1 Identification

- **Product identifier**
  - **Trade name:** AccuDent XD Syringe 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](image)
      - Health = 1
      - Fire = 0
      - Reactivity = 0
    - ![Fire](image)
    - ![Reactivity](image)
  - **HMIS-ratings (scale 0 - 4)**
    - ![Health](image)
      - Health = 1
      - Fire = 0
      - Reactivity = 0

(Contd. on page 2)
Trade name: AccuDent XD Syringe 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.

<table>
<thead>
<tr>
<th>CAS</th>
<th>Chemical Name</th>
<th>w/w</th>
</tr>
</thead>
<tbody>
<tr>
<td>16919-27-0</td>
<td>Dipotassium Hexafluorotitanate</td>
<td>1-5%</td>
</tr>
<tr>
<td>8042-47-5</td>
<td>White mineral oil (petroleum)</td>
<td>1-5%</td>
</tr>
<tr>
<td>7722-88-5</td>
<td>tetrasodium pyrophosphate</td>
<td>1-5%</td>
</tr>
<tr>
<td>1314-13-2</td>
<td>zinc oxide</td>
<td>1-5%</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.
- 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 respiratory 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)
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**:
  - **CAS: 7722-88-5 tetrasodium pyrophosphate**
    - **EL** Short-term value: 10 mg/m³
    - Long-term value: 5 mg/m³
  - **CAS: 1314-13-2 zinc oxide**
    - **EL** Short-term value: 10 mg/m³
    - Long-term value: 2 mg/m³
    - **EV** Short-term value: 10 mg/m³
    - Long-term value: 2 mg/m³
    - respirable

- **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.
9 Physical and chemical properties

- Information on basic physical and chemical properties
  - General Information
    - Appearance:
      - Form: Powder
      - Color: Orange
    - 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 selfigniting.
- 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.

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.
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
    - 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.
  - Ecotoxic effects:
    - Remark: Harmful to fish

- Additional ecological information:
  - General notes:
    - Water hazard class 2 (Self-assessment): hazardous for water
    - Do not allow product to reach ground water, water course or sewage system.
    - Harmful to 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.
  - 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

- UN-Number
  - DOT, TDG, ADN, IMDG, IATA: Void

- UN proper shipping name
  - DOT, TDG, ADN, IMDG, IATA: Void

- Transport hazard class(es)
  - DOT, TDG, ADN, IMDG, IATA: Void
    - Class: Void

- Packing group
  - DOT, TDG, IMDG, IATA: Void

- Environmental hazards:
  - Not applicable.

- Special precautions for user
  - Not applicable.

- Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
  - Not applicable.

- Transport/Additional information:
  - Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).

- UN "Model Regulation": Void

15 Regulatory information

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

  - Sara

    - Section 355 (extremely hazardous substances):
      - None of the ingredients is listed.

    - Section 313 (Specific toxic chemical listings):
      - CAS: 1314-13-2 zinc oxide

    - TSCA (Toxic Substances Control Act):
      - CAS: 8042-47-5 White mineral oil (petroleum)
      - CAS: 7722-88-5 tetrasodium pyrophosphate
      - CAS: 1314-13-2 zinc oxide

- Proposition 65

  - Chemicals known to cause cancer:
    - None of the ingredients is listed.

  - Chemicals known to cause reproductive toxicity for females:
    - None of the ingredients is listed.

  - Chemicals known to cause reproductive toxicity for males:
    - None of the ingredients is listed.

  - Chemicals known to cause developmental toxicity:
    - None of the ingredients is listed.

  - Carcinogenic categories
    - EPA (Environmental Protection Agency)
      - CAS: 1314-13-2 zinc oxide

(Contd. on page 7)
Trade name: AccuDent XD Syringe 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
  - vPvB: very Persistent and very Bioaccumulative