

Safety Data Sheet

acc. to OSHA HCS

Printing date 10/19/2015

Version number 1

Reviewed on 10/16/2015

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)**



- **HMIS-ratings (scale 0 - 4)**



(Contd. on page 2)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 10/19/2015

Version number 1

Reviewed on 10/16/2015

Trade name: **AccuDent XD Syringe 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	2.5-<10%
CAS: 8042-47-5	White mineral oil (petroleum)	2.5-<10%
CAS: 7722-88-5	tetrasodium pyrophosphate	2.5-<10%
CAS: 1314-13-2	zinc oxide	0.1-<2.5%

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.

US

(Contd. on page 3)

Safety Data Sheet

acc. to OSHA HCS

Printing date 10/19/2015

Version number 1

Reviewed on 10/16/2015

Trade name: **AccuDent XD Syringe 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: 7722-88-5 tetrasodium pyrophosphate

REL Long-term value: 5 mg/m³

TLV TLV withdrawn

CAS: 1314-13-2 zinc oxide

PEL Long-term value: 15* 5** mg/m³
*total dust **respirable fraction and fumeREL Short-term value: 10** mg/m³
Long-term value: 5* 5** mg/m³
Ceiling limit value: 15* mg/m³
*dust only **fumeTLV 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

(Contd. on page 4)

Safety Data Sheet

acc. to OSHA HCS

Printing date 10/19/2015

Version number 1

Reviewed on 10/16/2015

Trade name: AccuDent XD Syringe Material

(Contd. of page 3)

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.

(Contd. on page 5)

Safety Data Sheet

acc. to OSHA HCS

Printing date 10/19/2015

Version number 1

Reviewed on 10/16/2015

Trade name: **AccuDent XD Syringe Material**

(Contd. of page 4)

- **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**

- **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:**
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.

US

(Contd. on page 6)

Safety Data Sheet

acc. to OSHA HCS

Printing date 10/19/2015

Version number 1

Reviewed on 10/16/2015

Trade name: **AccuDent XD Syringe Material**

(Contd. of page 5)

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

· 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)

Safety Data Sheet

acc. to OSHA HCS

Printing date 10/19/2015

Version number 1

Reviewed on 10/16/2015

Trade name: AccuDent XD Syringe 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:**

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

US