

SECTIO	ON 1. Identification of the substance or mixture and of the supplier
1.1	Product identifier
	Trade Name:
	VINTAGE PRO "PASTE OPAQUE LIQUID"
1.2	Relevant identified uses of the substance or mixture and uses advised against
	Relevant identified uses: Dental material
	Uses advised against: No further data
1.3	Details of the supplier of the safety date sheet
	Company/Undertaking identification
	Manufacturer's Name: SHOFU DENTAL GmbH
	Address: An der Pönt 70, 40885 Ratingen, Germany
	Phone: +49 (0) 2102-8664-0
	Fax: +49 (0) 2102-8664-64
	E-Mail: info@shofu.de
	Section in Charge: Quality Management & Regulatory Affairs
1.4	Emergency Telephone Number
	+49-2102-8664-53 (SHOFU DENTAL GmbH) 24 hours / 7 days
SECTIO	DN 2. Hazards identification
2.1	Classification of the substance or mixture
	CLASSIFICATION (EC 1272/2008)
	Not applicable.
2.2	Label elements
	LABEL IN ACCORDANCE WITH (EC) NO.1272/2008
	Void
	HAZARD-DETERMINING COMPONENTS OF LABELLING
	SIGNAL WORD
	Void
	HAZARD STATEMENTS
	Void
	PRECAUTIONARY STATEMENTS
	Void
2.3	Other hazards
	Results of PBT and vPvB assessment
	PBT: Not applicable.
	vPvB: Not applicable.
SECTIO	ON 3. Composition/information on ingredients
3.1	Chemical characterization: Mixtures
3.2	Description: Mixture of substances listed below with nonhazardous additions.
3.3	Dangerous components: Void
	1,3-Butanediol [Cas No.107-88-0, EINECS 203-529-7] 50-60 %
	Glycerin [Cas No.56-81-5, EINECS 200-289-5]
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	Propylene Glycol [Cas No.57-55-6, EINECS 200-338-0]
3.4	Additional information: For the wording of the listed risk phrases refer to section 2.
SECTIO	ON 4. First-aid measures
4.1	Description of first aid measures
	Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present.
	and easy to do. If eye irritation persists, get medical advice/attention.
	Skin contact: Wash immediately with soap and plenty of water. If on skin, skin irritation, get
	medical advice/attention.
	Ingestion: Rinse mouth and seek medical advice if necessary.
	Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
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4.2	Most important symptoms and effects, both acute and delayed
10	No further relevant information available.
4.3	Indication of any immediate medical attention and special treatment needed
	No further relevant information available.
SECTIO	
5.1	Extinguishing Media:
	Water, Foam, CO ₂ , Powder, Dry sand
5.2	Special hazards arising from the substance or mixture:
	In case of fire, irritation gases and fumes may emit.
5.3	Advice for firefighters:
	Wear fire protective cloth and self-contained breathing apparatus, if necessary.
SECTIO	ON 6. Accidental release measures
6.1	Personal precautions, protective equipment and emergency procedures:
	Avoid contact with eyes and skin.
6.2	Environmental Precautions:
	No special measures required.
6.3	Methods and material for containment and cleaning Up:
	Wipe up and discard in a stable container.
6.4	Reference to other section:
0.1	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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7.1	Precautions for safe handling:
	Use in accordance with instruction. In case of grinding and polishing, wear dust mask and
	safety glasses, and using dust respirator and local exhaust.
7.2	Conditions for safe storage, including any incompatibilities:
	Store in a cool, dry and dark place with lid closed, and away from food and beverages.
7.3	
	No further relevant information available.
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SECTION 8. Exposure controls/personal protection

8.1 Control parameters: Exposure limits:

Exposure limits:			
Component		ACGIH	
Glycerin	TWA: 10 mg/m ³ 8 hr	TWA 10 mg/m ³	
	(mist only)	(Glycerin mist)	
Propylene Glycol	STEL; 450 ppm 15 min		
	STEL; 1422 mg/m ³ 15 min		
	STEL; 30 mg/m ³ 15 min		
	TWA; 150 ppm 8 hr		
	TWA; 474 mg/m ³ 8 hr		
	TWA; 10 mg/m ³ 8 hr		

8.2 Exposure controls:

Respiratory Protection:

Respiratory Frote	
	Dust mask
Skin Protection:	Hand Protection
	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.
	• For the permanent contact of a maximum of 15 minutes gloves made of
	the following materials are suitable:
	Butyl rubber, BR
	Nitrile rubber, NBR
Eye Protection:	Safety goggles
SECTION 9. Physical and ch	nemical properties
	nysical and chemical properties
Appearance/Odor/Colo	
Odour threshold	Not determined.
pH	Not determined.
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	Melting point/freezing point	t	Not dete			
	Boiling Point:		> 100 °C			
	Flash point:		112 ⁰C			
	Evaporation rate		Not dete	rmined.		
	Flammability (solid, gas)		Not appl	cable.		
	Upper/lower flammability of	r explosive limits	Not dete	rmined.		
	Vapour pressure		Not dete	rmined.		
	Vapour density		Not dete	rmined.		
	Relative Density:		1.05 (w	vater=1)		
	Solubility: water solubility		Soluble			
	Partition coefficient: n-octai	nol/water	Not dete	rmined.		
	Auto-ignition temperature		Not dete	rmined.		
	Decomposition temperature	e	Not dete	rmined.		
	Viscosity		Not dete	rmined.		
	Explosive properties		Not appl	cable.		
	Oxidising properties		Not appl	icable.		
9.2	Other information					
	No further relevant in	formation available	e.			
SECTIO	N 10. Stability and reacti	vity				
10.1	Reactivity:					
	No further relevant in	formation available	e.			
10.2	Chemical stability:					
	Stable under normal	temperatures and	pressure	S.		
10.3	Possibility of hazardous rea	actions:				
	No dangerous reaction	ons known.				
10.4	Condition to Avoid:					
	No further relevant in	formation available	e.			
10.5	Incompatible materials:					
	No further relevant in	formation available	e.			
10.6	Hazardous Decomposition	Products:				
	None under normal c		e and us	e.		
SECTIO	N 11. Toxicological infor	mation				
	Information on toxicologica					
	Acute toxicity:	1,3-Butanediol;	Oral	rat	LD50	18610 mg/kg
	···· <i>j</i> ·	,	Dermal	rabbit	LD50	> 20 g/kg
		Glycerin;	Oral	rat	LD50	12600 mg/kg
		, ,	Dermal		LD50	> 10 g/kg
			Inhalatio		_200	
				rat	LC50	> 570 mg/m ³ /1H
		Propylene Glycol;	Oral	rat	LD50	20 g/kg
		i Topyterie Glycol,		rabbit	LD50	20 g/kg 20800 mg/kg
	Skin corrosion/irritation:	Based on availabl				•••
		Dased off available	e uala, li	10 UIDSSIII		
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	Eye damage/irritation:	Based on available data, the classification criteria are not met.			
	Sensitization to the respi	ratory tract:			
		Based on available data, the classification criteria are not met.			
	Skin sensitization:	Based on available data, the classification criteria are not met.			
	Germ cell mutagenicity/G				
	e en matagementy, e	Based on available data, the classification criteria are not met.			
	Carcinogenicity:	Based on available data, the classification criteria are not met.			
	U ,				
	Reproductive toxicity: Based on available data, the classification criteria are not met.				
	Effects on or via lactation				
	Specific target organ toxi				
		Based on available data, the classification criteria are not met.			
	Specific target organ toxi	city (repeated exposure):			
		Based on available data, the classification criteria are not met.			
	Aspiration hazard:	Based on available data, the classification criteria are not met.			
SECTIC	ON 12. Ecological inform	hation			
12.1	Toxicity:				
	No further relevant	information available.			
12.2	Persistence and degrada	ıbility:			
	No further relevant	information available.			
12.3	Bioaccumulative potentia	d:			
-	•	information available.			
124	Mobility in soil:				
12.4	•	information available.			
125	Results of PBT and vPvE				
12.5					
40.0	Not applicable.				
12.6	Other adverse effects:				
	No further relevant	information available.			
	ON 13. Disposal conside				
13.1	Waste treatment method				
		s/container to in accordance with local/regional/national/international			
	regulations.				
	ON 14. Transport inform				
	UN number:	Void			
14.2	UN proper shipping name	e: Void			
14.3	Transport hazard class(e	s): Void			
14.4	Packing group:	Void			
	Environmental hazards:	No further relevant information available.			
14.6	Special precautions for u	ser: Not applicable.			
		ng to Annex II of MARPOL73/78 and the IBC Code:			
		Not applicable.			

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SECTION 15. Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:
 - EU REGULATIONS: See Section 2
 - Other regulations, limitations and prohibitive regulations:

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

15.2 Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

SECTION 16. Other information

This product is intended for use by dental professionals. (instrument/material)

Abbreviations and acronyms:

EINESC: 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