SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: Zircate Prophy Paste

1.2 Relevant identified uses of the substance or mixture and uses advised against

Application of the substance / the mixture
Tooth cleanser
Polishing paste

Uses advised against: No further relevant information available.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:
DENTSPLY DeTrey GmbH
De-Trey-Str. 1
D-78467 Konstanz
GERMANY
Tel.: +49-(0)7531-583-0
Fax: +49-(0)7531-583-104
email: KonstanzDEU.info-sdb@dentsplysirona.com

Further information obtainable from:
- Department Research & Development for technical information
- Department Marketing & Sales for distribution of the safety data sheets

1.4 Emergency telephone number: +49-(0)7531-583-0  8:00 - 17:00 (GMT + 1:00)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008
Acute Tox. 4  H332 Harmful if inhaled.
Skin Irrit. 2  H315 Causes skin irritation.
Eye Irrit. 2  H319 Causes serious eye irritation.
STOT SE 3  H335 May cause respiratory irritation.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008
The product is classified and labelled according to the CLP regulation.

Hazard pictograms

GHS07

Signal word: Warning

Hazard-determining components of labelling:
Zirconium Silicate

Hazard statements
H332 Harmful if inhaled.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

Precautionary statements
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P321 Specific treatment (see on this label).
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
Trade name: Zircate Prophy Paste

- **Additional information:**
  As this product is a medical device in the meaning of Directive 93/42/EEC and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according to regulation 1272/2008.

- **2.3 Other hazards**
  - **Results of PBT and vPvB assessment**
    - **PBT:** Not applicable.
    - **vPvB:** Not applicable.

* **SECTION 3: Composition/information on ingredients**

- **3.2 Chemical characterisation: Mixtures**
  - **Description:** Mixture of substances listed below with nonhazardous additions.

<table>
<thead>
<tr>
<th>CAS: 10101-52-7</th>
<th>Zirconium Silicate</th>
<th>50-100%</th>
</tr>
</thead>
</table>
| Acute Tox. 4, H332; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335

<table>
<thead>
<tr>
<th>CAS: 18282-10-5</th>
<th>tin dioxide</th>
<th>2.5-&lt;10%</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS: 242-159-0</td>
<td>substance with a Community workplace exposure limit</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS: 56-81-5</th>
<th>glycerol</th>
<th>2.5-&lt;10%</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS: 200-289-5</td>
<td>substance with a Community workplace exposure limit</td>
<td></td>
</tr>
</tbody>
</table>

- **Additional information** For the wording of the listed hazard phrases refer to section 16.

* **SECTION 4: First aid measures**

- **4.1 Description of first aid measures**
  - **After inhalation** Supply fresh air; consult doctor in case of complaints.
  - **After skin contact**
    - Immediately wash with water and soap and rinse thoroughly.
    - Rinse with warm water.
  - **After eye contact**
    - Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
  - **After swallowing**
    - If symptoms persist consult doctor.
    - Rinse out mouth and then drink plenty of water.

- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

- **Information for doctor** No further relevant information available.

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

* **SECTION 5: Firefighting measures**

- **5.1 Extinguishing media**
  - Suitable extinguishing agents
    - CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
  - For safety reasons unsuitable extinguishing agents
    - Water with full jet.

- **5.2 Special hazards arising from the substance or mixture**
  No further relevant information available.

- **5.3 Advice for firefighters**
  - Protective equipment: Self-contained respiratory protective device.

* **SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures** Wear protective clothing.

- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
Trade name: Zircate Prophy Paste

- 6.3 Methods and material for containment and cleaning up:
  - Ensure adequate ventilation.
  - Pick up mechanically.
- 6.4 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.

SECTION 7: Handling and storage

- 7.1 Precautions for safe handling
  - Observe normal care for working with chemicals.
  - Handling: Product is intended for dental use only.
  - Information about fire - and explosion protection: No special measures required.

- 7.2 Conditions for safe storage, including any incompatibilities
  - Storage
  - Requirements to be met by storerooms and receptacles: Store only in the original receptacle.
  - Information about storage in one common storage facility: Not required.
  - Further information about storage conditions: Keep receptacle tightly sealed.

- 7.3 Specific end use(s)
  - No further relevant information available.

SECTION 8: Exposure controls/personal protection

- 8.1 Control parameters
  - Additional information about design of technical facilities: No further data; see item 7.

- Ingredients with limit values that require monitoring at the workplace:
  - CAS: 18282-10-5 tin dioxide
    - WEL: Short-term value: 4 mg/m³
    - Long-term value: 2 mg/m³
      - as Sn
  - CAS: 56-81-5 glycerol
    - WEL: Long-term value: 10 mg/m³

- Regulatory information
  - WEL: EH40/2011
  - Additional information: The lists valid during the making were used as basis.

- 8.2 Exposure controls
  - Personal protective equipment
    - General protective and hygienic measures
      - Keep away from foodstuffs, beverages and feed.
      - Immediately remove all soiled and contaminated clothing.
      - Wash hands before breaks and at the end of work.
      - Avoid contact with the eyes and skin.
    - Respiratory protection:
      - In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
      - Not necessary if room is well-ventilated.
    - Protection of hands:
      - Protective gloves.

      The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
      Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **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 trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye protection:**
  Tightly sealed goggles.

- **Body protection:** Protective work clothing.

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### SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
  - **Appearance:**
    - **Form:** Pasty
    - **Colour:** Light grey
  - **Odour:** Product specific
  - **Odour 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:** Not applicable
  - **Decomposition temperature:** Not determined.
  - **Self-igniting:** Product is not selfigniting.
  - **Danger of explosion:** Product does not present an explosion hazard.
  - **Explosion limits:**
    - **Lower:** Not determined.
    - **Upper:** Not determined.
  - **Vapour pressure:** Not applicable.
  - **Density:** Not determined
  - **Relative density:** Not determined.
  - **Vapour density:** Not applicable.
  - **Evaporation rate:** Not applicable.
  - **Solubility in / Miscibility with**
    - **Water:** Insoluble
  - **Partition coefficient (n-octanol/water):** Not determined.
  - **Viscosity:**
    - **dynamic:** Not applicable.
Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 16.06.2016
Version number 4
Revision: 16.06.2016

Trade name: Zircate Prophy Paste

<table>
<thead>
<tr>
<th>kinematic:</th>
<th>Not applicable.</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Solvent content:</td>
<td></td>
</tr>
<tr>
<td>Organic solvents:</td>
<td>4.9 %</td>
</tr>
<tr>
<td>Water:</td>
<td>9.9 %</td>
</tr>
<tr>
<td>· Solids content:</td>
<td>85.0 %</td>
</tr>
<tr>
<td>· 9.2 Other information</td>
<td>No further relevant information available.</td>
</tr>
</tbody>
</table>

SECTION 10: Stability and reactivity

- 10.1 Reactivity: No further relevant information available.
- 10.2 Chemical stability
  - Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- 10.3 Possibility of hazardous reactions: No dangerous reactions known
- 10.4 Conditions to avoid: No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- 10.6 Hazardous decomposition products: No dangerous decomposition products known

SECTION 11: Toxicological information

- 11.1 Information on toxicological effects
  - Acute toxicity
    Harmful if inhaled.
  - LD/LC50 values relevant for classification:
    ATE (Acute Toxicity Estimates)
    Inhalative LC50/4 h 2.14 mg/l
    CAS: 10101-52-7 Zirconium Silicate
    Inhalative LC50/4 h 1.5 mg/l (ATE)
    CAS: 18282-10-5 tin dioxide
    Oral LD50 >20000 mg/kg (rat)
    CAS: 56-81-5 glycerol
    Oral LD50 12600 mg/kg (rat)
    Dermal LD50 > 18700 mg/kg (rabbit)
  - Primary irritant effect:
    - Skin corrosion/irritation
      Causes skin irritation.
    - Serious eye damage/irritation
      Causes serious eye irritation.
    - Respiratory or skin sensitisation
      Based on available data, the classification criteria are not met.
    - CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)
      - Germ cell mutagenicity
        Based on available data, the classification criteria are not met.
      - Carcinogenicity
        Based on available data, the classification criteria are not met.
      - Reproductive toxicity
        Based on available data, the classification criteria are not met.
    - STOT-single exposure
      May cause respiratory irritation.
    - STOT-repeated exposure
      Based on available data, the classification criteria are not met.
    - Aspiration hazard
      Based on available data, the classification criteria are not met.

(Contd. on page 6)
SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:
CAS: 56-81-5 glycerol
LC50/24h > 5000 mg/l (Fish acute toxicity study)
EC50/24h > 10000 mg/L (daphnia magna)

12.2 Persistence and degradability
No further relevant information available.

12.3 Bioaccumulative potential
No further relevant information available.

12.4 Mobility in soil
No further relevant information available.

Additional ecological information:

General notes:
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

12.5 Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

12.6 Other adverse effects
No further relevant information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Recommendation
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

European waste catalogue

18 01 06* chemicals consisting of or containing hazardous substances
HP 4 Irritant - skin irritation and eye damage
HP 5 Specific Target Organ Toxicity (STOT)/Aspiration Toxicity

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

SECTION 14: Transport information

14.1 UN-Number
ADR, ADN, IMDG, IATA Void

14.2 UN proper shipping name
ADR, ADN, IMDG, IATA Void

14.3 Transport hazard class(es)
ADR, ADN, IMDG, IATA Void

14.4 Packing group
ADR, IMDG, IATA Void

14.5 Environmental hazards:
Not applicable.

14.6 Special precautions for user
Not applicable.
SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

- Directive 2012/18/EU
- Named dangerous substances - ANNEX I None of the ingredients is listed.
- 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.

For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

- Relevant phrases
  H315 Causes skin irritation.
  H319 Causes serious eye irritation.
  H332 Harmful if inhaled.
  H335 May cause respiratory irritation.

- Department issuing SDS: Research & Development
- Contact: HotLine for urgent technical support: +49-7531-583-350

- Abbreviations and acronyms:
  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
  IATA: International Air Transport Association
  GHS: Globally Harmonised System of Classification and Labelling of Chemicals
  EINECS: European Inventory of Existing Commercial Chemical Substances
  ELINCS: European List of Notified Chemical Substances
  CAS: Chemical Abstracts Service (division of the American Chemical Society)
  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
  Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
  Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2
  STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

- * Data compared to the previous version altered.