the formulation. The associated risk(s) depends on the route(s) of exposure. The hazard rating system is based entirely on the existence of the risk(s) and does not take into account the likelihood of reduced risk(s) through proper usage and handling.

Avoid use of this product in patients with known allergies to methacrylate monomer or methacrylate polymer.
- **Label elements**
- **GHS label elements**
Exempt from labeling – medical devices and drugs do not require labeling according to HCS 2012.
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**

- **Signal word** Danger

(Contd. on page 2)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/07/2021

Version US-EN-Rev 1

Reviewed on 02/07/2021

Trade name: G-CEM ONE™ (Paste A, Shades: A2, AO3, BO1, Translucent, and White opaque)

(Contd. of page 1)

- **Hazard-determining components of labeling:**

urethane dimethacrylate (UDMA)

synergist**

- **Hazard statements**

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

May damage fertility or the unborn child.

- **Precautionary statements**

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.

If exposed or concerned: Get medical advice/attention.

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.

- **Hazard(s) not otherwise classified (HNOC):** None known.

- **Additional information:**

20.4 % of the mixture consists of component(s) of unknown toxicity.

- **Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**

- **Description:** Mixture of the substances listed below with nonhazardous additions.

- **Dangerous components:**

	dimethacrylate**	10 – < 25%
CAS: 72869-86-4	urethane dimethacrylate (UDMA)	10 – < 25%
CAS: 13463-67-7	titanium dioxide	1 – < 2.5%
	monomer**	0.2 – < 0.5%
	synergist**	0.2 – < 0.5%
	photoinitiator**	0.2 – < 0.5%
	stabilizer**	0.1 – < 0.2%
	initiator**	0.1 – < 0.2%

- **Additional information:**

Concentrations of dangerous components are expressed in percent by weight (% w/w).

If a substance is marked with **, then substance is a trade secret. This is allowed under OSHA's Hazard Communication Standard (HCS) as a trade secret and under GHS as Confidential Business Information (CBI).

US

(Contd. on page 3)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/07/2021

Version US-EN-Rev 1

Reviewed on 02/07/2021

Trade name: G-CEM ONE™ (Paste A, Shades: A2, AO3, BO1, Translucent, and White opaque)

(Contd. of page 2)

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; consult doctor in case of complaints.
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:**
Immediately wash with water and soap and rinse thoroughly.
Seek medical treatment.
- **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

- **Extinguishing media**
- **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**
In case of fire, the following can be released:
Carbon monoxide (CO)
Nitrogen oxides (NOx)
Carbon dioxide
- **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.
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 collected material according to regulations.

(Contd. on page 4)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/07/2021

Version US-EN-Rev 1

Reviewed on 02/07/2021

Trade name: G-CEM ONE™ (Paste A, Shades: A2, AO3, BO1, Translucent, and White opaque)

(Contd. of page 3)

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.

Protective Action Criteria for Chemicals

Protective Action Criterion (PAC); Protective Action Criteria (PACs); Lower Explosive Limit (LEL)

* indicates the PAC value is between 10% and up to 50% of the LEL ($10\% \text{ LEL} \leq \text{PAC} < 50\% \text{ LEL}$).** indicates the PAC value is between 50% and up to 100% of the LEL ($50\% \text{ LEL} \leq \text{PAC} < 100\% \text{ LEL}$).*** indicates the PAC value is at 100% or more of the LEL ($\text{PAC} \geq \text{LEL}$).

excerpt from Introduction to PAC Table 2 – PAC Rev. 29 – May 2016

PAC-1:

CAS: 65997-17-3	glass, oxide, chemicals	15 mg/m ³
CAS: 72869-86-4	urethane dimethacrylate (UDMA)	120 mg/m ³
	silane**	71 mg/m ³
CAS: 13463-67-7	titanium dioxide	30 mg/m ³
	colorant**	15 mg/m ³
CAS: 20344-49-4	iron hydroxide oxide	24 mg/m ³

PAC-2:

CAS: 65997-17-3	glass, oxide, chemicals	170 mg/m ³
CAS: 72869-86-4	urethane dimethacrylate (UDMA)	1,300 mg/m ³
	silane**	780 mg/m ³
CAS: 13463-67-7	titanium dioxide	330 mg/m ³
	colorant**	360 mg/m ³
CAS: 20344-49-4	iron hydroxide oxide	260 mg/m ³

PAC-3:

CAS: 65997-17-3	glass, oxide, chemicals	990 mg/m ³
CAS: 72869-86-4	urethane dimethacrylate (UDMA)	7,900 mg/m ³
	silane**	4,700 mg/m ³
CAS: 13463-67-7	titanium dioxide	2,000 mg/m ³
	colorant**	2,200 mg/m ³
CAS: 20344-49-4	iron hydroxide oxide	1,600 mg/m ³

7 Handling and storage

Handling:
Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

Observe instructions for use.

Avoid contact with the eyes and skin.

Information about protection against explosions and fires: Protect against electrostatic charges.

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.

(Contd. on page 5)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/07/2021

Version US-EN-Rev 1

Reviewed on 02/07/2021

Trade name: G-CEM ONE™ (Paste A, Shades: A2, AO3, BO1, Translucent, and White opaque)

(Contd. of page 4)

- **Further information about storage conditions:** Observe instructions for use / storage.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components 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.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
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.
- **Breathing equipment:**



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:**



Safety glasses

US

(Contd. on page 6)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/07/2021

Version US-EN-Rev 1

Reviewed on 02/07/2021

Trade name: G-CEM ONE™ (Paste A, Shades: A2, AO3, BO1, Translucent, and White opaque)

(Contd. of page 5)

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

Form:	Pasty
Color:	According to product specification
Odor:	Characteristic
Odor threshold:	Not determined.

· pH-value: Not determined.

· Change in condition

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	283 °C (541.4 °F)

· Flash point: > 100 °C (> 212 °F)

· Flammability (solid, gaseous): Not applicable.

· Ignition temperature: Undetermined.

· Decomposition temperature: Not determined.

· Auto igniting: Product is not self-igniting.

· Danger of explosion: Not determined.

· Explosion limits:

Lower:	Not determined.
Upper:	Not determined.

· Vapor pressure: Not determined.

· Density: Not determined.

· Relative density: Not determined.

· Vapor density: Not determined.

· Evaporation rate: Not determined.

· Solubility in / Miscibility with

Water: Insoluble.

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

· Viscosity:

Dynamic:	Not determined.
Kinematic:	Not determined.

· Solvent content:

VOC content: 0.00 %

Solids content: 69.6 %

· Other information: No further relevant information available.

10 Stability and reactivity

· **Reactivity** No further relevant information available.

· **Chemical stability** Stable at ambient temperature.

(Contd. on page 7)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/07/2021

Version US-EN-Rev 1

Reviewed on 02/07/2021

Trade name: G-CEM ONE™ (Paste A, Shades: A2, AO3, BO1, Translucent, and White opaque)

(Contd. of page 6)

- **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:**
Carbon dioxide
Carbon monoxide

11 Toxicological information

· Information on toxicological effects

· Acute toxicity:

· LD/LC50 values that are relevant for classification:

stabilizer**

Oral	LD50	530 mg/kg (mouse)
		910 mg/kg (rat male) (OECD 401)
Dermal	LD50	50 mg/kg (rabbit) (OECD 402)

· Primary irritant effect:

· **on the skin:** Irritant to skin and mucous membranes.

· **on the eye:** Irritating effect.

· **Sensitization:** Sensitization possible through skin contact.

· **Symptoms related to the physical, chemical and toxicological characteristics:** Allergic reactions

· **Subacute to chronic toxicity:** No further relevant information available.

· Numerical measures of toxicity:

ATEmix (Oral) is 17 689 mg/kg bodyweight.

ATEmix (Dermal) is 26 383 mg/kg bodyweight.

ATEmix is the acute toxicity estimate of the mixture.

· Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations:

Irritant

· Carcinogenic categories

· IARC (International Agency for Research on Cancer)

titanium dioxide	2B
colorant**	3

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

· Carcinogenic categories' legend:

IARC Group 1: The agent is carcinogenic to humans.

IARC Group 2A: The agent is probably carcinogenic to humans.

IARC Group 2B: The agent is possibly carcinogenic to humans.

IARC Group 3: The agent is not classifiable as to its carcinogenicity to humans.

IARC Group 4: The agent is probably not carcinogenic to humans.

NTP K: Known to be human carcinogen.

NTP R: Reasonably anticipated to be human carcinogen.

(Contd. on page 8)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/07/2021

Version US-EN-Rev 1

Reviewed on 02/07/2021

Trade name: G-CEM ONE™ (Paste A, Shades: A2, AO3, BO1, Translucent, and White opaque)

(Contd. of page 7)

- **Additional carcinogenic information:**
- **Repeated dose toxicity.** No further relevant information available.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
Repr. 1B
- **Germ cell mutagenicity** No further relevant information available.
- **Carcinogenicity** No further relevant information available.
- **Reproductive toxicity** No further relevant information available.
- **Specific target organ toxicity - single exposure** No further relevant information available.
- **Specific target organ toxicity - repeated exposure** No further relevant information available.
- **Aspiration hazard** No further relevant information available.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior 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 1 (German regulation, AwSV) (Self-assessment): slightly hazardous to water
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.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Dispose of contents / container in accordance with local / regional / national / international regulations.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|---|----------------|
| <ul style="list-style-type: none"> · UN-Number · DOT, ADR, IMDG, IATA | Not regulated. |
| <ul style="list-style-type: none"> · UN proper shipping name · DOT, ADR, IMDG, IATA | Not regulated. |
| <ul style="list-style-type: none"> · Transport hazard class(es) · DOT, ADR, ADN, IMDG, IATA · Class | Not regulated. |

(Contd. on page 9)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/07/2021

Version US-EN-Rev 1

Reviewed on 02/07/2021

Trade name: G-CEM ONE™ (Paste A, Shades: A2, AO3, BO1, Translucent, and White opaque)

(Contd. of page 8)

- | | |
|--|-----------------|
| · Packing group | |
| · DOT, ADR, IMDG, IATA | Not regulated. |
| · Environmental hazards: | Not applicable. |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | Not regulated. |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **SARA (Superfund Amendments and Reauthorization Act)**

- **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

- **Section 313 (Specific toxic chemical listings):**

initiator**

- **TSCA (Toxic Substances Control Act):**

glass, oxide, chemicals	ACTIVE
dimethacrylate**	ACTIVE
urethane dimethacrylate (UDMA)	ACTIVE
surface-treated silica**	ACTIVE
silane**	ACTIVE
titanium dioxide	ACTIVE
photoinitiator**	ACTIVE
synergist**	ACTIVE
photoinitiator**	ACTIVE
stabilizer**	ACTIVE
initiator**	ACTIVE
colorant**	ACTIVE
iron hydroxide oxide	ACTIVE

- **Additional information:**

If a substance is marked with **, then substance is a trade secret. This is allowed under OSHA's Hazard Communication Standard (HCS) as a trade secret and under GHS as Confidential Business Information (CBI).

- **Hazardous Air Pollutants**

None of the ingredients is listed.

- **Proposition 65**

- **Chemicals known to cause cancer:**

Titanium dioxide (TiO₂) is on California's Proposition 65 list of chemicals but only in the form of airborne, unbound particles of respirable size. Particles of respirable size have an aerodynamic diameter of less than or equal to 10 micrometers (≤10 µm). These sized particles are particulate matter (PM) known as PM₁₀.

(Contd. on page 10)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/07/2021

Version US-EN-Rev 1

Reviewed on 02/07/2021

Trade name: G-CEM ONE™ (Paste A, Shades: A2, AO3, BO1, Translucent, and White opaque)

(Contd. of page 9)

This GC product does contain titanium dioxide but not in the form of airborne, unbound particles. Titanium dioxide is wetted out in a paste.

titanium dioxide

Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

Carcinogenic categories
EPA (Environmental Protection Agency)

None of the ingredients is listed.

EPA carcinogenic categories' legend:

EPA weight-of-evidence (WoE): official codes and categories from EPA's 1986 guidelines and unofficial, derived codes from EPA's standard hazard descriptors from 1996, 1999, and 2005 guidelines

A: human carcinogen (1986)

B1: probable human carcinogen – based on limited evidence of carcinogenicity in humans (1986)

B2: probable human carcinogen – based on sufficient evidence of carcinogenicity in animals (1986)

C: possible human carcinogen (1986)

D: not classifiable as to human carcinogenicity (1986)

E: evidence of non-carcinogenicity for humans (1986)

CaH: carcinogenic to humans

CBD: carcinogenic potential cannot be determined

I: data are inadequate for an assessment of human carcinogenic potential

II: inadequate information to assess carcinogenic potential

K/L: known/likely human carcinogen

L: likely to be carcinogenic to humans

NL: not likely to be carcinogenic to humans

S: suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential

SC: suggestive evidence of carcinogenic potential

TLV (Threshold Limit Value)

titanium dioxide

A4

colorant**

A4

ACGIH carcinogenic categories' legend:

A1: confirmed human carcinogen

A2: suspected human carcinogen

A3: confirmed animal carcinogen with unknown relevance to humans

A4: not classifiable as a human carcinogen

A5: not suspected as a human carcinogen

NIOSH-Ca (National Institute for Occupational Safety and Health)

Titanium dioxide (TiO₂) is on the NIOSH-Ca list as a potential occupational carcinogen from occupational exposures by inhalation.

This GC product does contain titanium dioxide but not in the form of inhalable particles. Titanium dioxide is wetted out in a paste.

titanium dioxide

GHS label elements

Exempt from labeling – medical devices and drugs do not require labeling according to HCS 2012.

The product is classified and labeled according to the Globally Harmonized System (GHS).

(Contd. on page 11)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/07/2021

Version US-EN-Rev 1

Reviewed on 02/07/2021

Trade name: G-CEM ONE™ (Paste A, Shades: A2, AO3, BO1, Translucent, and White opaque)

(Contd. of page 10)

· Hazard pictograms

· Signal word Danger

· Hazard-determining components of labeling:

 urethane dimethacrylate (UDMA)
 synergist**

· Hazard statements

 Causes skin irritation.
 Causes serious eye irritation.
 May cause an allergic skin reaction.
 May damage fertility or the unborn child.

· Precautionary statements

 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.
 IF exposed or concerned: Get medical advice/attention.
 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.
· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

· Department issuing SDS: Regulatory Affairs

· Contact:

 Regulatory Affairs
 Telephone No. +1 (708) 597-0900
 SDS.gcamerica@gc.dental

· Date of preparation / last revision 02/07/2021 / -

· Abbreviations and acronyms:

 GHS: Globally Harmonized System of Classification and Labelling of Chemicals
 HCS: Hazard Communication Standard (USA)
 MSDS: Material Safety Data Sheet
 SDS: Safety Data Sheet
 ADN: Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
 ECHA: European Chemicals Agency
 OSHA: Occupational Safety and Health Administration (USA)
 PAC: Protective Action Criterion (USA)
 PACs: Protective Action Criteria (USA)
 HNOC: Hazard Not Otherwise Classified (USA)
 LEL: Lower Explosive Limit
 UEL: Upper Explosive Limit
 OSHA-Ca: Occupational Safety and Health Administration – Carcinogens or potential carcinogens regulated (USA)
 NIOSH-Ca: National Institute for Occupational Safety and Health – Carcinogen List (USA)
 NIOSH: National Institute for Occupational Safety and Health (USA)
 TSCA: Toxic Substances Control Act (USA)
 AwSV: Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (Ordinance on facilities for handling substances that are hazardous to water) (Germany)
 NOEC: No Observed Effect Concentration
 ADR: Accord européen relatif au transport international des marchandises dangereuses par route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

(Contd. on page 12)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/07/2021

Version US-EN-Rev 1

Reviewed on 02/07/2021

Trade name: G-CEM ONE™ (Paste A, Shades: A2, AO3, BO1, Translucent, and White opaque)

(Contd. of page 11)

OECD: Organization for Economic Cooperation and Development
 IMDG Code: International Maritime Dangerous Goods Code
 DOT: Department of Transportation (USA)
 IATA: International Air Transport Association
 CAS: Chemical Abstracts Service (division of the American Chemical Society)
 VOC: Volatile Organic Compounds (USA, EU)
 LC50: Lethal concentration, 50 percent
 LD50: Lethal dose, 50 percent
 PBT: Persistent, Bioaccumulative and Toxic
 vPvB: very Persistent and very Bioaccumulative
 TLV: Threshold Limit Value
 PEL: Permissible Exposure Limit
 REL: Recommended Exposure Limit
 Skin Irrit. 2: Skin corrosion/irritation – Category 2
 Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
 Skin Sens. 1: Skin sensitisation – Category 1
 Repr. 1B: Reproductive toxicity – Category 1B

Sources

- Manufacturers' MSDSs/SDSs
- OSHA (<https://www.osha.gov/dts/chemicalsampling/toc/chmcas.html>)
- PubChem (<https://pubchem.ncbi.nlm.nih.gov/>)
- ECHA (<http://echa.europa.eu/>)
- EnviChem (www.echemportal.org)

Notes:

CAS Registry Number® is a Registered Trademark of the American Chemical Society.
 CHEMTREC® is a registered service mark of the American Chemistry Council, Inc.

Disclaimer:

The information contained herein is believed to be true and accurate. However, all statements, recommendations or suggestions are made without any guarantee, representation or warranty, express or implied, on our part. Therefore, no warranty is made or to be implied that the information set out in this document is accurate or complete, and we accordingly exclude all liability in connection with the use of this information or the products referred to herein. All such risks are assumed by the purchaser/user. The information contained herein is also subject to change without notice. For the avoidance of doubt, however, nothing in this document excludes or limits our liability for death or personal injury caused by our negligence or for fraudulent misrepresentation.

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/08/2021

Version US-EN-Rev 1

Reviewed on 02/08/2021

1 Identification

- **Product identifier**

- **Trade name:** G-CEM ONE™ ADHESIVE ENHANCING PRIMER

- **Relevant identified uses of the substance or mixture and uses advised against**

Dental material

The product is intended for professional use.

To avoid risks for humans and environment obtain instructions.

- **Application of the substance / the mixture** Dental bonding material

- **Details of the supplier of the safety data sheet**

- **Manufacturer/Supplier:**

GC America Inc.

3737 W. 127th Street

Alsip, IL 60803

USA

SDS.gcamerica@gc.dental

- **Information department:** Regulatory Affairs

- **Emergency telephone number:**

During normal opening times (Monday–Friday 8:00 AM–5:00 PM Central Time): +1 (708) 597-0900

Transportation (CHEMTREC®) Emergency Telephone No. +1 (800) 424-9300

2 Hazard(s) identification

- **Classification of the substance or mixture**

Flam. Liq. 2 H225 Highly flammable liquid and vapor.

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2A H319 Causes serious eye irritation.

STOT SE 3 H335-H336 May cause respiratory irritation. May cause drowsiness or dizziness.

STOT RE 1 H372 Causes damage to organs through prolonged or repeated exposure.

- **Additional information:**

The information provided is in regards to the toxicity and hazard rating(s) of the individual component(s) in the formulation. The associated risk(s) depends on the route(s) of exposure. The hazard rating system is based entirely on the existence of the risk(s) and does not take into account the likelihood of reduced risk(s) through proper usage and handling.

Avoid use of this product in patients with known allergies to methacrylate monomer, methacrylate polymer, or ethyl alcohol (ethanol).

- **Label elements**

- **GHS label elements**

Exempt from labeling – medical devices and drugs do not require labeling according to HCS 2012.

The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**



- **Signal word** Danger

(Contd. on page 2)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/08/2021

Version US-EN-Rev 1

Reviewed on 02/08/2021

Trade name: G-CEM ONE™ ADHESIVE ENHANCING PRIMER

(Contd. of page 1)

Hazard-determining components of labeling:

ethyl alcohol
 dimethacrylate**
 phosphoric acid ester monomer**
 butylated hydroxytoluene

Hazard statements

Highly flammable liquid and vapor.
 Causes skin irritation.
 Causes serious eye irritation.
 May cause respiratory irritation. May cause drowsiness or dizziness.
 Causes damage to organs through prolonged or repeated exposure.

Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
 Do not breathe dust/fume/gas/mist/vapors/spray.
 Wear protective gloves/protective clothing/eye protection/face protection.
 If on skin (or hair): 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.
 Store locked up.
 Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC): Exothermic polymerization.

Additional information:

39 % of the mixture consists of component(s) of unknown toxicity.

Other hazards
Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

3 Composition/information on ingredients

Chemical characterization: Mixtures

Description: Mixture of the substances listed below with nonhazardous additions.

Dangerous components:

CAS: 64-17-5	ethyl alcohol	25 – < 50%
	dimethacrylate**	10 – < 25%
	phosphoric acid ester monomer**	5 – < 10%
CAS: 128-37-0	butylated hydroxytoluene	1 – < 2.5%
	initiator**	1 – < 2.5%

Additional information:

Concentrations of dangerous components are expressed in percent by weight (% w/w).

If a substance is marked with **, then substance is a trade secret. This is allowed under OSHA's Hazard Communication Standard (HCS) as a trade secret and under GHS as Confidential Business Information (CBI).

US

(Contd. on page 3)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/08/2021

Version US-EN-Rev 1

Reviewed on 02/08/2021

Trade name: G-CEM ONE™ ADHESIVE ENHANCING PRIMER

(Contd. of page 2)

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; consult doctor in case of complaints.
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:**
Immediately wash with water and soap and rinse thoroughly.
Rinse with warm water.
Seek medical treatment.
If symptoms persist consult doctor.
- **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**
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, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire fighting measures that suit the environment.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **Special hazards arising from the substance or mixture**
In case of fire, the following can be released:
Sulphur dioxide (SO₂)
Carbon monoxide (CO)
Carbon dioxide
- **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.

(Contd. on page 4)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/08/2021

Version US-EN-Rev 1

Reviewed on 02/08/2021

Trade name: G-CEM ONE™ ADHESIVE ENHANCING PRIMER

(Contd. of page 3)

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.
 Absorb liquid components with liquid-binding material.
 Dispose of the collected material 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.

Protective Action Criteria for Chemicals

Protective Action Criterion (PAC); Protective Action Criteria (PACs); Lower Explosive Limit (LEL)
 * indicates the PAC value is between 10% and up to 50% of the LEL ($10\% \text{ LEL} \leq \text{PAC} < 50\% \text{ LEL}$).
 ** indicates the PAC value is between 50% and up to 100% of the LEL ($50\% \text{ LEL} \leq \text{PAC} < 100\% \text{ LEL}$).
 *** indicates the PAC value is at 100% or more of the LEL ($\text{PAC} \geq \text{LEL}$).
 excerpt from Introduction to PAC Table 2 – PAC Rev. 29 – May 2016

PAC-1:

CAS: 64-17-5	ethyl alcohol	1,800 ppm
--------------	---------------	-----------

PAC-2:

CAS: 64-17-5	ethyl alcohol	3300* ppm
--------------	---------------	-----------

PAC-3:

CAS: 64-17-5	ethyl alcohol	15000* ppm
--------------	---------------	------------

7 Handling and storage

Handling:
Precautions for safe handling

Prevent formation of aerosols.
 Ensure good ventilation/exhaustion at the workplace.
 Observe instructions for use.
 Avoid contact with the eyes and skin.

Use caution when opening. The product is a highly flammable liquid and vapor; keep away from heat, hot surfaces, sparks, flames and other ignitions sources. Use with adequate ventilation. Do not ingest or breathe vapor. Personal Protective Equipment (PPE) such as gloves and safety eyewear are always to be worn. Check bottle with liquid before using. Make sure that upon removal of cap, the bottle opening has no obstructions. Some bottles may contain an insert (as a seal). The insert must be in the cap and not obstructing opening.

In case of contact, flush eyes with water for at least 15 minutes. Get prompt medical attention. If overcome by vapor, move to fresh air. If breathing is difficult, administer oxygen and seek medical attention. If swallowed, dilute by giving water to drink and seek medical attention. In case of contact with skin wash thoroughly with soap and water. Store securely. Store in a well ventilated place. Keep cool. Dispose of all waste according to local regulations.

Information about protection against explosions and fires:

Keep ignition sources away - Do not smoke.
 Protect against electrostatic charges.
 Do not spray on a naked flame or any incandescent material.

(Contd. on page 5)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/08/2021

Version US-EN-Rev 1

Reviewed on 02/08/2021

Trade name: G-CEM ONE™ ADHESIVE ENHANCING PRIMER

(Contd. of page 4)

- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
Store in a cool location.
Store only in unopened original receptacles.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:**
Protect from heat and direct sunlight.
Keep receptacle tightly sealed.
Observe instructions for use / storage.
Store in cool, dry conditions in well sealed receptacles.
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 systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.
At this time, the other constituents have no known exposure limits.

CAS: 64-17-5 ethyl alcohol

PEL	Long-term value: 1900 mg/m³, 1000 ppm
REL	Long-term value: 1900 mg/m³, 1000 ppm
TLV	Short-term value: 1880 mg/m³, 1000 ppm

Regulatory information

- PEL: Guide to Occupational Exposure Values (OSHA PELs)
- REL: Guide to Occupational Exposure Values (NIOSH RELs)
- TLV: Guide to Occupational Exposure Values (TLV)
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
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.
- **Breathing equipment:**



Suitable respiratory protective device recommended.

(Contd. on page 6)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/08/2021

Version US-EN-Rev 1

Reviewed on 02/08/2021

Trade name: G-CEM ONE™ ADHESIVE ENHANCING PRIMER

(Contd. of page 5)

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:


Safety glasses

9 Physical and chemical properties

Information on basic physical and chemical properties
General Information
Appearance:
Form:

Liquid

Color:

According to product specification

Odor:

Characteristic

Odor threshold:

Not determined.

pH-value:

Not determined.

Change in condition
Melting point/Melting range:

Undetermined.

Boiling point/Boiling range:

77 °C (170.6 °F)

Flash point:

11 °C (51.8 °F)

Flammability (solid, gaseous):

Not applicable.

Ignition temperature:

Undetermined.

Decomposition temperature:

Not determined.

Auto igniting:

Product is not self-igniting.

Danger of explosion:

Heating may cause an explosion.
Product is not explosive. However, formation of explosive air/vapor mixtures are possible.

Explosion limits:
Lower:

3.5 Vol %

Upper:

15 Vol %

Vapor pressure:

Not determined.

(Contd. on page 7)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/08/2021

Version US-EN-Rev 1

Reviewed on 02/08/2021

Trade name: G-CEM ONE™ ADHESIVE ENHANCING PRIMER

(Contd. of page 6)

- | | |
|---------------------------|-----------------|
| · Density: | Not determined. |
| · Relative density | Not determined. |
| · Vapor density | Not determined. |
| · Evaporation rate | Not determined. |

- | | |
|--|----------|
| · Solubility in / Miscibility with Water: | Soluble. |
|--|----------|

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

- | | |
|---------------------|-----------------|
| · Viscosity: | |
| Dynamic: | Not determined. |
| Kinematic: | Not determined. |

- | | |
|---------------------------|---------|
| · Solvent content: | |
| Organic solvents: | 29.0 % |
| Water: | 30.0 % |
| VOC content: | 29.00 % |

- | | |
|------------------------|-------|
| Solids content: | 3.0 % |
|------------------------|-------|

- | | |
|----------------------------|--|
| · Other information | No further relevant information available. |
|----------------------------|--|

10 Stability and reactivity

- **Reactivity** Danger of polymerization.
- **Chemical stability** Stable at ambient temperature.
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **Possibility of hazardous reactions**
Danger of receptacles bursting because of high vapor pressure if heated.
Spontaneous polymerization can be caused in unstabilized product e.g. by ambient heat.
Exothermic polymerization.
- **Conditions to avoid** Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
- **Incompatible materials:**
Reacts with peroxides and other radical forming substances.
Reacts with amines.
Reacts with heavy metals.
- **Hazardous decomposition products:**
Carbon dioxide
Carbon monoxide

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **LD/LC50 values that are relevant for classification:**

CAS: 128-37-0 butylated hydroxytoluene

Oral	LD50	10700 mg/kg (guinea pig)
		1040 mg/kg (mouse)
		> 2930 mg/kg (rat (f+m))

(Contd. on page 8)

-US-

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/08/2021

Version US-EN-Rev 1

Reviewed on 02/08/2021

Trade name: G-CEM ONE™ ADHESIVE ENHANCING PRIMER

(Contd. of page 7)

Dermal	LD50	> 2000 mg/kg (rat (f+m))
--------	------	--------------------------

- **Primary irritant effect:**

- **on the skin:** Irritant to skin and mucous membranes.

- **on the eye:** Irritating effect.

- **Sensitization:** No sensitizing effects known.

- **Symptoms related to the physical, chemical and toxicological characteristics:**

No further relevant information available.

- **Subacute to chronic toxicity:** No further relevant information available.

- **Numerical measures of toxicity:**

ATEmix (Oral) is 5 200 mg/kg bodyweight.

ATEmix (Dermal) is >2 229 mg/kg bodyweight.

ATEmix is the acute toxicity estimate of the mixture.

- **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:

Irritant

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

ethyl alcohol	1
butylated hydroxytoluene	3

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

- **Carcinogenic categories' legend:**

IARC Group 1: The agent is carcinogenic to humans.

IARC Group 2A: The agent is probably carcinogenic to humans.

IARC Group 2B: The agent is possibly carcinogenic to humans.

IARC Group 3: The agent is not classifiable as to its carcinogenicity to humans.

IARC Group 4: The agent is probably not carcinogenic to humans.

NTP K: Known to be human carcinogen.

NTP R: Reasonably anticipated to be human carcinogen.

- **Additional carcinogenic information:**

The substance, ethyl alcohol, also known as ethanol, is listed by IARC as a Group 1 carcinogen but in alcoholic beverage consumption. IARC Volume 100E (2012) "Personal Habits and Indoor Combustions" stated in its monograph "Consumption of Alcoholic Beverages" the following evaluation: "Ethanol in alcoholic beverages is carcinogenic to humans (Group 1)." GC products are not consumable alcoholic beverages.

- **Repeated dose toxicity.** No further relevant information available.

- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**

- **Germ cell mutagenicity** No further relevant information available.

- **Carcinogenicity** No further relevant information available.

- **Reproductive toxicity** No further relevant information available.

- **Specific target organ toxicity - single exposure** No further relevant information available.

- **Specific target organ toxicity - repeated exposure** No further relevant information available.

- **Aspiration hazard** No further relevant information available.

US

(Contd. on page 9)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/08/2021

Version US-EN-Rev 1

Reviewed on 02/08/2021

Trade name: G-CEM ONE™ ADHESIVE ENHANCING PRIMER

(Contd. of page 8)

12 Ecological information

- **Toxicity**

- **Aquatic toxicity:**

CAS: 128-37-0 butylated hydroxytoluene

NOEC-value Ecol. other effects	0.07 mg/l (daphnia magna) 21 day, reproductive effects
--------------------------------	---

- **Persistence and degradability** No further relevant information available.

- **Behavior in environmental systems:**

- **Bioaccumulative potential** No further relevant information available.

- **Mobility in soil** No further relevant information available.

- **Ecotoxicological effects:**

- **Remark:** Harmful to fish

- **Additional ecological information:**

- **General notes:**

Water hazard class 2 (German regulation, AwSV) (Self-assessment): clearly hazardous to 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.

Harmful to aquatic organisms

- **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:**

Dispose of contents / container in accordance with local / regional / national / international regulations.

- **Uncleaned packagings:**

- **Recommendation:** Disposal must be made according to official regulations.

- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

- **UN-Number**

- **DOT, ADR, IMDG, IATA**

UN1170

- **UN proper shipping name**

- **DOT**

- **ADR**

Ethanol solutions

1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

- **IMDG**

ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

- **IATA**

ETHANOL SOLUTION

(Contd. on page 10)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/08/2021

Version US-EN-Rev 1

Reviewed on 02/08/2021

Trade name: G-CEM ONE™ ADHESIVE ENHANCING PRIMER

(Contd. of page 9)

· Transport hazard class(es)
· DOT


· **Class** 3 Flammable liquids
 · **Label** 3

· ADR


· **Class** 3 (F1) Flammable liquids
 · **Label** 3

· IMDG, IATA


· **Class** 3 Flammable liquids
 · **Label** 3

· Packing group

· **DOT, ADR, IMDG, IATA** II

· **Environmental hazards:** Not applicable.

· **Special precautions for user** Warning: Flammable liquids

· **Hazard identification number (Kemler code):** 33

· **EMS Number:** F-E, S-D

· **Stowage Category** A

· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

· Transport/Additional information:
· ADR

· **Excepted quantities (EQ)** Code: E2
 Maximum net quantity per inner packaging: 30 ml
 Maximum net quantity per outer packaging: 500 ml

· IMDG

· **Limited quantities (LQ)** 1L
 · **Excepted quantities (EQ)** Code: E2
 Maximum net quantity per inner packaging: 30 ml
 Maximum net quantity per outer packaging: 500 ml

(Contd. on page 11)

US

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/08/2021

Version US-EN-Rev 1

Reviewed on 02/08/2021

Trade name: G-CEM ONE™ ADHESIVE ENHANCING PRIMER

(Contd. of page 10)

UN "Model Regulation":

UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, II

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **SARA (Superfund Amendments and Reauthorization Act)**

Section 355 (extremely hazardous substances):

None of the ingredients is listed.

Section 313 (Specific toxic chemical listings):

initiator**

TSCA (Toxic Substances Control Act):

water, distilled	ACTIVE
ethyl alcohol	ACTIVE
dimethacrylate**	ACTIVE
butylated hydroxytoluene	ACTIVE
initiator**	ACTIVE

Additional information:

If a substance is marked with **, then substance is a trade secret. This is allowed under OSHA's Hazard Communication Standard (HCS) as a trade secret and under GHS as Confidential Business Information (CBI).

Hazardous Air Pollutants

None of the ingredients is listed.

Proposition 65
Chemicals known to cause cancer:

None of the ingredients is listed.

Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

Chemicals known to cause developmental toxicity:

The substance ethyl alcohol, also known as ethanol, is on California's Proposition 65 list of "Chemicals Known to the State To Cause Cancer or Reproductive Toxicity" as a developmental toxicant but as "ethyl alcohol in alcoholic beverages." GC products are not consumable alcoholic beverages.

ethyl alcohol

Carcinogenic categories
EPA (Environmental Protection Agency)

None of the ingredients is listed.

EPA carcinogenic categories' legend:

EPA weight-of-evidence (WoE): official codes and categories from EPA's 1986 guidelines and unofficial, derived codes from EPA's standard hazard descriptors from 1996, 1999, and 2005 guidelines

A: human carcinogen (1986)

B1: probable human carcinogen – based on limited evidence of carcinogenicity in humans (1986)

B2: probable human carcinogen – based on sufficient evidence of carcinogenicity in animals (1986)

(Contd. on page 12)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/08/2021

Version US-EN-Rev 1

Reviewed on 02/08/2021

Trade name: G-CEM ONE™ ADHESIVE ENHANCING PRIMER

(Contd. of page 11)

C: possible human carcinogen (1986)
 D: not classifiable as to human carcinogenicity (1986)
 E: evidence of non-carcinogenicity for humans (1986)
 CaH: carcinogenic to humans
 CBD: carcinogenic potential cannot be determined
 I: data are inadequate for an assessment of human carcinogenic potential
 II: inadequate information to assess carcinogenic potential
 K/L: known/likely human carcinogen
 L: likely to be carcinogenic to humans
 NL: not likely to be carcinogenic to humans
 S: suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential
 SC: suggestive evidence of carcinogenic potential

· TLV (Threshold Limit Value)

ethyl alcohol	A3
butylated hydroxytoluene	A4

· ACGIH carcinogenic categories' legend:

A1: confirmed human carcinogen
 A2: suspected human carcinogen
 A3: confirmed animal carcinogen with unknown relevance to humans
 A4: not classifiable as a human carcinogen
 A5: not suspected as a human carcinogen

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

· GHS label elements

Exempt from labeling – medical devices and drugs do not require labeling according to HCS 2012.

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms

· Signal word Danger

· Hazard-determining components of labeling:

ethyl alcohol
 dimethacrylate**
 phosphoric acid ester monomer**
 butylated hydroxytoluene

· Hazard statements

Highly flammable liquid and vapor.
 Causes skin irritation.
 Causes serious eye irritation.
 May cause respiratory irritation. May cause drowsiness or dizziness.
 Causes damage to organs through prolonged or repeated exposure.

· Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
 Do not breathe dust/fume/gas/mist/vapors/spray.
 Wear protective gloves/protective clothing/eye protection/face protection.
 If on skin (or hair): 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.
 Store locked up.

(Contd. on page 13)

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/08/2021

Version US-EN-Rev 1

Reviewed on 02/08/2021

Trade name: G-CEM ONE™ ADHESIVE ENHANCING PRIMER

(Contd. of page 12)

Dispose of contents/container in accordance with local/regional/national/international regulations.

 • **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

 • **Department issuing SDS:** Regulatory Affairs

 • **Contact:**

Regulatory Affairs

Telephone No. +1 (708) 597-0900

SDS.gcamerica@gc.dental

 • **Date of preparation / last revision** 02/08/2021 / -

 • **Abbreviations and acronyms:**

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

HCS: Hazard Communication Standard (USA)

MSDS: Material Safety Data Sheet

SDS: Safety Data Sheet

ECHA: European Chemicals Agency

OSHA: Occupational Safety and Health Administration (USA)

PAC: Protective Action Criterion (USA)

PACs: Protective Action Criteria (USA)

HNOC: Hazard Not Otherwise Classified (USA)

LEL: Lower Explosive Limit

UEL: Upper Explosive Limit

OSHA-Ca: Occupational Safety and Health Administration – Carcinogens or potential carcinogens regulated (USA)

NIOSH-Ca: National Institute for Occupational Safety and Health – Carcinogen List (USA)

NIOSH: National Institute for Occupational Safety and Health (USA)

TSCA: Toxic Substances Control Act (USA)

AwSV: Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (Ordinance on facilities for handling substances that are hazardous to water) (Germany)

NOEC: No Observed Effect Concentration

ADR: Accord européen relatif au transport international des marchandises dangereuses par route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG Code: International Maritime Dangerous Goods Code

DOT: Department of Transportation (USA)

IATA: International Air Transport Association

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Flam. Liq. 2: Flammable liquids – Category 2

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

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1

 • **Sources**

• Manufacturers' MSDSs/SDSs

 • OSHA (<https://www.osha.gov/dts/chemicalsampling/toc/chmcas.html>)

 • PubChem (<https://pubchem.ncbi.nlm.nih.gov/>)

 • ECHA (<http://echa.europa.eu/>)

 • EnviChem (www.echemportal.org)

 • **Notes:**

CAS Registry Number® is a Registered Trademark of the American Chemical Society.

CHEMTREC® is a registered service mark of the American Chemistry Council, Inc.

(Contd. on page 14)

Safety Data Sheet
acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/08/2021

Version US-EN-Rev 1

Reviewed on 02/08/2021

Trade name: G-CEM ONE™ ADHESIVE ENHANCING PRIMER

(Contd. of page 13)

Disclaimer:

The information contained herein is believed to be true and accurate. However, all statements, recommendations or suggestions are made without any guarantee, representation or warranty, express or implied, on our part. Therefore, no warranty is made or to be implied that the information set out in this document is accurate or complete, and we accordingly exclude all liability in connection with the use of this information or the products referred to herein. All such risks are assumed by the purchaser/user. The information contained herein is also subject to change without notice. For the avoidance of doubt, however, nothing in this document excludes or limits our liability for death or personal injury caused by our negligence or for fraudulent misrepresentation.

US