Printing date 14.01.2021

ivoclar

vivadent:

Version number 1

Revision: 14.01.2021

1 Identification of the substance or mixture and of the supplier · Product identifier · Trade name: IPS Paste Opaquer Liquid · CAS Number: 107-88-0 • EC number: 203-529-7 · Relevant identified uses of the substance or mixture and uses advised against No further relevant information available. · Application of the substance / the mixture Auxiliary for manufacture of dental prothesis · 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 Ltd. 12 Omega St, Rosedale, Auckland New Zealand Tel: + 64 9 914 9999 / Fax: + 64 9 914 9990 · Further information obtainable from: Regulatory Affairs sds@ivoclarvivadent.com · Emergency telephone number: 0800 764 766 (National Poison Centre - 24 hours / 7 days) **2** Hazards 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
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

3 Composition/Information on ingredients

- · Chemical characterisation: Substances
- · CAS No. Description
- 107-88-0 1,3-Butanediol
- · Identification number(s)
- EC number: 203-529-7

(Contd. on page 2)

Printing date 14.01.2021

Version number 1

Revision: 14.01.2021

Trade name: IPS Paste Opaquer Liquid

(Contd. of page 1)

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. 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.
- \cdot Indication of any immediate medical attention and special treatment needed
- No further relevant information available.

5 Fire fighting 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:
- 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.
- · 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:
- This product is hygroscopic.

(Contd. on page 3)

Printing date 14.01.2021

Version number 1

Revision: 14.01.2021

Trade name: IPS Paste Opaquer Liquid

(Contd. of page 2)

Keep container tightly sealed.

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.

- · Control parameters
- · 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.

- · Exposure controls
- · Personal protective equipment:
- General protective and hygienic measures:
- Usual hygienic measures for dental practice and dental laboratories.
- Keep away from foodstuffs, beverages and feed.
- Wash hands before breaks and at the end of work.
- *Respiratory protection:* Use respiratory protective device against the effects of fumes/dust/aerosol.
- · Recommended filter device for short term use: Combination filter A-P2
- 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 Butyl rubber, BR Fluorocarbon rubber (Viton) PVC gloves
- **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

Information on basic physical and of General Information	hemical properties	
Appearance:	F1 · 1	
Form: Colour:	Fluid	
Odour:	Colourless	
Odour: Odour threshold:	Nearly odourless Not determined.	
Oaour inresnoia:	Not determined.	
pH-value:	Not determined.	
_	Not applicable.	
Change in condition		
Melting point/freezing point:	-57 °C	
Initial boiling point and boiling ra		
Flash point:	121 °C	
Flammability (solid, gas):	Not applicable.	
Ignition temperature:	375 °C	

Printing date 14.01.2021

Version number 1

Revision: 14.01.2021

Trade name: IPS Paste Opaquer Liquid

		(Contd. of page 3)
• Auto-ignition temperature:	Not determined.	
· Explosive properties:	Product does not present an explosion hazard.	
· Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
· Vapour pressure:	Not determined.	
· Density at 20 °C:	$l g/cm^3$	
· Relative density	Not determined.	
· Vapour density	Not determined.	
Evaporation rate	Not determined.	
· Solubility in / Miscibility with		
water:	Fully miscible.	
	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

· LD/LC50 values relevant for classification:

CAS: 107-88-0 1,3-Butanediol

Oral LD50 18610 mg/kg (rat)

- $Dermal \ LD50 > 20000 \ mg/kg \ (rabbit)$
- · Skin corrosion/irritation No irritant effect.
- Serious eye damage/irritation No irritating effect.
- · Respiratory or skin sensitisation No sensitising effects known.
- Additional toxicological information:

No further relevant information available.

The substance is not subject to classification according to the latest version of the EU lists.

(Contd. on page 5)

Printing date 14.01.2021

Version number 1

Revision: 14.01.2021

Trade name: IPS Paste Opaquer Liquid

(Contd. of page 4)

12 Ecological information

· Toxicity

• Aquatic toxicity:

CAS: 107-88-0 1,3-Butanediol

LC50/48 h > 2000 mg/l (fish)

· 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) (Assessment by list): 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.

• Uncleaned packaging:

• Recommendation: Disposal must be made according to official regulations.

14 Transport information

⁷ oid ⁷ oid ⁷ oid
<i>Void</i>
<i>Void</i>
<i>Void</i>
<i>Void</i>
No
Not applicable.
Not applicable.
Product is not classified as a dangerous good for ransport (ADR, IMDG, IATA).

Printing date 14.01.2021

Version number 1

Revision: 14.01.2021

(Contd. of page 5)

Trade name: IPS Paste Opaquer Liquid

· UN "Model Regulation":

Void

15 Regulatory information

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

· New Zealand Inventory of Chemicals

Substance is listed.

· HSNO Approval numbers

HSR005606

· 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 the 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.

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
EINECS: European Inventory of Existing Commercial Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative