Safety Data Sheet  
according to HPR, Schedule 1

1 Identification

· Product identifier
· Trade name: GRADIA DIE-HARDNER
· Application of the substance / the mixture: Auxiliary for manufacture of dental prosthesis
· 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
  Flammable Liquids - Category 2 H225 Highly flammable liquid and vapour.
  Acute Toxicity (Dermal) – Category 4 H312 Harmful in contact with skin.
  Skin Irritation - Category 2 H315 Causes skin irritation.
  Eye Irritation - Category 2B H320 Causes eye irritation.
  Specific Target Organ Toxicity - Single Exposure - Category 3 H335-H336 May cause respiratory irritation. May cause drowsiness or dizziness.
  Specific Target Organ Toxicity - Repeated Exposure - Category 1 H372 Causes damage to organs through prolonged or repeated exposure.
· 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
  GHS02  GHS07  GHS08
· Signal word: Danger
Hazard-determining components of labeling:
ethyl alcohol

Hazard statements
Highly flammable liquid and vapour.
Harmful in contact with skin.
Causes skin and eye irritation.
May cause respiratory irritation. May cause drowsiness or dizziness.
Causes damage to organs through prolonged or repeated exposure.

Precautionary statements
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Do not breathe dust/fume/gas/mist/vapours/spray.
Wear protective gloves/protective clothing/eye protection/face protection.
IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.

Additional information:
24% of the mixture consists of an ingredient or ingredients of unknown acute toxicity.

Classification system:
NFPA ratings (scale 0 - 4)

Health = 1
Fire = 3
Reactivity = 0

HMIS-ratings (scale 0 - 4)

Health = 1
Fire = 3
Reactivity = 0

3 Composition/Information on ingredients
Chemical characterization: Mixtures
Description: Mixture of the substances listed below with nonhazardous additions.

Dangerous components:
CAS: 64-17-5 ethyl alcohol 60 - 100% 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.
Rinse with warm water.
If symptoms persist consult doctor.

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

5 Firefighting 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
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.
Keep away from ignition sources
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:
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.
7 Handling and storage

· Handling:
  · Precautions for safe handling
    Observe instructions for use.
    Avoid contact with the eyes and skin.
    Use caution when opening. The product is a highly flammable liquid and vapor; keep away from heat, hot surfaces, sparks, flames and other ignitions sources. Use with adequate ventilation. Do not ingest or breathe vapor. Personal Protective Equipment (PPE) such as gloves and safety eyewear are always to be worn. Check bottle with liquid before using. Make sure that upon removal of cap, the bottle opening has no obstructions. Some bottles may contain an insert (as a seal). The insert must be in the cap and not obstructing opening.
    In case of contact, flush eyes with water for at least 15 minutes. Get prompt medical attention. If overcome by vapor, move to fresh air. If breathing is difficult, administer oxygen and seek medical attention. If swallowed, dilute by giving water to drink and seek medical attention. In case of contact with skin wash thoroughly with soap and water. Store securely. Store in a well ventilated place. Keep cool. Dispose of all waste according to local regulations.
  · Information about protection against explosions and fires:
    Keep ignition sources away - Do not smoke.
    Protect against electrostatic charges.
    Do not spray on a naked flame or any incandescent material.
· Conditions for safe storage, including any incompatibilities
· Storage:
  · Requirements to be met by storerooms and receptacles:
    Store in a cool location.
    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.
  Keep receptacle tightly sealed.
  Store in cool, dry conditions in well sealed receptacles.
  Protect from heat and direct sunlight.
  Store in a cool place.
· 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:
    CAS: 64-17-5 ethyl alcohol
    EL Short-term value: 1000 ppm
    EV Long-term value: 1,900 mg/m³, 1,000 ppm
· 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:

Manufacturing sites:
Wear safety glasses with side shields (or goggles).
Distribution, Workplace, and Household Settings:
No special protective equipment required

9 Physical and chemical properties

· Information on basic physical and chemical properties
· General Information
· Appearance:
  · Form: Liquid
  · Color: Clear
· Odor:
  · Odor: Characteristic
  · Odor threshold: Not determined.
· pH-value:
  · pH-value: Not determined.

· Change in condition
  · Melting point/Melting range: Undetermined.
  · Boiling point/Boiling range: Undetermined.

· Flash point:
  · Flash point: 13 °C

· Flammability (solid, gaseous):
  · Flammability (solid, gaseous): Not applicable.
Safety Data Sheet
according to HPR, Schedule 1

Trade name: GRADIA DIE-HARDNER

- Ignition temperature: Undetermined.
- Decomposition temperature: Not determined.
- Auto igniting: Product is not self-igniting.
- Danger of explosion: Product is not explosive. However, formation of explosive air/vapor mixtures are possible.
- Explosion limits:
  - Lower: 3.5 Vol %
  - Upper: 15 Vol %
- 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:
  - Organic solvents: 76.0 %
- 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: No further relevant information available.
- Primary irritant effect:
  - on the skin: Irritant to skin and mucous membranes.
  - on the eye: Irritating effect.
- Sensitization: No sensitizing effects known.

(Contd. on page 7)
46.1.5.2  
· Experience with humans:  
  May cause damage to central nervous system.  
  May cause damage to lungs.  
· 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)  
    ethyl alcohol  
  · 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.  
    NTP K: Known to be human carcinogen.  
    NTP R: Reasonably anticipated to be human carcinogen.  
· Additional carcinogenic information:  
  The substance ethyl alcohol, also known as ethanol, is listed by IARC as a Group 1 carcinogen but in alcoholic beverage consumption. IARC Volume 100E (2012) "Personal Habits and Indoor Combustions" stated in its monograph “Consumption of Alcoholic Beverages” the following evaluation: “Ethanol in alcoholic beverages is carcinogenic to humans (Group 1).” GC products are not consumable alcoholic beverages.  
· Repeated dose toxicity. No further relevant information available.  
· CMR effects (carcinogenity, 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.  
· 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

<table>
<thead>
<tr>
<th>DOT, TDG, IMDG, IATA</th>
<th>UN1170</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>UN proper shipping name</strong></td>
<td>Ethanol solution</td>
</tr>
<tr>
<td><strong>DOT</strong></td>
<td>1170 Ethanol solution</td>
</tr>
<tr>
<td><strong>TDG</strong></td>
<td>ETHANOL SOLUTION solution</td>
</tr>
</tbody>
</table>

- **Transport hazard class(es)**
  - **DOT**
    - **Class** 3
    - **Label** 3
  - **TDG (Transport dangerous goods):**
    - **Class** 3 (F1)
    - **Label** 3
  - **IMDG, IATA**
    - **Class** 3
    - **Label** 3

- **Packing group**
  - **DOT, TDG, IMDG, IATA** II

- **Environmental hazards:**
  - **Marine pollutant:** No
  - **Special precautions for user**
    - **Warning:** Flammable liquids
  - **Danger code (Kemler):** 33
  - **EMS Number:** F-E,S-D
### Trade name: GRADIA DIE-HARDNER

<table>
<thead>
<tr>
<th>· Stowage Category</th>
<th>A</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</td>
<td>Not applicable.</td>
</tr>
</tbody>
</table>

### Transport/Additional information:

<table>
<thead>
<tr>
<th>· TDG</th>
<th>Code: E2</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Excepted quantities (EQ)</td>
<td>Maximum net quantity per inner packaging: 30 ml</td>
</tr>
<tr>
<td></td>
<td>Maximum net quantity per outer packaging: 500 ml</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>· IMDG</th>
<th>1L</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Limited quantities (LQ)</td>
<td>Code: E2</td>
</tr>
<tr>
<td>· Excepted quantities (EQ)</td>
<td>Maximum net quantity per inner packaging: 30 ml</td>
</tr>
<tr>
<td></td>
<td>Maximum net quantity per outer packaging: 500 ml</td>
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</tbody>
</table>

| · UN "Model Regulation": | UN 1170 ETHANOL SOLUTION, 3, II |

### 15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
- SARA (Superfund Amendments and Reauthorization Act)

<table>
<thead>
<tr>
<th>· Section 355 (extremely hazardous substances):</th>
</tr>
</thead>
<tbody>
<tr>
<td>None of the ingredients is listed.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>· Section 313 (Specific toxic chemical listings):</th>
</tr>
</thead>
<tbody>
<tr>
<td>None of the ingredients is listed.</td>
</tr>
</tbody>
</table>

| · TSCA (Toxic Substances Control Act): | ethyl alcohol |
| --- | polymethylphenylsiloxane |

<table>
<thead>
<tr>
<th>· Canadian substance listings:</th>
</tr>
</thead>
</table>

| · Canadian Domestic Substances List (DSL) | ethyl alcohol |
| --- | polymethylphenylsiloxane |

| · Canadian Ingredient Disclosure list (limit 0.1%) | ethyl alcohol |

<table>
<thead>
<tr>
<th>· Canadian Ingredient Disclosure list (limit 1%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None of the ingredients is listed.</td>
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</tbody>
</table>

- GHS label elements
  - The product is classified and labeled according to the Globally Harmonized System (GHS).
- Hazard pictograms
  - GHS02
  - GHS07
  - GHS08
Trade name: GRADIA DIE-HARDNER

· **Signal word** Danger
· **Hazard-determining components of labeling:** ethyl alcohol
· **Hazard statements**
  Highly flammable liquid and vapour.
  Harmful in contact with skin.
  Causes skin and eye irritation.
  May cause respiratory irritation. May cause drowsiness or dizziness.
  Causes damage to organs through prolonged or repeated exposure.
· **Precautionary statements**
  Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
  Do not breathe dust/fume/gas/mist/vapours/spray.
  Wear protective gloves/protective clothing/eye protection/face protection.
  IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
  IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  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.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
  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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