

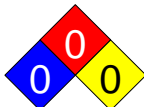
## 1 Identification

- **Product identifier**
- **Trade name: *IPS Style Ceram Add-On***
- **Application of the substance / the mixture** *Manufacture of dental prosthesis*
- **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*
  - **Classification system:**
  - **NFPA ratings (scale 0 - 4)**
- 

Health = 0  
Fire = 0  
Reactivity = 0
- **HMIS-ratings (scale 0 - 4)**
- |            |   |                |
|------------|---|----------------|
| HEALTH     | 0 | Health = 0     |
| FIRE       | 0 | Fire = 0       |
| REACTIVITY | 0 | Reactivity = 0 |
- **Other hazards**  
*Dust generation*  
*Particular danger of slipping on leaked/spilled product.*

## Safety Data Sheet acc. to OSHA HCS

Printing date 11/04/2015

Version number 1

Reviewed on 09/29/2015

**Trade name: IPS Style Ceram Add-On**

(Contd. of page 1)

- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### 3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Leucite oxyapatite metal ceramic
- **Dangerous components:** Void

### 4 First-aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:**  
Supply fresh air; consult doctor in case of complaints.  
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:**  
Rinse with water.  
Generally the product does not irritate the skin.
- **After eye contact:**  
Rinse opened eye for several minutes under running water. Then consult a doctor.  
Mechanical effects only.
- **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 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
The product is not flammable.  
Use fire fighting measures that suit the environment.
- **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** Avoid formation of dust.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**  
Pick up mechanically.  
Ensure adequate ventilation.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.

(Contd. on page 3)

## Safety Data Sheet acc. to OSHA HCS

Printing date 11/04/2015

Version number 1

Reviewed on 09/29/2015

**Trade name: IPS Style Ceram Add-On**

See Section 13 for disposal information.

(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.  
Ensure good ventilation/exhaustion at the workplace.  
Prevent formation of dust.
- **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.  
Store in dry conditions.
- **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:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **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.  
Vacuum clean contaminated clothing. Do not blow or brush off contamination.  
Do not inhale dust / smoke / mist.
- **Breathing equipment:** Use respiratory protective device against the effects of dust.
- **Recommended filter device for short term use:**



FFP2

- **Protection of hands:** Not required.
- **Material of gloves -**
- **Penetration time of glove material -**
- **Eye protection:** Safety glasses

US

(Contd. on page 4)

## Safety Data Sheet

acc. to OSHA HCS

Printing date 11/04/2015

Version number 1

Reviewed on 09/29/2015

Trade name: **IPS Style Ceram Add-On**

(Contd. of page 3)

### 9 Physical and chemical properties

· <b>Information on basic physical and chemical properties</b>	
· <b>General Information</b>	
· <b>Appearance:</b>	
<b>Form:</b>	Powder
<b>Color:</b>	Different according to coloring
· <b>Odor:</b>	Odorless
· <b>Odor threshold:</b>	Not determined.
· <b>pH-value:</b>	Not applicable.
· <b>Change in condition</b>	
<b>Melting point/Melting range:</b>	Undetermined.
<b>Boiling point/Boiling range:</b>	Undetermined.
· <b>Flash point:</b>	Not applicable.
· <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 applicable.
· <b>Density:</b>	Not determined.
· <b>Relative density</b>	Not determined.
· <b>Vapor density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.
· <b>Solubility in / Miscibility with</b>	
<b>Water:</b>	Insoluble.
· <b>Partition coefficient (n-octanol/water):</b> Not determined.	
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not applicable.
<b>Kinematic:</b>	Not applicable.
· <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.

US

(Contd. on page 5)

## Safety Data Sheet acc. to OSHA HCS

Printing date 11/04/2015

Version number 1

Reviewed on 09/29/2015

Trade name: **IPS Style Ceram Add-On**

(Contd. of page 4)

### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **LD/LC50 values that are relevant for classification:**  
Based on available data, the classification criteria are not met.
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**  
The product is not subject to classification according to internally approved calculation methods for preparations:
- **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.
- **Additional ecological information:**
- **General notes:** Generally not hazardous for water
- **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

- **UN-Number**
- **DOT, ADR, RID, ADN, ADN, IMDG, IATA** Void
- **UN proper shipping name**
- **DOT, ADR, RID, ADN, ADN, IMDG, IATA** Void

(Contd. on page 6)

## Safety Data Sheet

acc. to OSHA HCS

Printing date 11/04/2015

Version number 1

Reviewed on 09/29/2015

**Trade name: IPS Style Ceram Add-On**

(Contd. of page 5)

· <b>Transport hazard class(es)</b>	
· <b>DOT, ADR, RID, ADN, IMDG, IATA</b>	
· <b>Class</b>	Void
· <b>Packing group</b>	
· <b>DOT, ADR, RID, ADN, IMDG, IATA</b>	Void
· <b>Environmental hazards:</b>	
· <b>Marine pollutant:</b>	No
· <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):**

None of the ingredients is listed.

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

None of the ingredients is listed.

· **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)**

None of the ingredients is listed.

· **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

(Contd. on page 7)

## Safety Data Sheet

acc. to OSHA HCS

Printing date 11/04/2015

Version number 1

Reviewed on 09/29/2015

**Trade name: IPS Style Ceram Add-On**

(Contd. of page 6)

- **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** 11/04/2015 / -
- **Abbreviations and acronyms:**  
*RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)*  
*ICAO: International Civil Aviation Organisation*  
*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