

Safety Data Sheet according to WHS Regulations

Printing date 15.02.2024

Version number 3

Revision: 06.02.2024

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

1 Identification

- **Product identifier**
- **Trade name:** ***IPS InLine Margin Build-Up Liquid***
- **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 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@ivoclar.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).
- **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 and 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.

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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.
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:**
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.
- **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.
- **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:** Keep container tightly sealed.
- **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 section 7.

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· **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.

· **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:**



Protective gloves (EN 374)

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: | Odourless |
| · Odour threshold: | Not determined. |
| · pH-value: | Not determined. |

· **Change in condition**

- | | |
|---|---|
| · Melting point/freezing point: | Undetermined. |
| · Initial boiling point and boiling range: | 100 °C |
| · Flash point: | Not applicable. |
| · 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. |

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- | | |
|--|--|
| · 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. |
| · 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:** Not hazardous for water.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

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13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Smaller quantities can be disposed of with household waste.
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.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

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

- **Australian Inventory of Industrial Chemicals**

All ingredients are listed.

- **Standard for the Uniform Scheduling of Medicines and Poisons**

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.

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- **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.

- **Contact:**
- **Abbreviations and acronyms:**
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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