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(s) 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 = 1, Fire = 0, Reactivity = 0]
  - **HMIS-ratings (scale 0 - 4)**
    - HEALTH = 1
    - FIRE = 0
    - REACTIVITY = 0

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

4.2.6 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</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>16919-27-0</td>
<td>Dipotassium Hexafluorotitanate</td>
<td>2.5-&lt;10%</td>
</tr>
<tr>
<td>8042-47-5</td>
<td>White mineral oil (petroleum)</td>
<td>2.5-&lt;10%</td>
</tr>
<tr>
<td>7722-88-5</td>
<td>Tetrasodium pyrophosphate</td>
<td>2.5-&lt;10%</td>
</tr>
<tr>
<td>1314-13-2</td>
<td>Zinc oxide</td>
<td>0.1-&lt;2.5%</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.
  · 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 Fire-fighting 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.
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

<table>
<thead>
<tr>
<th>CAS</th>
<th>REL Long-term value: 5 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TLV TLV withdrawn</td>
</tr>
<tr>
<td>CAS: 7722-88-5 tetrasodium pyrophosphate</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS: 1314-13-2 zinc oxide</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEL</td>
</tr>
<tr>
<td>REL</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

TLV Short-term value: 10* mg/m³
Long-term value: 2* mg/m³
*as respirable fraction

- 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
1 Safety Data Sheet

Trade name: AccuDent XD Syringe Material

2.2.2.6 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: 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.
11 Toxicological information

- Acute toxicity:
  - 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

<table>
<thead>
<tr>
<th>Item</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>UN-Number</strong></td>
<td>DOT, ADR, RID, ADN, ADN, IMDG, IATA</td>
</tr>
<tr>
<td><strong>UN proper shipping name</strong></td>
<td>Void</td>
</tr>
<tr>
<td><strong>Transport hazard class(es)</strong></td>
<td>DOT, ADR, RID, ADN, ADN, IMDG, IATA</td>
</tr>
<tr>
<td><strong>Class</strong></td>
<td>Void</td>
</tr>
<tr>
<td><strong>Packing group</strong></td>
<td>DOT, ADR, RID, ADN, IMDG, IATA</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 MARPOL 73/78 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>Item</th>
<th>Value</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>CAS: 1314-13-2 zinc oxide</td>
<td></td>
</tr>
<tr>
<td><strong>TSCA (Toxic Substances Control Act):</strong></td>
<td></td>
</tr>
<tr>
<td>CAS: 8042-47-3 White mineral oil (petroleum)</td>
<td></td>
</tr>
<tr>
<td>CAS: 7722-88-5 tetrasodium pyrophosphate</td>
<td></td>
</tr>
<tr>
<td>CAS: 1314-13-2 zinc oxide</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>CAS: 1314-13-2 zinc oxide</td>
<td>D, I, II</td>
</tr>
</tbody>
</table>

(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:
  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
  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
1 Identification

- **Product identifier**
  - **Trade name:** AccuDent XD Tray Adhesive

- **Application of the substance / the mixture**
  - Auxiliary for dental technology

- **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(s) identification

- **Classification of the substance or mixture**
  - Flam. Liq. 2  H225  Highly flammable liquid and vapor.
  - Skin Irrit. 2  H315  Causes skin irritation.
  - Eye Irrit. 2A  H319  Causes serious eye irritation.
  - Repr. 2  H361  Suspected of damaging fertility or the unborn child.
  - STOT SE 3  H336  May cause drowsiness or dizziness.
  - STOT RE 2  H373  May cause damage to organs through prolonged or repeated exposure.
  - Asp. Tox. 1  H304  May be fatal if swallowed and enters airways.

- **Label elements**
  - GHS label elements
    - The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**
  - GHS02
  - GHS07
  - GHS08

- **Signal word**
  - Danger

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

- **Hazard-determining components of labeling:**
  - toluene
  - propan-2-ol

- **Hazard statements**
  - Highly flammable liquid and vapor.
  - Causes skin irritation.
  - Causes serious eye irritation.
  - Suspected of damaging fertility or the unborn child.
  - May cause drowsiness or dizziness.
  - May cause damage to organs through prolonged or repeated exposure.
  - May be fatal if swallowed and enters airways.

- **Precautionary statements**
  - Obtain special instructions before use.
  - Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
  - Wear protective gloves/protective clothing/eye protection/face protection.
  - If swallowed: Immediately call a poison center/doctor.
  - If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
  - In case of fire: Use for extinction: CO2, powder or water spray.

- **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 = 1
    - Fire = 3
    - Reactivity = 0
  - **HMIS-ratings (scale 0 - 4)**
    - Health = *1
    - Fire = 3
    - Reactivity = 0
  - **Other hazards**
  - **Results of PBT and vPvB assessment**
    - PBT: Not applicable.
    - vPoB: Not applicable.

### 3 Composition/information on ingredients
- **Chemical characterization:** Mixtures
- **Description:** Mixture of the substances listed below with nonhazardous additions.

<table>
<thead>
<tr>
<th>Dangerous components:</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS: 67-63-0</td>
<td>propan-2-ol</td>
<td>50-100%</td>
</tr>
<tr>
<td>CAS: 108-88-3</td>
<td>toluene</td>
<td>20-&lt;25%</td>
</tr>
</tbody>
</table>

### 4 First-aid measures
- **Description of first aid measures**
- **General information:**
  - Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
41.1.9

· **After inhalation:**
  Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.
  In case of unconsciousness place patient stably in side position for transportation.

· **After skin contact:**
  Immediately rinse with water.
  If skin irritation continues, consult a doctor.

· **After eye contact:**
  Rinse opened eye for several minutes under running water. Then consult a doctor.

· **After swallowing:**
  Do not induce vomiting; immediately call for medical help.

· **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.

· **For safety reasons unsuitable extinguishing agents:**
  Water with full jet

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

· **Advice for firefighters**
  · Protective equipment: Mouth respiratory protective device.
  · Additional information Cool endangered receptacles with water spray.

6 **Accidental release measures**

· **Personal precautions, protective equipment and emergency procedures**
  Wear protective equipment. Keep unprotected persons away.

· **Environmental precautions:**
  Do not allow to enter sewers/ surface or ground water.

· **Methods and material for containment and cleaning up:**
  Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
  Dispose contaminated material as waste according to item 13.
  Ensure adequate ventilation.
  Do not flush with water or aqueous cleansing agents

· **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.

7 **Handling and storage**

· **Handling:**
  · Precautions for safe handling
    Ensure good ventilation/exhaustion at the workplace.
    Prevent formation of aerosols.
  · Information about protection against explosions and fires:
    Keep ignition sources away - Do not smoke.
    Protect against electrostatic charges.

· **Conditions for safe storage, including any incompatibilities**

· **Storage:**
  · Requirements to be met by storerooms and receptacles: Store in a cool location.

(Contd. of page 2)
8 Exposure controls/personal protection

- Additional information about design of technical systems: No further data; see item 7.

- Components with limit values that require monitoring at the workplace:

  **CAS: 67-63-0 propan-2-ol**
  - PEL Long-term value: 980 mg/m³, 400 ppm
  - REL Short-term value: 1225 mg/m³, 500 ppm
  - Long-term value: 980 mg/m³, 400 ppm
  - TLV Short-term value: 984 mg/m³, 400 ppm
  - Long-term value: 492 mg/m³, 200 ppm

  **CAS: 108-88-3 toluene**
  - PEL Long-term value: 200 ppm
  - Ceiling limit value: 300; 500* ppm
  - *10-min peak per 8-hr shift
  - REL Short-term value: 560 mg/m³, 150 ppm
  - Long-term value: 375 mg/m³, 100 ppm
  - TLV Long-term value: 75 mg/m³, 20 ppm

- Ingredients with biological limit values:

  **CAS: 67-63-0 propan-2-ol**
  - BEI 40 mg/L
    - Medium: urine
    - Time: end of shift at end of workweek
    - Parameter: Acetone (background, nonspecific)

  **CAS: 108-88-3 toluene**
  - BEI 0.02 mg/L
    - Medium: blood
    - Time: prior to last shift of workweek
    - Parameter: Toluene
    - 0.03 mg/L
    - Medium: urine
    - Time: end of shift
    - Parameter: Toluene
    - 0.3 mg/g creatinine
    - Medium: urine
    - Time: end of shift
    - Parameter: o-Cresol with hydrolysis (background)

- Additional information: The lists that were valid during the creation were used as basis.
41.1.9· Exposure controls
- Personal protective equipment:
- General protective and hygienic measures:
  Usual hygienic measures for dental practice.
  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.
- Breathing equipment:
  In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- Recommended filter device for short term use:
  Filter A1
  Filter A2
  Filter A3
- Protection of hands:
  Protective gloves
  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
  Fluorocarbon rubber (Viton)
  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:
  Tightly sealed goggles

9 Physical and chemical properties

- Information on basic physical and chemical properties
- General Information
- Appearance:
  Form: Fluid
  Color: Yellow
- Odor: Characteristic
- Odor threshold: Not determined.
- pH-value: Not determined.

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

<table>
<thead>
<tr>
<th>CAS: 67-63-0 propan-2-ol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
</tr>
<tr>
<td>Dermal</td>
</tr>
<tr>
<td>Inhalative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS: 108-88-3 toluene</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
</tr>
<tr>
<td>Dermal</td>
</tr>
<tr>
<td>Inhalative</td>
</tr>
</tbody>
</table>
Trade name: AccuDent XD Tray Adhesive

- on the skin: Irritant to skin and mucous membranes.
- on the eye: Irritating effect.
- Additional toxicological information: No further relevant information available.
- Carcinogenic categories
  - IARC (International Agency for Research on Cancer)
    CAS: 67-63-0 propan-2-ol 3
    CAS: 108-88-3 toluene 3
  - 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.
- Additional ecological information:
- General notes:
  Water hazard class 2 (Self-assessment): hazardous for water
  Do not allow product to reach groundwater, 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.
- Uncleaned packagings:
  - Recommendation: Disposal must be made according to official regulations.

14 Transport information

- UN-Number
  - DOT, ADR, RID, ADN, IMDG, IATA: UN1993
- UN proper shipping name
  - DOT: Flammable liquids, n.o.s. (Isopropanol, Toluene)
  - ADR/RID/ADN: 1993 Flammable liquids, n.o.s. (Isopropanol, Toluene)
  - IMDG, IATA: FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL (ISOPROPYL ALCOHOL), TOLUENE)
Trade name: AccuDent XD Tray Adhesive

- Transport hazard class(es)
  - DOT
  - Class: 3 Flammable liquids
  - Label: 3
  - ADR/RID/ADN
  - Class: 3 (F1) Flammable liquids
  - Label: 3
  - IMDG, IATA
  - Class: 3 Flammable liquids
  - Label: 3
- Packing group
  - DOT, ADR,RID,ADN, IMDG, IATA
  - Packing group: II
- Environmental hazards:
  - Marine pollutant: No
- Special precautions for user
  - Warning: Flammable liquids
  - Danger code (Kemler): 33
  - EMS Number: F-E,S-E
- Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
  - Not applicable.

- Transport/Additional information:
  - ADR/RID/ADN
    - Excepted quantities (EQ)
      - Code: E2
      - Maximum net quantity per inner packaging: 30 ml
      - Maximum net quantity per outer packaging: 500 ml
  - IMDG
    - Limited quantities (LQ)
      - 1L
    - Excepted quantities (EQ)
      - Code: E2
      - Maximum net quantity per inner packaging: 30 ml
      - Maximum net quantity per outer packaging: 500 ml
  - UN "Model Regulation": UN 1993 FLAMMABLE LIQUIDS, N.O.S. (ISOPROPANOL, TOLUENE), 3, II
### 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):** All ingredients are listed.
    - **TSCA (Toxic Substances Control Act):** All ingredients are listed.

- **Proposition 65**
  - **Chemicals known to cause cancer:** None of the ingredients is listed.
  - **Chemicals known to cause reproductive toxicity for females:**
    - CAS: 108-88-3 toluene
  - **Chemicals known to cause reproductive toxicity for males:** None of the ingredients is listed.
  - **Chemicals known to cause developmental toxicity:**
    - CAS: 108-88-3 toluene

- **Carcinogenic categories**
  - **EPA (Environmental Protection Agency)**
    - CAS: 108-88-3 toluene II
  - **TLV (Threshold Limit Value established by ACGIH)**
    - CAS: 67-63-0 propan-2-ol A4
    - CAS: 108-88-3 toluene 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**
    - GHS02
    - GHS07
    - GHS08

- **Signal word** Danger
  - **Hazard-determining components of labeling:**
    - toluene
    - propan-2-ol
  - **Hazard statements**
    - Highly flammable liquid and vapor.
    - Causes skin irritation.
    - Causes serious eye irritation.
    - Suspected of damaging fertility or the unborn child.
    - May cause drowsiness or dizziness.
    - May cause damage to organs through prolonged or repeated exposure.

(Contd. on page 10)
Trade name: AccuDent XD Tray Adhesive

May be fatal if swallowed and enters airways.

Precautionary statements
- Obtain special instructions before use.
- Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
- Wear protective gloves/protective clothing/eye protection/face protection.
- If swallowed: Immediately call a poison center/doctor.
- If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
- In case of fire: Use for extinction: CO2, powder or water spray.

National regulations:
- Other regulations, limitations and prohibitive regulations
  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 08/17/2015 / -

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
- 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)
- VOC: Volatile Organic Compounds (USA, EU)
- LC50: Lethal concentration, 50 percent
- LD50: Lethal dose, 50 percent
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative
- Flam. Liq. 2: Flammable liquids, Hazard Category 2
- Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
- Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A
- Begr. 2: Reproductive toxicity, Hazard Category 2
- STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3
- STOT RE 2: Specific target organ toxicity - Repeated exposure, Hazard Category 2
- Asp. Tox. 1: Aspiration hazard, Hazard Category 1
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(s) identification

- Classification of the substance or mixture
  - Repr. 2. H361 Suspected of damaging fertility or the unborn child.

- Label elements
  - GHS label elements
    The product is classified and labeled according to the Globally Harmonized System (GHS).

- Hazard pictograms

  GHS08

- Signal word Warning
- Hazard statements
  Suspected of damaging fertility or the unborn child.

Precautionary statements
Obtain special instructions before use.
Wear eye protection / face protection.
Do not handle until all safety precautions have been read and understood.
IF exposed or concerned: Get medical advice/attention.
Store locked up.
Trade name: AccuDent XD Tray Material

- **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
- **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>Chemical Name</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>16919-27-0</td>
<td>Dipotassium Hexafluorotitanate</td>
<td>2.5-&lt;10%</td>
</tr>
<tr>
<td>1314-13-2</td>
<td>zinc oxide</td>
<td>0.1-&lt;2.5%</td>
</tr>
<tr>
<td>77-09-8</td>
<td>phenolphthalein</td>
<td>0.1-&lt;1%</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 Fire-fighting 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.

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

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.

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>PEL</td>
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<td></td>
</tr>
<tr>
<td>REL</td>
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<td></td>
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<td></td>
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<tr>
<td>TLV</td>
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<td></td>
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</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.
Safety Data Sheet
acc. to OSHA HCS

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

Trade name: AccuDent XD Tray Material

(Contd. of page 3)

- 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.
- Eye protection: Safety glasses

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 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.

(Contd. on page 5)
Trade name: AccuDent XD Tray Material

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.
### 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, ADR, RID, ADN, IMDG, IATA Void

- **UN proper shipping name**
  - DOT, ADR, RID, ADN, IMDG, IATA Void

- **Transport hazard class(es)**
  - DOT, ADR, RID, ADN, IMDG, IATA Void

- **Packing group**
  - DOT, ADR, RID, ADN, 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
Safety Data Sheet
acc. to OSHA HCS

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

Trade name: AccuDent XD Tray Material

· 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 D, I, II
  · 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
  The product is classified and labeled according to the Globally Harmonized System (GHS).
  · Hazard pictograms

  GHS08

  · Signal word Warning
  · Hazard statements
    Suspected of damaging fertility or the unborn child.
  · Precautionary statements
    Obtain special instructions before use.
    Wear eye protection / face protection.
    Do not handle until all safety precautions have been read and understood.
    IF exposed or concerned: Get medical advice/attention.
    Store locked up.

· 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:
  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
Table: AccuDent XD Tray Material

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
Repr. 2: Reproductive toxicity, Hazard Category 2