1 Identification

· Product identifier

· Trade name: G-ænial Sculpt (Shades: A1, A2, A3, A3.5, A4, AE, AO1, AO2, AO3, B1, B2, B3, BW, C3, CV, JE, and XBW)

· Application of the substance / the mixture Dental filling 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.com

· Information department: Regulatory Affairs

· Emergency telephone number: During normal opening times (Mon.-Fri. 8:00 AM-5:00 PM CST): +1 (708) 597-0900
  Transportation (CHEMTREC®) Emergency Telephone No. +1 (800) 424-9300

2 Hazard identification

· Classification of the substance or mixture

  Respiratory Sensitizer - Category 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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

· Hazard pictograms

  GHS08

· Signal word Danger

· Hazard-determining components of labeling:
  urethane dimethacrylate (UDMA)
  dimethacrylate component**
  Colorant
  stabilizer**
  UV-light absorber**

· Hazard statements
  May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Trade name: G-ænial Sculpt (Shades: A1, A2, A3, A3.5, A4, AE, AO1, AO2, AO3, B1, B2, B3, BW, C3, CV, JE, and XBW)

May cause an allergic skin reaction.

Precautionary statements
Avoid breathing dust/fume/gas/mist/vapours/spray.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves.
[In case of inadequate ventilation] wear respiratory protection.
If experiencing respiratory symptoms: Call a poison center/doctor.
Dispose of contents/container in accordance with local/regional/national/international regulations.

Classification system:
NFPA ratings (scale 0 - 4)

Health = 2
Fire = 1
Reactivity = 0

HMIS-ratings (scale 0 - 4)

Health = 2
Fire = 1
Reactivity = 0

3 Composition/Information on ingredients

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

Dangerous components:

<table>
<thead>
<tr>
<th>CAS</th>
<th>Description</th>
<th>% w/w</th>
</tr>
</thead>
<tbody>
<tr>
<td>41637-38-1</td>
<td>ethoxylated bisphenol-A dimethacrylate (Bis-EMA)</td>
<td>7 - 13% w/w</td>
</tr>
<tr>
<td>72869-86-4</td>
<td>urethane dimethacrylate (UDMA)</td>
<td>3 - 7% w/w</td>
</tr>
<tr>
<td></td>
<td>dimethacrylate component**</td>
<td>1 - 5% w/w</td>
</tr>
<tr>
<td></td>
<td>Colorant</td>
<td>≤ 1% w/w</td>
</tr>
<tr>
<td></td>
<td>stabilizer**</td>
<td>≤ 1% w/w</td>
</tr>
<tr>
<td></td>
<td>UV-light absorber**</td>
<td>≤ 1% w/w</td>
</tr>
</tbody>
</table>

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.
5 Firefighting measures

- Extinguishing media
  - Suitable extinguishing agents: CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
  - 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.

- 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:
  - 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.

7 Handling and storage

- Handling:
- Precautions for safe handling
  - Observe instructions for use.
  - Ensure good ventilation/exhaustion at the workplace.
Trade name: G-ænial Sculpt (Shades: A1, A2, A3, A3.5, A4, AE, AO1, AO2, AO3, B1, B2, B3, BW, C3, CV, JE, and XBW)

Do not inhale dust / smoke / mist. Prevent formation of aerosols. 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.
  · 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:
  Manufacturing sites:
  Wear safety glasses with side shields (or goggles).
### 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: Undetermined.
-  **Flash point:** Not applicable.
-  **Flammability (solid, gaseous):** Not applicable.
-  **Ignition temperature:** Undetermined.
-  **Decomposition temperature:** Not determined.
-  **Auto igniting:** Product is not self-igniting.
-  **Danger of explosion:** Product does not present an explosion hazard.
-  **Explosion limits:**
  - Lower: Not determined.
  - Upper: Not determined.
-  **Vapor pressure:** Not determined.
-  **Density:** Not determined.
-  **Relative density**
-  **Vapor density**
-  **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:**
  - Solids content: 70.2 %
-  **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.
- **Hazardous decomposition products**: No dangerous decomposition products known.

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 (f+m)) (OECD 401)
  - **Primary irritant effect**:
    - **on the skin**: No irritant effect.
    - **on the eye**: No irritating effect.
  - **Sensitization**:
    - Sensitization possible through inhalation.
    - Sensitization possible through skin contact.
  - **Additional toxicological information**:
    - **Carcinogenic categories**
      - **IARC (International Agency for Research on Cancer)**
        - glass, oxide, chemicals: 65997-17-3
        - silicon dioxide, amorphous: 3
        - titanium dioxide: 2B
        - Colorant: 3
      - **NTP (National Toxicology Program)**
        - 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.
  - **Repeated dose toxicity**: No further relevant information available.
  - **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
    - 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 (Self-assessment): slightly hazardous for 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

· UN-Number
  · DOT, TDG, ADN, IMDG, IATA: Void
· UN proper shipping name
  · DOT, TDG, ADN, IMDG, IATA: Void
· Transport hazard class(es)
  · DOT, TDG, ADN, IMDG, IATA:
    · Class: Void
· Packing group
  · DOT, TDG, IMDG, IATA: Void
· Environmental hazards:
  · Marine pollutant: No
· Special precautions for user
  · Not applicable.
Trade name: G-ænial Sculpt (Shades: A1, A2, A3, A3.5, A4, AE, AO1, AO2, AO3, B1, B2, B3, BW, C3, CV, JE, and XBW)

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

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):
  glass, oxide, chemicals
  ethoxylated bisphenol-A dimethacrylate (Bis-EMA)
  urethane dimethacrylate (UDMA)
  dimethacrylate component**
  silane**
  methacrylate**
  synergist**
  terephthalate component**
  photoinitiator**
  stabilizer**
  UV-light absorber**

· Canadian substance listings:

· Canadian Domestic Substances List (DSL)
  glass, oxide, chemicals
  ethoxylated bisphenol-A dimethacrylate (Bis-EMA)
  dimethacrylate component**
  silane**
  silicon dioxide, amorphous
  methacrylate**
  synergist**
  titanium dioxide
  Colorant
  triiron tetroxide
  terephthalate component**
  photoinitiator**
  stabilizer**
  UV-light absorber**
Trade name: G-ænial Sculpt (Shades: A1, A2, A3, A3.5, A4, AE, AO1, AO2, AO3, B1, B2, B3, BW, C3, CV, JE, and XBW)

- stabilizer**
- UV-light absorber**
- photoinitiator**

- Canadian Ingredient Disclosure list (limit 0.1%)
  None of the ingredients is listed.

- Canadian Ingredient Disclosure list (limit 1%)
  - dimethacrylate component**
  - silane**

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

- Hazard pictograms
  GHS08

- Signal word: Danger

- Hazard-determining components of labeling:
  - urethane dimethacrylate (UDMA)
  - dimethacrylate component**
  - Colorant
  - stabilizer**
  - UV-light absorber**

- Hazard statements
  May cause allergy or asthma symptoms or breathing difficulties if inhaled.
  May cause an allergic skin reaction.

- Precautionary statements
  Avoid breathing dust/fume/gas/mist/vapours/spray.
  Contaminated work clothing should not be allowed out of the workplace.
  Wear protective gloves.
  [In case of inadequate ventilation] wear respiratory protection.
  If experiencing respiratory symptoms: Call a poison center/doctor.
  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.com
- Date of preparation / last revision: 03/13/2018 / -
- 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
**Trade name:** G-ænial Sculpt (Shades: A1, A2, A3, A3.5, A4, AE, AO1, AO2, AO3, B1, B2, B3, BW, C3, CV, JE, and XBW)

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**Sources**

- Manufacturers’ MSDS/SDSs
- TOXNET (http://toxnet.nlm.nih.gov/)
- ECHA (http://echa.europa.eu/
- EnviChem (www.echemportal.org)

**Notes:**

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

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