1 Identification

- **Product identifier**
- **Trade name:** GRADIA DIAPOLISHER
- **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** Auxiliar for 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
    - 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(s) identification

- **Classification of the substance or mixture**
  - Aquatic Acute 1 H400 Very toxic to aquatic life.
  - Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.
  - Acute Tox. 4 H332 Harmful if inhaled.
  - STOT SE 3 H335 May cause respiratory irritation.
  - Eye Irrit. 2B H320 Causes eye irritation.
- **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**
    - ![GHS07](image) ![GHS09](image)
- **Signal word** Warning
- **Hazard-determining components of labeling:**
  - zinc oxide

(Contd. on page 2)
Trade name: GRADIA DIAPOLISHER

· Hazard statements
  Harmful if inhaled.
  Causes eye irritation.
  May cause respiratory irritation.
  Very toxic to aquatic life.
  Very toxic to aquatic life with long lasting effects.

· Precautionary statements
  Avoid breathing dust/fume/gas/mist/vapors/spray
  If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  If INHALED: Remove person to fresh air and keep comfortable for breathing.
  Call a poison center/doctor if you feel unwell.
  Store locked up.
  Dispose of contents/container in accordance with local/regional/national/international regulations.

· Additional information:
  20% of the mixture consists of component(s) of unknown toxicity.

· Classification system:
  · NFPA ratings (scale 0 - 4)
    Health = 2
    Fire = 0
    Reactivity = 0
  · HMIS-ratings (scale 0 - 4)
    HEALTH Health = 1
    FIRE Fire = 0
    REACTIVITY Reactivity = 0

· 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:

<table>
<thead>
<tr>
<th>Substance ID</th>
<th>Description</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1314-13-2</td>
<td>zinc oxide</td>
<td>25-50%</td>
</tr>
<tr>
<td>112926-00-8</td>
<td>silicon dioxide, amorphous</td>
<td>10-20%</td>
</tr>
<tr>
<td>14807-96-6</td>
<td>talc (Mg3H2(SiO3)4)</td>
<td>10-20%</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 or oxygen; call for doctor.
    In case of unconsciousness place patient stably in side position for transportation.
    Do not use mouth to mouth or mouth to nose resuscitation.
  - After skin contact:
    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 Fire-fighting 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 formation of dust.
  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.
Trade name: GRADIA DIAPOLISHER

Methods and material for containment and cleaning up:
Pick up mechanically.
Prevent formation of dust.
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.

Handling and storage

Handling:
Precautions for safe handling
Observe instructions for use.
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of dust.
Do not inhale dust / smoke / mist.
Any deposit of dust which cannot be avoided must be regularly removed.
Avoid contact with the eyes and skin.

Information about protection against explosions and fires:
Dust can combine with air to form an explosive mixture.

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.

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:

<table>
<thead>
<tr>
<th>Component</th>
<th>PEL</th>
<th>REL</th>
<th>TLV</th>
</tr>
</thead>
<tbody>
<tr>
<td>1314-13-2 zinc oxide</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Long-term value: 15* 5** mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>*total dust **respirable fraction and fume</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term value: 10** mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Long-term value: 5* 5** mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ceiling limit value: 15* mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>*dust only **fume</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term value: 10* mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Long-term value: 2* 10** mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>*as respirable fraction **total dust</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

112926-00-8 silicon dioxide, amorphous

PEL Long-term value: 2 mg/m³
20mppcf or 80mg/m3 %SiO2; 1mppcf = 0.1 mg/m³
REL Long-term value: 6 mg/m³
See Pocket Guide App. C

(Contd. on page 5)
Trade name: GRADIA DIAPOLISHER

<table>
<thead>
<tr>
<th>TLV</th>
<th>TLV Withdrawn</th>
</tr>
</thead>
<tbody>
<tr>
<td>14807-96-6 talc (Mg3H2(SiO3)4)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PEL</th>
<th>Long-term value: 20 mmpcf ppm (containing &lt;1% Quartz)</th>
</tr>
</thead>
<tbody>
<tr>
<td>REL</td>
<td>Long-term value: 2* mg/m³ *respirable dust</td>
</tr>
<tr>
<td>TLV</td>
<td>Long-term value: 2* mg/m³ *as respirable fraction; E</td>
</tr>
</tbody>
</table>

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.
Do not inhale dust / smoke / mist.
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

Information on basic physical and chemical properties

General Information

Appearance:
Form: Solid
Color: White
Odor: Odorless
Odor threshold: Not determined.

pH-value: Not applicable.

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

Flash point: Not applicable.

Flammability (solid, gaseous): Not determined.

Ignition temperature: Undetermined.
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**:
    - 1314-13-2 zinc oxide
      - Oral LD50: 7900 mg/kg (rat (f+m))
- **Primary irritant effect**:
  - **on the skin**: No irritant effect.
  - **on the eye**: Irritating effect.
Safety Data Sheet
acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/24/2015
Reviewed on 02/24/2015

Trade name: GRADIA DIAPOLISHER

- Sensitization: No sensitizing effects known.

- 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)
    | Substance                     | IARC Group |
    |--------------------------------|------------|
    | silicon dioxide, amorphous     | 3          |
    | talc (Mg3H2(SiO3)4)            | 2B         |
  - NTP (National Toxicology Program)
    None of the ingredients is listed.
  - 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.

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.
  - Ecotoxicological effects:
  - Remark: Very toxic for 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.
    Also poisonous for fish and plankton in water bodies.
    Very toxic for 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: Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· Uncleaned packagings:
  · Recommendation: Disposal must be made according to official regulations.

14 Transport information

· UN-Number
  · DOT, ADR, ADN, IMDG, IATA Void

· UN proper shipping name
  · DOT, ADR, ADN, IMDG, IATA Void

· Transport hazard class(es)
  · DOT, ADR, ADN, IMDG, IATA
    · Class Void
  · Packing group
    · DOT, ADR, 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": -

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 ingredient is listed.
    · Section 313 (Specific toxic chemical listings):
      zinc oxide
  · TSCA (Toxic Substances Control Act):
    zinc oxide
    japan wax
    talc (Mg3H2(SiO3)4)
    diamond
    octadecan-1-ol

(Contd. on page 9)
Safety Data Sheet acc. to OSHA HCS 29 CFR 1910.1200

Printing date 02/24/2015 Reviewed on 02/24/2015

Trade name: GRADIA DIAPOLISHER

• Carcinogenic categories
  • EPA (Environmental Protection Agency)
    zinc oxide  D, I, II
  • TLV (Threshold Limit Value established by ACGIH)
    talc (Mg3H2(SiO3)4)  A4
  • NIOSH-Ca (National Institute for Occupational Safety and Health)
    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  GHS09

• Signal word  Warning

• Hazard-determining components of labeling:
  zinc oxide

• Hazard statements
  Harmful if inhaled.
  Causes eye irritation.
  May cause respiratory irritation.
  Very toxic to aquatic life.
  Very toxic to aquatic life with long lasting effects.

• Precautionary statements
  Avoid breathing dust/fume/gas/mist/vapors/spray
  If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy
  to do. Continue rinsing.
  IF INHALED: Remove person to fresh air and keep comfortable for breathing.
  Call a poison center/doctor if you feel unwell.
  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 MSDS: Regulatory Affairs
• Contact:
  Regulatory Affairs
  Telephone No. +1 (708) 597-0900
  sds@gcamerica.com
• Date of preparation / last revision 02/24/2015 / -
• 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)
Trade name: GRADIA DIAPOLISHER

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
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
Acute Tox. 4: Acute toxicity, Hazard Category 4
Eye Irrit. 2B: Serious eye damage/eye irritation, Hazard Category 2B
STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3
Aquatic Acute 1: Hazardous to the aquatic environment - AcuteHazard, Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1

Sources
- Manufacturers’ MSDSs/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.

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