

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

Printing date 09/30/2019

Version number 6

Reviewed on 09/09/2019

**1 Identification**

- **Product identifier**
- **Trade name:** ***Accu Dent System 1 / 2 - Tray Accu Gel***
- **Application of the substance / the mixture** *Auxiliary for manufacture of dental prothesis*
- **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**

Acute Toxicity (Oral) - Category 4	H302 Harmful if swallowed.
Serious Eye Damage - Category 1	H318 Causes serious eye damage.
Skin Sensitizer - Category 1	H317 May cause an allergic skin reaction.
Specific Target Organ Toxicity - Single Exposure - Category 3	H335 May cause respiratory irritation.
Specific Target Organ Toxicity - Repeated Exposure - Category 2	H373 May cause damage to organs through prolonged or repeated exposure.

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

- **Hazard pictograms**



- **Signal word** *Danger*
- **Hazard-determining components of labeling:**  
*dipotassium hexafluorotitanate*

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*Kieselguhr, soda ash flux-calcined*

· **Hazard statements**

*Harmful if swallowed.*

*Causes serious eye damage.*

*May cause an allergic skin reaction.*

*May cause respiratory irritation.*

*May cause damage to organs through prolonged or repeated exposure.*

· **Precautionary statements**

*Do not breathe dust/fume/gas/mist/vapours/spray.*

*Wash thoroughly after handling.*

*Do not eat, drink or smoke when using this product.*

*Use only outdoors or in a well-ventilated area.*

*Contaminated work clothing should not be allowed out of the workplace.*

*Wear protective gloves/protective clothing/eye protection/face protection.*

*If swallowed: Call a poison center/doctor if you feel unwell.*

*If on skin: Wash with plenty of water.*

*IF INHALED: Remove person to fresh air and keep comfortable for breathing.*

*Immediately call a poison center/doctor.*

*IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.*

*Specific treatment (see on this label).*

*Get medical advice/attention if you feel unwell.*

*Rinse mouth.*

*Take off contaminated clothing and wash it before reuse.*

*If skin irritation or rash occurs: Get medical advice/attention.*

*Store in a well-ventilated place. Keep container tightly closed.*

*Store locked up.*

*Dispose of contents/container in accordance with local/regional/national/international regulations.*

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 3

Fire = 0

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = \*3

Fire = 0

Reactivity = 0

### 3 Composition/Information on ingredients

· **Chemical characterization: Mixtures**

· **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 68855-54-9	Kieselguhr, soda ash flux-calcined	30-60% w/w *
CAS: 16919-27-0	dipotassium hexafluorotitanate	5-7% w/w *
CAS: 1314-13-2	zinc oxide	3-5% w/w *

\* Actual concentration ranges are withheld as a trade secret.

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### 4 First aid measures

- **Description of first aid measures**
- **After inhalation:**  
Supply fresh air and to be sure call for a doctor.  
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:**  
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:**  
Rinse out mouth and then drink plenty of water.  
If symptoms persist consult doctor.
- **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:** No special measures required.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Ensure adequate ventilation
- **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:** Keep receptacle tightly sealed.

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· **Specific end use(s)** No further relevant information available.

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### 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:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **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 and dental laboratories.  
Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.  
Avoid contact with the eyes and skin.
- **Breathing equipment:** Not required.
- **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**  
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:**

<b>Form:</b>	Pasty
<b>Color:</b>	Different according to coloring
<b>Odor:</b>	like peppermint
<b>Odor threshold:</b>	Not determined.
- **pH-value:** Not applicable.
- **Change in condition**

<b>Melting point/Melting range:</b>	Undetermined.
<b>Boiling point/Boiling range:</b>	Undetermined.
- **Flash point:** Not applicable.

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· <b>Flammability (solid, gaseous):</b>	Not applicable.
· <b>Auto igniting:</b>	Product is not selfigniting.
· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapor pressure:</b>	Not determined.
· <b>Density:</b>	Not determined.
· <b>Relative density</b>	Not determined.
· <b>Vapor density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with Water:</b>	Not determined.
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not determined.
<b>Kinematic:</b>	Not determined.
· <b>Other information</b>	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)

- **on the skin:** No irritant effect.

- **on the eye:** Irritating effect.

- **Sensitization:** Sensitization possible through skin contact.

- **Additional toxicological information:** No further relevant information available.

- **Carcinogenic categories**

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

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### 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:** Toxic for fish
- **Additional ecological information:**
- **General notes:**  
*Also poisonous for fish and plankton in water bodies.  
 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:**  
*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

- |   |
|---|
| <ul style="list-style-type: none"> <li>· <b>UN-Number</b></li> <li>· <b>DOT/TDG, ADR, ADN, IMDG, IATA</b>      <i>Void</i></li> </ul>   |
| <ul style="list-style-type: none"> <li>· <b>UN proper shipping name</b></li> <li>· <b>DOT/TDG, ADR, ADN, IMDG, IATA</b>      <i>Void</i></li> </ul>                                     |
| <ul style="list-style-type: none"> <li>· <b>Transport hazard class(es)</b></li> <li>· <b>DOT, ADR, ADN, IMDG, IATA</b></li> <li>· <b>Class</b>      <i>Void</i></li> </ul>              |
| <ul style="list-style-type: none"> <li>· <b>Packing group</b></li> <li>· <b>DOT/TDG, ADR, IMDG, IATA</b>      <i>Void</i></li> </ul>  |
| <ul style="list-style-type: none"> <li>· <b>Environmental hazards:</b>      <i>Not applicable.</i></li> </ul>   |
| <ul style="list-style-type: none"> <li>· <b>Special precautions for user</b>      <i>Not applicable.</i></li> </ul>   |
| <ul style="list-style-type: none"> <li>· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>      <i>Not applicable.</i></li> </ul>                          |
| <ul style="list-style-type: none"> <li>· <b>Transport/Additional information:</b>      <i>Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).</i></li> </ul> |

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· 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):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

CAS: 68855-54-9 Kieselguhr, soda ash flux-calcined

CAS: 16919-27-0 dipotassium hexafluorotitanate

CAS: 1314-13-2 zinc oxide

· **GHS label elements**

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

· **Hazard pictograms**



GHS05   GHS07   GHS08

· **Signal word** *Danger*

· **Hazard-determining components of labeling:**

dipotassium hexafluorotitanate

Kieselguhr, soda ash flux-calcined

· **Hazard statements**

Harmful if swallowed.

Causes serious eye damage.

May cause an allergic skin reaction.

May cause respiratory irritation.

May cause damage to organs through prolonged or repeated exposure.

· **Precautionary statements**

Do not breathe dust/fume/gas/mist/vapours/spray.

Wash thoroughly after handling.

Do not eat, drink or smoke when using this product.

Use only outdoors or in a well-ventilated area.

Contaminated work clothing should not be allowed out of the workplace.

Wear protective gloves/protective clothing/eye protection/face protection.

If swallowed: Call a poison center/doctor if you feel unwell.

If on skin: Wash with plenty of water.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

Immediately call a poison center/doctor.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Specific treatment (see on this label).

Get medical advice/attention if you feel unwell.

Rinse mouth.

Take off contaminated clothing and wash it before reuse.

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*If skin irritation or rash occurs: Get medical advice/attention.*

*Store in a well-ventilated place. Keep container tightly closed.*

*Store locked up.*

*Dispose of contents/container in accordance with local/regional/national/international regulations.*

· **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 the latest revision of the safety data sheet** 09/30/2019 / 5

· **Abbreviations and acronyms:**

*IMDG: International Maritime Code for Dangerous Goods*

*DOT: US Department of Transportation*

*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)*

*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*

· **\* Data compared to the previous version altered.**

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