

## Safety Data Sheet

### Section 1: Identification of the material and the Supplier

<b>Product identifier</b>	<b>IPS e.max Ceram: Dentin, Deep Dentin, Incisal, Transpa Incisal, Transpa, Essence, Gingiva, Margin, Intensive Margin</b>
Product use	Fluorapatite glass-ceramic Manufacture of dental prothesis
<b>Distributor information</b>	
Company identification	<b>Ivoclar Vivadent (NZ) Ltd</b>
Address	12 Omega Street, Rosedale, Auckland, New Zealand
Telephone Number	0508 486 252
Emergencies within New Zealand	<b>0800 764 766 (National Poison Control Centre)</b>

### Section 2: Hazards Identification

Classification of the substance or mixture:	
Classification according to Regulation (EC) No 1272/2008	The substance is not classified according to the CLP regulation.
Classification according to Directive 67/548/EEC or Directive 1999/45/EC	Not applicable.
Information concerning particular hazards for human and environment	Not applicable.
Label elements:	
Labelling according to Regulation (EC) No 1272/2008	Void.
Hazard pictograms	Void.
Signal word	Void.
Hazard Statements	Void.
Additional information	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.

### Section 3: Composition/Information on Ingredients

Chemical characterization	Substances.
CAS No. Description	66402-68-4 ceramic materials
Identification number(s)	
EC number	266-340-9

### Section 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. If symptoms persist, 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.

#### Section 5: Fire Fighting Measures

Extinguishing media:	
Suitable extinguishing agents	The product is not flammable.
Special hazards arising from the substance or mixture	No further relevant information available.
Advice for firefighters:	
Protective equipment	No special measures required.

#### Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures	Particular danger of slipping on leaked/spilled product.
Environmental precautions	No special measures required.
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.

#### Section 7: Handling and Storage

Handling:	
Precautions for safe handling	Only adequately trained personnel should handle this product. Prevent formation of dust. Ensure good ventilation/exhaustion at the workplace.
Information about fire and explosion protection	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	Keep container tightly sealed. Store in dry conditions.
Specific end use(s)	No further relevant information available.

#### Section 8: Exposure Controls/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	Not required.
Additional information	The lists valid during the making were used as basis.
Exposure controls:	
Personal protective equipment:	
General protective and hygienic measures	Usual hygienic measures for dental practice. Wash hands before breaks and at the end of work. Keep away from foodstuffs, beverages and feed. Vacuum clean contaminated clothing. Do not blow or brush off contamination. Do not inhale dust/smoke/mist.
Respiratory protection:	In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
Recommended filter device for short term use	Filter P2.
Protection of hands	Not required.
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.
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.

### Section 9: Physical and Chemical Properties

Information on basic physical and chemical properties:

General Information:

Appearance:

Form	Powder
Colour	According to product specification
Odour	Odourless
Odour 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)	Product is not flammable
Self-igniting	Not determined
Danger of explosion	Product does not present an explosion hazard
Explosion limits:	
Lower	Not determined
Upper	Not determined
Vapour pressure	Not applicable
Density:	Not determined
Relative density	Not determined
Vapour density	Not applicable
Evaporation rate	Not applicable
Solubility in/Miscibility with water	Insoluble

Partition coefficient (n-octanol/water)	Not determined
Viscosity:	
Dynamic	Not applicable
Kinematic	Not applicable
Other information	No further relevant information available

#### Section 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.

#### Section 11: Toxicological Information

Information on toxicological effects:	
Acute toxicity:	
Primary irritant effect:	
On the skin	No irritant effect.
On the eye	Mechanical effects only.
Sensitization	No sensitizing effects known.
Additional toxicological information:	The substance is not subject to classification according to the latest version of the EU lists.

#### Section 12: Ecological Information

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

#### Section 13: Disposal Considerations

Waste treatment methods:	
Recommendation	Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

**European waste catalogue**

08 02 99

wastes not otherwise specified

Uncleaned packaging:

Recommendation

Disposal must be made according to official regulations.

**Section 14: Transport Information**

This product is not a Dangerous Good for Road and Rail transport in New Zealand according to NZS 5433 Safe Transport of Dangerous Goods.

**Section 15: Regulatory Information**

Safety, health and environmental regulations/legislation specific for the substance or mixture:

National regulations:

Other regulations, limitations and prohibitive regulations

The product is a medical device according to the EC-directive 93/42/EEC.

Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

**Section 16: Other Information**

This document has been compiled by Ivoclar Vivadent Ltd on behalf of the manufacturer of the product and serves as the manufacturer's Safety Data Sheet ('SDS'). It is based on information concerning the product which has been provided to Ivoclar Vivadent (NZ) Ltd by the manufacturer or obtained from third party sources and is believed to represent the current state of knowledge as to the appropriate safety and handling precautions for the product at the time of issue. Further clarification regarding any aspect of the product should be obtained directly from the manufacturer. While Ivoclar Vivadent (NZ) Ltd has taken all care to include accurate and up-to-date information in this SDS, it does not provide any warranty as to accuracy or completeness. As far as lawfully possible, Ivoclar Vivadent (NZ) Ltd accepts no liability or any loss, injury or damage (including consequential loss) which may be suffered or incurred by any person as a consequence of their reliance on the information contained in this SDS. The information herein is given in good faith, but no warranty, express or implied is made.

Issue date: 24 January 2013

Date Ivoclar Vivadent Ltd prepared: 18 September 2014

Review date: 24 January 2018