

Safety Data Sheet
acc. to OSHA HCS

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(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**
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- 
- GHS08
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- **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.

(Contd. on page 2)

Safety Data Sheet

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Trade name: **AccuDent XD Tray Material**

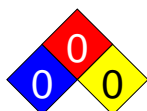
(Contd. of page 1)

· **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:**

CAS: 16919-27-0	Dipotassium Hexafluorotitanate	2.5-<10%
CAS: 1314-13-2	zinc oxide	0.1-<2.5%
CAS: 77-09-8	phenolphthalein	0.1-<1%

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)

US

Safety Data Sheet acc. to OSHA HCS

Printing date 10/19/2015

Version number 1

Reviewed on 10/19/2015

Trade name: AccuDent XD Tray Material

(Contd. of page 2)

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:**

CAS: 1314-13-2 zinc oxide

PEL	Long-term value: 15* 5** mg/m ³ *total dust **respirable fraction and fume
REL	Short-term value: 10** mg/m ³ Long-term value: 5* 5** mg/m ³ Ceiling limit value: 15* mg/m ³ *dust only **fume
TLV	Short-term value: 10* mg/m ³ Long-term value: 2* mg/m ³ *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.

(Contd. on page 4)

Safety Data Sheet acc. to OSHA HCS

Printing date 10/19/2015

Version number 1

Reviewed on 10/19/2015

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)

Safety Data Sheet acc. to OSHA HCS

Printing date 10/19/2015

Version number 1

Reviewed on 10/19/2015

Trade name: AccuDent XD Tray Material

(Contd. of page 4)

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.

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
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- **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.

(Contd. on page 6)

US

Safety Data Sheet

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Version number 1

Reviewed on 10/19/2015

Trade name: AccuDent XD Tray Material

(Contd. of page 5)

· **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, ADR,RID,ADN, ADN, IMDG, IATA** Void
- **UN proper shipping name**
- **DOT, ADR,RID,ADN, ADN, IMDG, IATA** Void
- **Transport hazard class(es)**
- **DOT, ADR,RID,ADN, ADN, IMDG, IATA**
- **Class** 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

(Contd. on page 7)

US

Safety Data Sheet acc. to OSHA HCS

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Trade name: AccuDent XD Tray Material

(Contd. of page 6)

· **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

(Contd. on page 8)

Safety Data Sheet
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Trade name: AccuDent XD Tray Material

(Contd. of page 7)

*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*

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