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Version number 3

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SECTION 1: Identification of the substance/mixture and of the company/undertaking · 1.1 Product identifier · Trade name: IPS InLine PoM Ingots · CAS Number: 66402-68-4 • EC number: 266-340-9 · 1.2 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 Manufacture of dental prothesis \cdot 1.3 Details of the supplier of the safety data sheet · Manufacturer/Supplier: Ivoclar Vivadent AG Bendererstrasse 2 FL-9494 Schaan PRINCIPALITY OF LIECHTENSTEIN Tel: +423 235 35 35 Fax: +423 235 33 60 · Further information obtainable from: **Regulatory Affairs** sds@ivoclarvivadent.com • 1.4 Emergency telephone number: +423/235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein) **SECTION 2: Hazards identification** · 2.1 Classification of the substance or mixture · Classification according to Regulation (EC) No 1272/2008 The substance is not classified according to the CLP regulation. · 2.2 Label elements · Labelling according to Regulation (EC) No 1272/2008 Void · Hazard pictograms Void · Signal word Void · Hazard statements Void · 2.3 Other hazards Avoid breathing sanding dust /swarf. · Results of PBT and vPvB assessment · **PBT:** Not applicable. · vPvB: Not applicable. **SECTION 3: Composition/information on ingredients** · 3.1 Chemical characterisation: Substances · CAS No. Description 66402-68-4 ceramic materials · Identification number(s) ---· EC number: 266-340-9 GB

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SECTION 4: First aid measures

· 4.1 Description of first aid measures

- \cdot 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.

• 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.

• 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

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

SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- 6.2 Environmental precautions: No special measures required.
- 6.3 Methods and material for containment and cleaning up: Pick up mechanically.
- · 6.4 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

· 7.1 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.
- \cdot 7.2 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 conditions: None.
- 7.3 Specific end use(s) No further relevant information available.

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SECTION 8: Exposure controls/personal protection

• Additional information about design of technical facilities: No further data; see item 7.

- · 8.1 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.

- · Personal protective equipment:
- General protective and hygienic measures: Usual hygienic measures for dental practice.
- 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).

SECTION 9: Physical and chemical properties

9.1 Information on basic physical a 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/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/wat	er): Not determined.	
Viscosity:		
Dynamic:	Not applicable.	
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^{· 8.2} Exposure controls

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Kinematic:

• 9.2 Other information

Not applicable. No further relevant information available.

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

· 10.2 Chemical stability Stable under normal handling and storage conditions.

• Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

• 10.3 Possibility of hazardous reactions No dangerous reactions known.

• 10.4 Conditions to avoid No further relevant information available.

• 10.5 Incompatible materials: No further relevant information available.

• 10.6 Hazardous decomposition products: None under normal conditions of storage and use.

SECTION 11: Toxicological information

· 11.1 Information on toxicological effects

• Acute toxicity:

· Primary irritant effect:

• on the skin: No irritant effect.

• on the eye: No irritating effect.

· Sensitisation: No sensitising effects known.

• Additional toxicological information: No further relevant information available.

SECTION 12: Ecological information

· 12.1 Toxicity

• Aquatic toxicity: No further relevant information available.

· 12.2 Persistence and degradability No further relevant information available.

· 12.3 Bioaccumulative potential No further relevant information available.

· 12.4 Mobility in soil No further relevant information available.

• Additional ecological information:

- · General notes: Generally not hazardous for water
- · 12.5 Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- · **vPvB:** Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

· 13.1 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.

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· 14.1 UN-Number	
· ADR, ADN, IMDG, IATA	Void
· 14.2 UN proper shipping name	17 . 1
· ADR, ADN, IMDG, IATA	Void
· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA	
· Class	Void
· 14.4 Packing group	
· ADR, IMDG, IATA	Void
· 14.5 Environmental hazards:	
· Marine pollutant:	No
\cdot 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Anne	x II of
MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	Product is not classified as a dangerous good for transpor (ADR, IMDG, IATA).
· UN "Model Regulation":	

SECTION 15: Regulatory information

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

· National regulations:

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· Other regulations, limitations and prohibitive regulations

- The product is a medical device according to the Directive 93/42/EEC.
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 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.

 Abbreviations and acronyms: RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail) ICAO: International Civil Aviation Organisation ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society)
* Data compared to the previous version altered.