

**Safety Data Sheet**  
according to WHS Regulations

Printing date 23.04.2020

Version number 1

Revision: 23.04.2020

Not classified as hazardous according to criteria of Australian Safety and Compensation Council.

### 1 Identification

- **Product identifier**
- **Trade name:** ***IPS Style Ceram Add-On***
- **Relevant identified uses of the substance or mixture and uses advised against**  
*No further relevant information available.*
- **Application of the substance / the mixture** *Manufacture of dental prosthesis*
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
*Ivoclar Vivadent AG  
Bendererstrasse 2  
9494 Schaan  
PRINCIPALITY OF LIECHTENSTEIN  
Tel: +423 235 35 35 / Fax: +423 235 33 60*
- **Importer:**  
*Ivoclar Vivadent Pty. Ltd.  
1- 5 Overseas Drive  
Noble Park North VIC 3174  
Tel: + 61 3 9795 9599 / Fax: + 61 3 9795 9645*
- **Further information obtainable from:**  
*Regulatory Affairs  
sds@ivoclarvivadent.com*
- **Emergency telephone number:** *131 126 (Poisons Information Centre - 24 hours / 7 days)*

### 2 Hazard(s) Identification

- **Classification of the substance or mixture**  
*The product is not classified, according to the Globally Harmonised System (GHS).*

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- **Label elements**
- **GHS label elements** *Void*
- **Hazard pictograms** *Void*
- **Signal word** *Void*
- **Hazard statements** *Void*
- **Other hazards**  
*Dust generation  
Particular danger of slipping on leaked/spilled product.*
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

### 3 Composition and Information on Ingredients

- **Chemical characterisation:** *Mixtures*
- **Description:** *Leucite oxyapatite metal ceramic*
- **Dangerous components:** *Void*
- **Additional information:** *For the wording of the listed hazard phrases refer to section 16.*

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### 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 extinguishing methods suitable to surrounding conditions.
- **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.  
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.  
Ensure good ventilation/exhaustion at the workplace.  
Prevent formation of dust.
- **Information about fire - and explosion protection:** No special measures required.

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- **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 container tightly sealed.
  - Store in dry conditions.
- **Specific end use(s)** No further relevant information available.

### 8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**
- **Ingredients 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 and dental laboratories.
  - 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.
- **Respiratory protection:** 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

### 9 Physical and Chemical Properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Powder
Colour:	Different according to colouring
Odour:	Odourless
Odour threshold:	Not determined.
- **pH-value:** Not applicable.
- **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.
- **Flash point:** Not applicable.

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· <b>Flammability (solid, gas):</b>	<i>Not applicable.</i>
· <b>Auto-ignition temperature:</b>	<i>Product is not selfigniting.</i>
· <b>Explosive properties:</b>	<i>Product does not present an explosion hazard.</i>
· <b>Explosion limits:</b>	
<b>Lower:</b>	<i>Not determined.</i>
<b>Upper:</b>	<i>Not determined.</i>
· <b>Vapour pressure:</b>	<i>Not applicable.</i>
· <b>Density:</b>	<i>Not determined.</i>
· <b>Relative density</b>	<i>Not determined.</i>
· <b>Vapour density</b>	<i>Not applicable.</i>
· <b>Evaporation rate</b>	<i>Not applicable.</i>
· <b>Solubility in / Miscibility with water:</b>	<i>Insoluble.</i>
· <b>Partition coefficient: n-octanol/water:</b>	<i>Not determined.</i>
· <b>Viscosity:</b>	
<b>Dynamic:</b>	<i>Not applicable.</i>
<b>Kinematic:</b>	<i>Not applicable.</i>
· <b>Other information</b>	<i>No further relevant information available.</i>

### 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 relevant for classification:** *Based on available data, the classification criteria are not met.*
- **Skin corrosion/irritation** *No irritant effect.*
- **Serious eye damage/irritation** *No irritating effect.*
- **Respiratory or skin sensitisation** *No sensitising effects known.*
- **Additional toxicological information:**  
*The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.*

### 12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** *No further relevant information available.*
- **Persistence and degradability** *No further relevant information available.*

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- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** 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 packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- |   |  |
|---|--|
| · <b>UN-Number</b>  |  |
| · <b>ADG, ADN, IMDG, IATA</b>   | Void   |
| · <b>UN proper shipping name</b>  |  |
| · <b>ADG, ADN, IMDG, IATA</b>   | Void   |
| · <b>Transport hazard class(es)</b>   |  |
| · <b>ADG, ADN, IMDG, IATA</b>   |  |
| · <b>Class</b>  | Void   |
| · <b>Packing group</b>  |  |
| · <b>ADG, 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 Marpol 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**

· <b>Australian Inventory of Chemical Substances</b>
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All ingredients are listed.
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· <b>Standard for the Uniform Scheduling of Medicines and Poisons</b>
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None of the ingredients is listed.
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· **Australia: Priority Existing Chemicals**

None of the ingredients is listed.

· **GHS label elements** Void

· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **National regulations:**

· **Other regulations, limitations and prohibitive regulations**

The product is a medical device according to the Directive 93/42/EEC.

· **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.

· **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

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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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