Safety Data Sheet
acc. to OSHA HCS 29 CFR 1910.1200

Printing date 10/30/2026 Version US-EN-Rev 1 Reviewed on 10/30/2026

1 Identification

· **Product identifier**

· **Trade name:** GC GRADIA PREMi (Shades: A1, A2, A3, AO2, B1, and U)

· **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** Manufacture of dental prothesis

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
GC America Inc.
3737 W. 127th Street
Alsip, IL 60803
USA

Telephone No. +1 (708) 597-0900
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**

Sensitization - Skin 1	H317 May cause an allergic skin reaction.
Toxic to Reproduction 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

· **Hazard-determining components of labeling:**
urethane dimethacrylate (UDMA)
photoinitiator**

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dimethacrylate component**
synergist**

· **Hazard statements**
H317 May cause an allergic skin reaction.
H360 May damage fertility or the unborn child.

· **Precautionary statements**
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P321 Specific treatment (see on this label).
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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

· **Additional information:**
1.6 % 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)	5 – < 10%
	dimethacrylate component**	2.5 – < 5%
	surface-treated silica**	1 – < 2.5%
	photoinitiator**	0.2 – < 0.5%
	synergist**	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.
· **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.

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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
· **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 dioxide
Carbon monoxide (CO)
Nitrogen oxides (NOx)
· **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.
· **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

· **Handling:**
· **Precautions for safe handling**
Observe instructions for use.
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.

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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.
· **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 section 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.
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.

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· **Eye protection:**



Safety glasses

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Paste
Color:	According to product specification
· **Odor:**	Nearly odorless
· **Odor threshold:**	Not determined
· **pH-value:**	Not determined
· **Change in condition**	
Melting point/Melting range:	Undetermined
Boiling point/Boiling range:	Undetermined
· **Flash point:**	Not determined.
· **Flammability:**	Not applicable
· **Auto igniting:**	Undetermined.
· **Decomposition temperature:**	Not determined
· **Ignition temperature:**	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 %

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Solids content:	62.8 %
· **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**
High heat
Direct sunlight
Open flame
Sparks
Static
· **Incompatible materials:** Strong oxidant
· **Hazardous decomposition products:**
In case of fire, the following can be released:
Carbon dioxide
Carbon monoxide
Nitrogen oxides (NOx)

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.
· **Symptoms related to the physical, chemical and toxicological characteristics:** Allergic reactions
· **Subacute to chronic toxicity:** No further relevant information available.
· **Numerical measures of toxicity:**
No ATEmix is calculated because ingredients of the mixture with LD50 or LC50 values are not considered relevant because of low concentration, a less severe acute toxicity category, or both. (ATEmix is the acute toxicity estimate of the mixture.)

· **Additional toxicological information:**

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**	
titanium dioxide	2B
colorant**	3

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

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· **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:** No further relevant information available.
· **Repeated dose toxicity.** No further relevant information available.
· **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
May damage fertility or the unborn child.
Toxic to Reproduction 1B
· **Germ cell mutagenicity** No further relevant information available.
· **Carcinogenicity** No further relevant information available.
· **Reproductive toxicity** May damage fertility or the unborn child.
· **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.

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· **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
· **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):**
None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**
All components have the value 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)
photoinitiator**
dimethacrylate component**
synergist**

· **Hazard statements**
H317 May cause an allergic skin reaction.
H360 May damage fertility or the unborn child.

· **Precautionary statements**
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P321 Specific treatment (see on this label).
P405 Store locked up.
P501 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** 10/30/2026 / -
· **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)
HNOC: Hazard Not Otherwise Classified (USA)
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)
WEEL: Workplace Environmental Exposure Level
IMDG Code: International Maritime Dangerous Goods Code
DOT: Department of Transportation (USA)
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists

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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
Sensitization - Skin 1: Skin sensitisation – Category 1
Toxic to Reproduction 1B: Reproductive toxicity – Category 1B

· **Sources**
• Manufacturers' MSDSs/SDSs
• OSHA (https://www.osha.gov/chemicaldatabase)
• PubChem (https://pubchem.ncbi.nlm.nih.gov/)
• ECHA (http://echa.europa.eu/)
• EnviChem (www.echemportal.org)

· **Notes:**
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