Safety data sheet according to 1907/2006/EC, Article 31

Printing date 08.03.2013

Version number 4

Revision: 07.03.2013

1 Identification of the substance/mixture and of the company/undertaking

· Product identifier

• Trade name: IPS Classic Glaze Paste

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

- · Application of the substance / the preparation Auxiliary for manufacture of dental prothesis
- · 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 msds@ivoclarvivadent.com
Emergency telephone number: +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

2 Hazards identification

- · Classification of the substance or mixture
- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC Not applicable.
- *Classification system: The classification is according to the latest editions of the EU-lists, and extended by company and literature data.*
- · Label elements
- Labelling according to EU guidelines: The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (German GefStoffV).
- Special labelling of certain preparations:
- Safety data sheet available for professional user on request.

• Other hazards

- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

3 Composition/information on ingredients

- · Chemical characterization: Mixtures
- · Description: dental ceramic

-			
• Dangerous compone	ents:		
CAS: 56-81-5 EINECS: 200-289-5		substance with a Community workplace exposure limit	
· Additional informati	ion: For the wording of	f the listed risk phrases refer to section 16.	

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10-25%

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4 First aid measures

- · Description of 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. If symptoms persist, 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 Firefighting measures

- · Extinguishing media
- · 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.
- · Advice for firefighters
- · Protective equipment: No special measures required.

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- 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.
- · 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.

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• Further information about storage conditions:

This product is hygroscopic.

Keep container tightly sealed.

Store in dry conditions.

• *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 item 7.

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

56-81-5 glycerol

WEL () Long-term value: 10 mg/m^3

• Additional information: The lists valid during the making were used as basis.

- · Exposure controls
- · Personal protective equipment:
- General protective and hygienic measures: Usual hygienic measures for dental practice. Keep away from foodstuffs, beverages and feed. Wash hands before breaks and at the end of work.
- 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:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. After use of gloves apply skin-cleaning agents and skin cosmetics.

· Material of gloves

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

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

· Appearance:		
Form:	Pasty	
Colour: • Odour:	According to product specification	
	Characteristic	
• Odour threshold:	Not determined.	
· pH-value:	Not determined.	

[·] Control parameters

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· Change in condition		
Melting point/Melting range:	Undetermined.	
Boiling point/Boiling range:	Undetermined.	
· Flash point:	Undetermined.	
· Self-igniting:	Product is not selfigniting.	
· Danger of explosion:	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:	Partly soluble.	
Partition coefficient (n-octanol/wat	er): 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:
- Primary irritant effect:
- on the skin: No irritant effect.
- \cdot on the eye: No irritating effect.
- Sensitization: No sensitizing effects known.
- Additional toxicological information:
- The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

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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:
- 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.

· European waste catalogue

08 02 99 wastes not otherwise specified

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

14 Transport information

· UN-Number	
· ADR, ADN, IMDG, IATA	Void
· UN proper shipping name · ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
· ADR, ADN, IMDG, IATA · Class	Void
· Packing group · ADR, IMDG, IATA	Void
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user	Not applicable.
• Transport in bulk according to Annex II og MARPOL73/78 and the IBC Code	f Not applicable.

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15 Regulatory information

 \cdot Safety, health and environmental regulations/legislation specific for the substance or mixture

· National regulations:

• Other regulations, limitations and prohibitive regulations

The product is a medical device according to the EC-directive 93/42/EEC.

· 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.