

**Safety Data Sheet**  
according to HPR, Schedule 1

Printing date 10/19/2015

Version number 1

Reviewed on 10/19/2015

**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)**



- **HMIS-ratings (scale 0 - 4)**
- |            |   |                |
|------------|---|----------------|
| HEALTH     | 0 | Health = *0    |
| FIRE       | 0 | Fire = 0       |
| REACTIVITY | 0 | Reactivity = 0 |

(Contd. on page 2)

## 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**

(Contd. of page 1)

- **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:**

CAS: 16919-27-0	Dipotassium Hexafluorotitanate	1-5% w/w
CAS: 1314-13-2	zinc oxide	1-5% w/w
CAS: 77-09-8	phenolphthalein	<1% w/w

- **SVHC**

CAS: 77-09-8	phenolphthalein
--------------	-----------------

### 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:**  
CO<sub>2</sub>, 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.

CA

(Contd. on page 3)

## 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**

(Contd. of page 2)

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

EL	Short-term value: 10 mg/m <sup>3</sup> Long-term value: 2 mg/m <sup>3</sup>
EV	Short-term value: 10 mg/m <sup>3</sup> Long-term value: 2 mg/m <sup>3</sup> 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.
- **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.

(Contd. on page 4)

CA

## 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**

· **Eye protection:** Safety glasses

(Contd. of page 3)

### 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.

· **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.

· **Hazardous decomposition products:** None under normal conditions of storage and use.

CA

(Contd. on page 5)

## 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**

(Contd. of page 4)

### 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.

CA

(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**

(Contd. of page 5)

#### 14 Transport information

· <b>UN-Number</b> · <b>DOT, TDG, ADN, IMDG, IATA</b>	Void
· <b>UN proper shipping name</b> · <b>DOT, TDG, ADN, IMDG, IATA</b>	Void
· <b>Transport hazard class(es)</b> · <b>DOT, TDG, ADN, IMDG, IATA</b> · <b>Class</b>	Void
· <b>Packing group</b> · <b>DOT, TDG, 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 MARPOL73/78 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**

· **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

D, I, II

(Contd. on page 7)

CA

## 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**

(Contd. of page 6)

· **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

CA