Safety Data Sheet
according to WHS Regulations

Printing date 15.02.2024 *Version number 1* *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 System Opaquer, Intensive Opaquer, Opaquer F**

· **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.

· **Application of the substance / the mixture** Leucite metal-ceramic

· **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:** dental ceramic

· **Dangerous components:**		
CAS: 56-81-5	glycerol	2.5-10%

· **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.
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

· **Suitable extinguishing agents:** 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:** Do not allow to enter sewers/ surface or ground water.
· **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.

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.
Store in dry conditions.

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· **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.

· **Ingredients with limit values that require monitoring at the workplace:**

CAS: 56-81-5 glycerol

NES	Long-term value: 10 mg/m³
WES	Long-term value: 10 mg/m³

· **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:**
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.
· **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:**	Pasty
· **Colour:**	According to product specification
· **Odour:**	Characteristic
· **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.

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· **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:**	Not determined.
· **Density:**	Not determined.
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
· **water:**	Not miscible or difficult to mix.
· **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.

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· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water
Do not allow product to reach ground water, water course or sewage system, even in small quantities.
Danger to drinking water if even extremely small quantities leak into the ground.
· **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** Disposal must be made according to official regulations.

· **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
· **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

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· **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.

· **Contact:**
· **Abbreviations and acronyms:**
ICAO: International Civil Aviation Organisation
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