1 Identification

· Product identifier
· Trade name: GRADIA DIRECT (Posterior, Shades: P-A1, P-A2, P-A3, P-A3.5, P-NT, and P-WT)

· 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
  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
  Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device.
  The product is classified and labeled according to the Globally Harmonized System (GHS).
· Hazard pictograms

  GHS07

· Signal word Warning
· Hazard-determining components of labeling:
  urethane dimethacrylate (UDMA)
  bismethacrylate**
· Hazard statements
  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.

(Contd. on page 2)
46.1.5.2

Wear protective gloves.

If skin irritation or rash occurs: Get medical advice/attention.

Specific treatment (see on this label).

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

Additional information:

13.9 % of the mixture consists of an ingredient or ingredients of unknown acute toxicity.

Classification system:

NFPA ratings (scale 0 - 4)

- Health = 1
- Fire = 1
- Reactivity = 1

HMIS-ratings (scale 0 - 4)

- Health = 1
- Fire = 1
- Reactivity = 1

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: 72869-86-4</th>
<th>urethane dimethacrylate (UDMA)</th>
<th>10 - 30% w/w</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>bismethacrylate**</td>
<td>1 - 5% w/w</td>
</tr>
<tr>
<td></td>
<td>dimethacrylate**</td>
<td>1 - 5% 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.

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.
5 Firefighting 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.
· 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.
  See Section 13 for disposal information.
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. 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Form: Pasty</td>
</tr>
<tr>
<td></td>
<td>Color: According to product specification</td>
</tr>
<tr>
<td></td>
<td>Odor: Characteristic</td>
</tr>
<tr>
<td></td>
<td>Odor threshold: Not determined.</td>
</tr>
<tr>
<td>pH-value</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Change in condition</td>
<td>Melting point/Melting range: Undetermined.</td>
</tr>
<tr>
<td></td>
<td>Boiling point/Boiling range: Undetermined.</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Flammability (solid, gaseous)</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Ignition temperature</td>
<td>Undetermined.</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Auto igniting</td>
<td>Product is not self-igniting.</td>
</tr>
<tr>
<td>Danger of explosion</td>
<td>Product does not present an explosion hazard.</td>
</tr>
<tr>
<td>Explosion limits</td>
<td>Lower: Not determined.</td>
</tr>
<tr>
<td></td>
<td>Upper: Not determined.</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Density</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Relative density</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Vapor density</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Solubility in / Miscibility with Water</td>
<td>Insoluble.</td>
</tr>
<tr>
<td>Partition coefficient (n-octanol/water)</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Dynamic: Not determined.</td>
</tr>
<tr>
<td></td>
<td>Kinematic: Not determined.</td>
</tr>
<tr>
<td>Solvent content</td>
<td>Solids content: 100.0 %</td>
</tr>
<tr>
<td></td>
<td>Other information: No further relevant information available.</td>
</tr>
</tbody>
</table>

10 Stability and reactivity

<table>
<thead>
<tr>
<th>Property</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>No further relevant information available.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable at ambient temperature.</td>
</tr>
<tr>
<td>Thermal decomposition / conditions to be avoided</td>
<td>No decomposition if used according to specifications.</td>
</tr>
</tbody>
</table>
Trade name: GRADIA DIRECT (Posterior, Shades: P-A1, P-A2, P-A3, P-A3.5, P-NT, and P-WT)

11 Toxicological information

- 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: 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)
        | Chemical                  | IARC Code |
        |----------------------------|-----------|
        | glass, oxide, chemicals    | 65997-17-3|
        | silicon dioxide, amorphous | 3         |
        | butylated hydroxytoluene (BHT) | 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.
    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 3 (Self-assessment): extremely hazardous for water
  Do not allow product to reach ground water, water course or sewage system, even in small quantities.
  Danger to drinking water if even extremely small quantities leak into the ground.
Trade name: GRADIA DIRECT (Posterior, Shades: P-A1, P-A2, P-A3, P-A3.5, P-NT, and P-WT)

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: Void

- Packing group
  DOT, TDG, IMDG, IATA: Void

- Environmental hazards:
  Marine pollutant: No

- 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": 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
    urethane dimethacrylate (UDMA)
Trade name: GRADIA DIRECT (Posterior, Shades: P-A1, P-A2, P-A3, P-A3.5, P-NT, and P-WT)

- Canadian substance listings:
  - Canadian Domestic Substances List (DSL)
    - glass, oxide, chemicals
    - silicon dioxide, amorphous
    - bismethacrylate**
    - photoinitiator**
    - UV-light absorber**
    - stabilizer**
    - initiator**
    - silane**
    - butylated hydroxytoluene (BHT)

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

- Canadian Ingredient Disclosure list (limit 1%)
  None of the ingredients is listed.

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

- Hazard pictograms
  ![GHS07]

  - Signal word Warning

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

  - Hazard statements
    - 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.
    - If skin irritation or rash occurs: Get medical advice/attention.
    - Specific treatment (see on this label).
    - 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
46.1.5.2

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
- 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)
- LEL: Lower Explosive Limit
- UEL: Upper Explosive Limit
- IMDG: International Maritime Code for Dangerous Goods
- DOT: US Department of Transportation
- IATA: International Air Transport Association
- CAS: Chemical Abstracts Service (division of the American Chemical Society)
- NFPA: National Fire Protection Association (USA)
- HMIS: Hazardous Materials Identification System (USA)
- LC50: Lethal concentration, 50 percent
- LD50: Lethal dose, 50 percent
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative

Sources:
- Manufacturers’ MSDS/SDSs
- 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.