1 Identification

· Product identifier

· **Trade name:** GRADIA DIRECT (Anterior, Shades: A1, A2, A3, A3.5, A4, AO2, AO3, AO4, B1, B2, B3, BW, C3, CT, CV, CVD, CVT, DT, GT, NT, WT, 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**
  - Skin Sensitizer - Category 1 H317 May cause an allergic skin reaction.
  - Aquatic Acute 3 H402 Harmful to aquatic life.
  - Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

· **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)

· **Hazard statements**
  - May cause an allergic skin reaction.
  - Harmful to aquatic life.
  - Harmful to aquatic life with long lasting effects.

(Contd. on page 2)
Safety Data Sheet  
according to HPR, Schedule 1

Trade name: GRADIA DIRECT (Anterior, Shades: A1, A2, A3, A3.5, A4, AO2, AO3, AO4, B1, B2, B3, BW, C3, CT, CV, CVD, CVT, DT, GT, NT, WT, and XBW)

- Precautionary statements
  Avoid breathing dust/fume/gas/mist/vapours/spray.
  Contaminated work clothing should not be allowed out of the workplace.
  Avoid release to the environment.
  Wear protective gloves.
  If skin irritation or rash occurs: Get medical advice/attention.
  Dispose of contents/container in accordance with local/regional/national/international regulations.

- Additional information:
  14.9 % 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 Health = 1
  FIRE Fire = 1
  REACTIVITY Reactivity = 1

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) 10 - 30% w/w
  dimethacrylate** 5 - 10% w/w
  trimethacrylate** 5 - 10% w/w

- 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
  · Indication of any immediate medical attention and special treatment needed:
    No further relevant information available.

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

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.

7 Handling and storage

· Handling:
  · Precautions for safe handling:
    Observe instructions for use.
    Ensure good ventilation/exhaustion at the workplace.
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

- **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: 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:**
  - Solids content: 100.0 %
  - Other information: No further relevant information available.

### 10 Stability and reactivity

- **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:** 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)**
      
      | Substance                        | 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:**
    - *trimethacrylate* **
      - **LC50/96h (dynamic):** > 1 mg/L (Onchorhynchus mykiss) (OECD Guideline 203 (Fish, Acute Toxicity Test))
      - **Test organism:** Rainbow trout (Onchorhynchus mykiss)
  - **Persistence and degradability**
    No further relevant information available.
46.1.5.2

- Behavior in environmental systems:
  - Bioaccumulative potential: No further relevant information available.
  - Mobility in soil: No further relevant information available.
- Ecotoxicical effects:
  - Remark: Harmful to fish
- 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.
    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.

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
- Class: 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):
    urethane dimethacrylate (UDMA)
    glass, oxide, chemicals
dimethacrylate**
trimethacrylate**

· Canadian substance listings:
  · Canadian Domestic Substances List (DSL)
    glass, oxide, chemicals
    silicon dioxide, amorphous
    trimethacrylate**
    stabilizer**
    photoinitiator**
    UV-light absorber**
    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)
· Hazard statements
  May cause an allergic skin reaction.
  Harmful to aquatic life.
  Harmful to aquatic life with long lasting effects.
46.1.5.2

· Precautionary statements

Avoid breathing dust/fume/gas/mist/vapours/spray.
Contaminated work clothing should not be allowed out of the workplace.
Avoid release to the environment.
Wear protective gloves.
If skin irritation or rash occurs: Get medical advice/attention.
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
  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’ 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.

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