

SAFETY DATA SHEETS

This SDS packet was issued with item:

071313675

N/A

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

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- **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).

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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.

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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.

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

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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:**



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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.

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- **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.

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- **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. |

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· 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.

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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).

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· 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)

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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.

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