

**Safety Data Sheet**  
according to WHS Regulations

Printing date 29.01.2020

Version number 1

Revision: 29.01.2020

Not classified as hazardous according to criteria of Australian Safety and Compensation Council.

## 1 Identification

- **Product identifier**
- **Trade name:** **AccuDent XD Syringe Material**
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **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
- **Importer:**  
Ivoclar Vivadent Pty. Ltd.  
1- 5 Overseas Drive  
Noble Park North VIC 3174  
Tel: + 61 3 9795 9599 / Fax: + 61 3 9795 9645
- **Further information obtainable from:**  
Regulatory Affairs  
sds@ivoclarvivadent.com
- **Emergency telephone number:** 131 126 (Poisons Information Centre - 24 hours / 7 days)

## 2 Hazard(s) Identification

- **Classification of the substance or mixture**  
The product is not classified, according to the Globally Harmonised System (GHS).

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- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Precautionary statements**  
Do not expose to temperatures exceeding 50 °C/122 °F.
- **Additional information:**  
Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

## 3 Composition and Information on Ingredients

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

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**· Dangerous components:**

CAS: 16919-27-0	dipotassium hexafluorotitanate Eye Dam. 1, H318; Acute Tox. 4, H302; Skin Irrit. 2, H315; STOT SE 3, H335	2.5-10%
CAS: 8042-47-5	White mineral oil, petroleum Asp. Tox. 1, H304	2.5-10%
CAS: 7722-88-5	tetrasodium pyrophosphate	2.5-10%
CAS: 1314-13-2	zinc oxide	<2.5%

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

### 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:** Use fire extinguishing methods suitable to surrounding conditions.
- **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 fire - and explosion protection:** No special measures required.

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- **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 and personal protection

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

· **Ingredients with limit values that require monitoring at the workplace:**

**CAS: 7722-88-5 tetrasodium pyrophosphate**

NES Long-term value: 5 mg/m<sup>3</sup>

WES Long-term value: 5 mg/m<sup>3</sup>

**CAS: 1314-13-2 zinc oxide**

NES Short-term value: 10\*\* mg/m<sup>3</sup>

Long-term value: 10\* 5\*\* mg/m<sup>3</sup>  
\*dust \*\*fume

WES Short-term value: 10\*\* mg/m<sup>3</sup>

Long-term value: 10\* 5\*\* mg/m<sup>3</sup>  
\*dust \*\*fume

- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Usual hygienic measures for dental practice and dental laboratories.  
Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.
- **Respiratory protection:** 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

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### 9 Physical and Chemical Properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· <b>Form:</b>	Powder
· <b>Colour:</b>	Orange
· <b>Odour:</b>	like peppermint
· <b>Odour threshold:</b>	Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

· <b>Melting point/freezing point:</b>	Undetermined.
· <b>Initial boiling point and boiling range:</b>	Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gas):** Not determined.

· **Auto-ignition temperature:** Product is not selfigniting.

· **Explosive properties:** Product does not present an explosion hazard.

· **Explosion limits:**

· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.

· **Vapour pressure:** Not applicable.

· <b>Density:</b>	Not determined.
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.

· **Solubility in / Miscibility with water:** Partly miscible.

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

· **Viscosity:**

· <b>Dynamic:</b>	Not applicable.
· <b>Kinematic:</b>	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.
- **Hazardous decomposition products:** None under normal conditions of storage and use.

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### 11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity**

· <b>LD/LC50 values relevant for classification:</b>
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<b>CAS: 1314-13-2 zinc oxide</b>
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Oral	LD50	> 5000 mg/kg (rat)
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### 12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour 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:**  
*Water hazard class 2 (German Regulation) (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 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 packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- |                                     |      |
|-------------------------------------|------|
| · <b>UN-Number</b>                  |      |
| · <b>ADG, ADN, IMDG, IATA</b>       | Void |
| · <b>UN proper shipping name</b>    |      |
| · <b>ADG, ADN, IMDG, IATA</b>       | Void |
| · <b>Transport hazard class(es)</b> |      |
| · <b>ADG, ADN, IMDG, IATA</b>       |      |
| · <b>Class</b>                      | Void |

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· <b>Packing group</b>	
· <b>ADG, IMDG, IATA</b>	Void
· <b>Environmental hazards:</b>	Not applicable.
· <b>Special precautions for user</b>	Not applicable.
· <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· <b>UN "Model Regulation":</b>	Void

### 15 Regulatory information

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

· **Australian Inventory of Chemical Substances**

CAS: 7722-88-5 tetrasodium pyrophosphate

CAS: 1314-13-2 zinc oxide

· **Standard for the Uniform Scheduling of Medicines and Poisons**

None of the ingredients is listed.

· **GHS label elements** Void

· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· **Precautionary statements**

Do not expose to temperatures exceeding 50 °C/122 °F.

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **National regulations:**

· **Other regulations, limitations and prohibitive regulations**

The product is a medical device according to the Directive 93/42/EEC.

· **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.

· **Relevant phrases**

H302 Harmful if swallowed.

H304 May be fatal if swallowed and enters airways.

H315 Causes skin irritation.

H318 Causes serious eye damage.

H335 May cause respiratory irritation.

· **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

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)

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*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 – Category 4*

*Skin Irrit. 2: Skin corrosion/irritation – Category 2*

*Eye Dam. 1: Serious eye damage/eye irritation – Category 1*

*STOT SE 3: Specific target organ toxicity (single exposure) – Category 3*

*Asp. Tox. 1: Aspiration hazard – Category 1*

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