

**Safety Data Sheet
in accordance with HSNO**

Printing date 11.10.2024

Version number 7

Revision: 11.10.2024

1 Identification of the substance or mixture and of the supplier

- **Product identifier**
- **Trade name:** ***IPS e.max Ceram ZirLiner Build-Up Liquid allround***
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** *Ceramic mixing liquid*
- **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 Ltd.
12 Omega St, Rosedale, Auckland
New Zealand
Tel: + 64 9 914 9999 / Fax: + 64 9 914 9990*
- **Further information obtainable from:**
*Regulatory Affairs
sds@ivoclar.com*
- **Emergency telephone number:** *0800 764 766 (National Poison Centre - 24 hours / 7 days)*

2 Hazards identification

- **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonised System (GHS).
- **Label elements**
- **GHS label elements** *Void*
- **Hazard pictograms** *Void*
- **Signal word** *Void*
- **Hazard statements** *Void*
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

3 Composition/Information on ingredients

- **Chemical characterisation:** *Mixtures*
- **Description:** *Mixture of substances listed below with nonhazardous additions.*
- **Dangerous components:** *Void*
- **Additional information:** *For the wording of the listed hazard phrases refer to section 16.*

*** 4 First aid measures**

- **General information:** *No special measures required.*
- **After inhalation:** *Supply fresh air; consult doctor in case of complaints.*
- **After skin contact:**
Rinse with water.

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Generally the product does not irritate the skin.

· **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 Fire fighting measures

· **Suitable extinguishing agents:**

CO₂, 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.

· **Protective equipment:** No special measures required.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**

Wear protective equipment. Keep unprotected persons away.

· **Environmental precautions:**

No special measures required.

Do not allow to enter sewers/ surface or ground water.

· **Methods and material for containment and cleaning up:**

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

· **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 fire - and explosion protection:** No special measures required.

· **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:**

This product is hygroscopic.

Keep container tightly sealed.

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

8 Exposure controls/personal protection

· **Additional information about design of technical facilities:** No further data; see section 7.

· **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.

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- **Additional information:** The lists valid during the making were used as basis.
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Usual hygienic measures for dental practice and dental laboratories.
Wash hands before breaks and at the end of work.
Keep away from foodstuffs, beverages and feed.
- **Respiratory protection:** Not required.
- **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **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

- **General Information**
- **Appearance:**
- **Form:** Fluid
- **Colour:** Colourless
- **Odour:** Nearly odourless
- **Odour threshold:** Not determined.
- **pH-value:** Not determined.
- **Change in condition**
- **Melting point/freezing point:** Undetermined.
- **Initial boiling point and boiling range:** Undetermined.
- **Flash point:** Undetermined.
- **Flammability (solid, gas):** Not applicable.
- **Ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Explosion limits:**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Vapour pressure at 20 °C:** 23 hPa
- **Density:** Not determined.
- **Relative density** Not determined.
- **Vapour density** Not determined.
- **Evaporation rate** Not determined.
- **Solubility in / Miscibility with**
- **water:** Fully miscible.
- **Partition coefficient: n-octanol/water:** Not determined.
- **Viscosity:**
- **Dynamic:** Not determined.
- **Kinematic:** Not determined.

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· **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.
- **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** Based on available data, the classification criteria are not met.
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **Additional toxicological information:** No further relevant information available.

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:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **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.

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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· UN-Number · NZS/RID/ADN, ADN, IMDG, IATA	Void
· UN proper shipping name · NZS/RID/ADN, ADN, IMDG, IATA	Void
· Transport hazard class(es) · NZS/RID/ADN, ADN, IMDG, IATA · Class	Void
· Packing group · NZS/RID/ADN, IMDG, IATA	Void
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of Marpol 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**

- **New Zealand Inventory of Chemicals**

All ingredients are 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 Regulation 2017/745 on Medical Devices (MDR).

- **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.

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· **Contact:**

· **Abbreviations and acronyms:**

IMO: International Maritime Organization

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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

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