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: Research and Development
· 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
  The product is not classified, according to the GB CLP regulation.
· 2.2 Label elements
· Labelling according to Regulation (EC) No 1272/2008 Void
· Hazard pictograms Void
· Signal word Void
· Hazard statements Void
· Additional information:
  As this product is a medical device in the meaning of Directive 93/42/EEC and regulation (EC) 2017/745 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 (EC) 1272/2008.
  EUH208 Contains Oils, peppermint. May produce an allergic reaction.
  EUH210 Safety data sheet available on request.
· 2.3 Other hazards
· Results of PBT and vPvB assessment
· PBT: Not applicable.
· vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Mixtures
· Description: Mixture of substances listed below with nonhazardous additions.
· Dangerous components:
  | CAS: 18282-10-5 | tin dioxide |
  | EINECS: 242-159-0 | substance with a Community workplace exposure limit |
  | | 2.5 – 10% |
  | CAS: 56-81-5 | glycerol |
  | EINECS: 200-289-5 | substance with a Community workplace exposure limit |
  | | 2.5 – 10% |
  | CAS: 8006-90-4 | Oils, peppermint |
  | | Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317 |
  | | ≥ 0.1 – < 1% |
  | CAS: 99-76-3 | Methyl-4-hydroxybenzoat |
  | EINECS: 202-785-7 | Aquatic Chronic 2, H411 |
  | | < 0.25% |

(Contd. on page 2)
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.
  If skin irritation continues, consult a doctor.
- **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.
- **Information for doctor** No further relevant information available.

4.2 Most important symptoms and effects, both acute and delayed
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** Use fire extinguishing methods suitable to surrounding conditions.
- **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:** No special measures required.

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.

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

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.

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

Ingredients with limit values that require monitoring at the workplace:

<table>
<thead>
<tr>
<th>CAS</th>
<th>Ingredient</th>
<th>WEL Short-term value</th>
<th>Long-term value</th>
</tr>
</thead>
<tbody>
<tr>
<td>18282-10-5</td>
<td>tin dioxide</td>
<td>4 mg/m³</td>
<td>2 mg/m³ as Sn</td>
</tr>
<tr>
<td>56-81-5</td>
<td>glycerol</td>
<td></td>
<td>10 mg/m³</td>
</tr>
</tbody>
</table>

Regulatory information: WEL: EH40/2020

Additional information: The lists valid during the making were used as basis.

8.2 Exposure controls

Appropriate engineering controls: No further data; see section 7.

Individual protection measures, such as personal protective equipment

General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Respiratory protection:

Not necessary if room is well-ventilated.

Hand protection

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 breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye/face protection:

Safety glasses

Body protection:

Protective work clothing.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Physical state: Solid.

Colour: Light grey

Odour: Product specific

Odour threshold: Not determined.

Melting point/freezing point: Undetermined.

Boiling point or initial boiling point and boiling range: Not determined.

Flammability: Not determined.

Lower and upper explosion limit

Lower: Not determined.

Upper: Not determined.

Flash point: Not applicable

Auto-ignition temperature: Not applicable.

Decomposition temperature: Not determined.

pH: Not applicable.
56.0.21

- Viscosity:
  - Kinematic viscosity: Not applicable.
  - Dynamic: Not applicable.
- Solubility
  - Water: Insoluble
- Partition coefficient n-octanol/water (log value): Not determined.
- Vapour pressure: Not applicable.
- Density and/or relative density
  - Density: Not determined
  - Relative density: Not determined
  - Vapour density: Not applicable.

- 9.2 Other information
  - Appearance: Pasty
  - Form:
  - Important information on protection of health and environment, and on safety.
  - Ignition temperature: Product is not selfigniting.
  - Explosive properties: Product does not present an explosion hazard.
- Solvent content:
  - Organic solvents: 4.9 %
  - Water: 9.9 %
  - Solids content: 85.0 %
- Change in condition
  - Evaporation rate: Not applicable.

- Information with regard to physical hazard classes
  - Explosives: Void
  - Flammable gases: Void
  - Aerosols: Void
  - Oxidising gases: Void
  - Gases under pressure: Void
  - Flammable liquids: Void
  - Flammable solids: Void
  - Self-reactive substances and mixtures: Void
  - Pyrophoric liquids: Void
  - Pyrophoric solids: Void
  - Self-heating substances and mixtures: Void
  - Substances and mixtures, which emit flammable gases in contact with water: Void
  - Oxidising liquids: Void
  - Oxidising solids: Void
  - Organic peroxides: Void
  - Corrosive to metals: Void
  - Desensitised explosives: Void

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.
  - 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 hazard classes as defined in Regulation (EC) No 1272/2008

- Acute toxicity: Based on available data, the classification criteria are not met.

LD/LC50 values relevant for classification:

<table>
<thead>
<tr>
<th>CAS</th>
<th>Oral LD50 (mg/kg, rat)</th>
<th>Dermal LD50 (mg/kg, rabbit)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18282-10-5</td>
<td>&gt; 20,000</td>
<td></td>
</tr>
<tr>
<td>56-81-5</td>
<td>&gt; 20,000</td>
<td>&gt; 18,700</td>
</tr>
<tr>
<td>99-76-3</td>
<td>&gt; 2000</td>
<td>&gt; 18,700</td>
</tr>
</tbody>
</table>

- Skin corrosion/irritation: Based on available data, the classification criteria are not met.
- Serious eye damage/irritation: Based on available data, the classification criteria are not met.
- Respiratory or skin sensitisation: Based on available data, the classification criteria are not met.
- Germ cell mutagenicity: 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: Based on available data, the classification criteria are not met.
- 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.

- STOT-single exposure: Based on available data, the classification criteria are not met.
- 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.

11.2 Information on other hazards

- Endocrine disrupting properties

CAS: 99-76-3 Methyl-4-hydroxybenzoat List II

SECTION 12: Ecological information

12.1 Toxicity

- Aquatic toxicity:

<table>
<thead>
<tr>
<th>CAS</th>
<th>LC50/24h (mg/l, fish)</th>
<th>EC50/24h (mg/L, daphnia magna)</th>
</tr>
</thead>
<tbody>
<tr>
<td>56-81-5</td>
<td>&gt; 5,000</td>
<td>&gt; 10,000</td>
</tr>
<tr>
<td>99-76-3</td>
<td></td>
<td>41.1 mg/L</td>
</tr>
</tbody>
</table>

- 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.
- 12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

- 12.6 Endocrine disrupting properties: For information on endocrine disrupting properties see section 11.

- 12.7 Other adverse effects

- Additional ecological information:

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

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

**SECTION 14: Transport information**

- **14.1 UN number or ID number**
  - **ADR, IMDG, IATA** Void

- **14.2 UN proper shipping name**
  - **ADR, 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.

- **14.7 Maritime transport in bulk according to IMO instruments**
  - Not applicable.

- **UN "Model Regulation":**
  - Void

**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.
  - H317 May cause an allergic skin reaction.
  - H319 Causes serious eye irritation.
Trade name: Zircate Prophy Paste

H411 Toxic to aquatic life with long lasting effects.

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

Abbreviations and acronyms:
- ADR: Accord relatif au transport international 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
- Skin Irrit. 2: Skin corrosion/irritation – Category 2
- Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
- Skin Sens. 1: Skin sensitisation – Category 1
- Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
- * Data compared to the previous version altered.