Safety Data Sheet
according to WHS Regulations

Date of issue: 05.02.2025 *Version number 5* *Revision: 05.02.2025*

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

*
1 Identification

· ***Other means of identification***

· ***Trade name:*** ***IPS Empress CAD / IPS Empress CAD Multi***

· ***CAS Number:***
66402-68-4
· ***EC number:***
266-340-9
· ***Relevant identified uses of the substance or mixture and uses advised against***
No further relevant information available.
· ***Application of the substance / the mixture*** *Leucite glass-ceramic block*

· ***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 substance 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*** *Avoid breathing sanding dust /swarf.*
· ***Results of PBT and vPvB assessment***
· ***PBT:*** *Not applicable.*
· ***vPvB:*** *Not applicable.*

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3 Composition and Information on Ingredients

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

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· **Description:** Leucite-reinforced glass-ceramic blocks

4 First Aid Measures

· **General information:** No special measures required.
· **After inhalation:** Grinding dust: Supply fresh air; consult doctor in case of complaints.
· **After skin contact:** Generally the product does not irritate the skin.
· **After eye contact:**
Grinding dust: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
Mechanical effects only.
· **After swallowing:**
Grinding dust: 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.
· **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** Not required.
· **Environmental precautions:** No special measures required.
· **Methods and material for containment and cleaning up:** Pick up mechanically.
· **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.

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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:** None.
· **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

· **Appropriate engineering controls** No further data; see section 7.

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· **Ingredients with limit values that require monitoring at the workplace:** Not required.
· **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.
· **Respiratory protection:** Use respiratory protective device against the effects of dust.
· **Protection of hands:** Not required.
· **Material of gloves** -
· **Penetration time of glove material** -
· **Eye protection:**
Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling).

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9 Physical and Chemical Properties

· **General Information**	
· **Appearance:**	
· **Form:**	Solid
· **Colour:**	According to product specification
· **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.
· **Flammability**	Product is not flammable.
· **Ignition temperature:**	Not determined.
· **Explosive properties:**	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.
· **Particle characteristics**	Not applicable.

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.

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· **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.
Based on available data, the classification criteria are not met.
· **Specific symptoms in biological assay:**
· **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.

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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.

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

· **UN-Number**	
· **ADG, ADN, IMDG, IATA**	Void
· **UN proper shipping name**	
· **ADG, ADN, IMDG, IATA**	Void

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· **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

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15 Regulatory information

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

· **Australian Inventory of Industrial Chemicals**

Substance is not listed.

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

Substance is not listed.

· **GHS label elements** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void

· **Directive 2012/18/EU**
· **Named dangerous substances - ANNEX I** Substance is not 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.

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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:**
ICAO: International Civil Aviation Organisation
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
CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic

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vPvB: very Persistent and very Bioaccumulative

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