1 Identification

- Product identifier
  - Trade name: **AccuDent XD Tray Material**
- Application of the substance / the mixture: Dental impression material
- Details of the supplier of the safety data sheet
  - Manufacturer/Supplier:
    - Ivoclar Vivadent Inc.
      175 Pineview Drive, Amherst, N.Y. 14228
      USA
      Tel. +1 800 533 6825
      Fax +1 716 691 2285
    - Ivoclar Vivadent Inc.
      1-6600 Dixie Road
      Mississauga, Ontario
      L5T 2Y2
      Canada
      Phone: +1 905 670 8499
      Fax: +1 905 670 3102
- Information department: Quality Assurance / Regulatory Affairs
- Emergency telephone number:
  - 24 Hour Emergency Assistance:
    - Emergency-Call USA - Infotrac: 1-800-535-5053
    - Emergency-Call Canada - Canutec: 1-613-996-6666
  - General SDS Assistance:
    - US: 1-800-533-6825
    - Canada: 1-800-263-8182

2 Hazard identification

- Classification of the substance or mixture
  - The product is not classified according to the Globally Harmonized System (GHS).
- Label elements
  - GHS label elements Void
  - Hazard pictograms Void
  - Signal word Void
  - Hazard statements Void
- Additional information:
  - Medical devices are exempt from the labeling provisions of GHS according to the Hazard Communication Standard (HCS).
- Classification system:
  - NFPA ratings (scale 0 - 4)
    - Health = 0
    - Fire = 0
    - Reactivity = 0
  - HMIS-ratings (scale 0 - 4)
    - Health = *0
    - Fire = 0
    - Reactivity = 0

(Contd. on page 2)
Trade name: **AccuDent XD Tray Material**

- 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>CAS</th>
<th>Substance</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>16919-27-0</td>
<td>Dipotassium Hexafluorotitanate</td>
<td>1-5% w/w</td>
</tr>
<tr>
<td>1314-13-2</td>
<td>zinc oxide</td>
<td>1-5% w/w</td>
</tr>
<tr>
<td>77-09-8</td>
<td>phenolphthalein</td>
<td>&lt;1% w/w</td>
</tr>
</tbody>
</table>

**SVHC**

<table>
<thead>
<tr>
<th>CAS</th>
<th>Substance</th>
</tr>
</thead>
<tbody>
<tr>
<td>77-09-8</td>
<td>phenolphthalein</td>
</tr>
</tbody>
</table>

### 4 First aid measures

- **Description of first aid measures**
  - **After inhalation:** Supply fresh air; consult doctor in case of complaints.
  - **After skin contact:** Rinse with water.
  - **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
  - **After swallowing:** Seek medical treatment.

- **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, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
  - **Special hazards arising from the substance or mixture:** No further relevant information available.

- **Advice for firefighters**
  - **Protective equipment:**
    - Do not inhale explosion gases or combustion gases.
    - Wear self-contained respirator protective device.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures:** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.

- **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.

(Contd. on page 3)
Trade name: AccuDent XD Tray Material

7 Handling and storage

- Handling:
  - Precautions for safe handling
    Only adequately trained personnel should handle this product.
    For use in dentistry only.
  - Information about protection against explosions and fires: No special measures required.

- 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:
    Store receptacle in a well ventilated area.
    Protect from heat and direct sunlight.
  - 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:

<table>
<thead>
<tr>
<th>CAS: 1314-13-2 zinc oxide</th>
</tr>
</thead>
<tbody>
<tr>
<td>EL Short-term value: 10 mg/m³</td>
</tr>
<tr>
<td>Long-term value: 2 mg/m³</td>
</tr>
<tr>
<td>EV Short-term value: 10 mg/m³</td>
</tr>
<tr>
<td>Long-term value: 2 mg/m³</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:
    Usual hygienic measures for dental practice.
    Keep away from foodstuffs, beverages and feed.
    Wash hands before breaks and at the end of work.
  - Breathing equipment: Use suitable respiratory protective device in case of insufficient ventilation.
  - Recommended filter device for short term use:
    Filter P1
    Filter P2
    Filter P3

- Protection of hands:
  - The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
  - After use of gloves apply skin-cleaning agents and skin cosmetics.

- 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.
Trade name: **AccuDent XD Tray Material**

- **Eye protection**: Safety glasses

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### 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
  - **General Information**
  - **Appearance**:
    - **Form**: Powder
    - **Color**: Blue
    - **Odor**: like peppermint
    - **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.

- **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 applicable.

- **Density**: Not determined.
  - **Relative density**: Not determined.
  - **Vapor density**: Not applicable.
  - **Evaporation rate**: Not applicable.

- **Solubility in / Miscibility with Water**: Partly miscible.

- **Partition coefficient (n-octanol/water)**: Not determined.

- **Viscosity**
  - **Dynamic**: Not applicable.
  - **Kinematic**: Not applicable.

- **Other information**: No further relevant information available.

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### 10 Stability and reactivity

- **Reactivity**: No further relevant information available.
- **Chemical stability**: Stable under normal handling and storage conditions.
- **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**: None under normal conditions of storage and use.
11 Toxicological information

- Information on toxicological effects
  - Acute toxicity:
    - LD/LC50 values that are relevant for classification:
      - CAS: 1314-13-2 zinc oxide
        - Oral LD50 > 5000 mg/kg (rat)
  - Additional toxicological information:
    - Carcinogenic categories
      - IARC (International Agency for Research on Cancer)
        - CAS: 77-09-8 phenolphthalein
          - 2B
      - NTP (National Toxicology Program)
        - None of the ingredients is listed.
      - OSHA-Ca (Occupational Safety & Health Administration)
        - None of the ingredients is listed.

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: Harmful to fish
- Additional ecological information:
- General notes:
  - Harmful to aquatic organisms
  - Water hazard class 2 (Self-assessment): hazardous for water
  - Do not allow product to reach ground water, water course or sewage system.
  - Danger to drinking water if even 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:
    - Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
    - Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- Uncleaned packagings
  - Recommendation: Disposal must be made according to official regulations.
## 14 Transport information

<table>
<thead>
<tr>
<th><strong>Transport information</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>UN-Number</strong></td>
<td>Void</td>
</tr>
<tr>
<td><strong>DOT, TDG, ADN, IMDG, IATA</strong></td>
<td>Void</td>
</tr>
<tr>
<td><strong>UN proper shipping name</strong></td>
<td>Void</td>
</tr>
<tr>
<td><strong>DOT, TDG, ADN, IMDG, IATA</strong></td>
<td>Void</td>
</tr>
<tr>
<td><strong>Transport hazard class(es)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>DOT, TDG, ADN, IMDG, IATA</strong></td>
<td>Void</td>
</tr>
<tr>
<td><strong>Class</strong></td>
<td>Void</td>
</tr>
<tr>
<td><strong>Packing group</strong></td>
<td>Void</td>
</tr>
<tr>
<td><strong>DOT, TDG, IMDG, IATA</strong></td>
<td>Void</td>
</tr>
<tr>
<td><strong>Environmental hazards:</strong></td>
<td>Not applicable.</td>
</tr>
<tr>
<td><strong>Special precautions for user</strong></td>
<td>Not applicable.</td>
</tr>
<tr>
<td><strong>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</strong></td>
<td>Not applicable.</td>
</tr>
<tr>
<td><strong>Transport/Additional information:</strong></td>
<td>Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).</td>
</tr>
<tr>
<td><strong>UN &quot;Model Regulation&quot;:</strong></td>
<td>Void</td>
</tr>
</tbody>
</table>

## 15 Regulatory information

<table>
<thead>
<tr>
<th><strong>Regulatory information</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Safety, health and environmental regulations/legislation specific for the substance or mixture</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Sara</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Section 355 (extremely hazardous substances):</strong></td>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td><strong>Section 313 (Specific toxic chemical listings):</strong></td>
<td></td>
</tr>
<tr>
<td><strong>CAS: 1314-13-2 zinc oxide</strong></td>
<td></td>
</tr>
<tr>
<td><strong>TSCA (Toxic Substances Control Act):</strong></td>
<td></td>
</tr>
<tr>
<td><strong>CAS: 8042-47-3 White mineral oil (petroleum)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>CAS: 7722-88-5 tetrasodium pyrophosphate</strong></td>
<td></td>
</tr>
<tr>
<td><strong>CAS: 1314-13-2 zinc oxide</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Proposition 65</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Chemicals known to cause cancer:</strong></td>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td><strong>Chemicals known to cause reproductive toxicity for females:</strong></td>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td><strong>Chemicals known to cause reproductive toxicity for males:</strong></td>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td><strong>Chemicals known to cause developmental toxicity:</strong></td>
<td>None of the ingredients is listed.</td>
</tr>
<tr>
<td><strong>Carcinogenic categories</strong></td>
<td></td>
</tr>
<tr>
<td><strong>EPA (Environmental Protection Agency)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>CAS: 1314-13-2 zinc oxide</strong></td>
<td>D, I, H</td>
</tr>
</tbody>
</table>

(Contd. on page 6)
Safety Data Sheet
according to HPR, Schedule 1

Printing date 10/19/2015
Version number 1
Reviewed on 10/19/2015

Trade name: AccuDent XD Tray Material

- TLV (Threshold Limit Value established by ACGIH)
  None of the ingredients is listed.

- NIOSH-Ca (National Institute for Occupational Safety and Health)
  None of the ingredients is listed.

- GHS label elements Void
- Hazard pictograms Void
- Signal word Void
- Hazard statements Void

- National regulations:
  - Other regulations, limitations and prohibitive regulations
    The product is a medical device according to the Directive 93/42/EEC.
    This product is classified as a medical device under US and Canadian regulations and has been reviewed by
    the US Food and Drug Administration and Health Canada.
  - Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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.

- Date of preparation / last revision 10/19/2015 / -
- Abbreviations and acronyms:
  IMDG: International Maritime Code for Dangerous Goods
  DOT: US Department of Transportation
  IATA: International Air Transport Association
  ACGIH: American Conference of Governmental Industrial Hygienists
  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)
  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
  SVHC: Substances of Very High Concern
  vPvB: very Persistent and very Bioaccumulative