

SECTIO	ON 1. Identification of the substance/mixture and of the company/undertaking			
1.1	Product identifier			
	Trade Name:			
	BEAUTIFIL-Bulk Flowable			
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	ON 2. Hazards identification			
2.1	Classification of the substance or mixture			
2	CLASSIFICATION (EC 1272/2008)			
	Skin Irrit. 2 H315 Causes skin irritation			
	Skin Sens. 1 H317 May cause an allergic skin reaction			
	Eye Irrit. 2 H319 Causes serious eye irritation			
2.2	Label elements			
	LABEL IN ACCORDANCE WITH (EC) NO.1272/2008			
	\wedge			
	$\mathbf{\nabla}$			
	GHS07			
	HAZARD-DETERMINING COMPONENTS OF LABELLING			
	UDMA			
	SIGNAL WORD			
	Warning			
	HAZARD STATEMENTS			
	H315 Causes skin irritation.			
	H317 May cause an allergic skin reaction.			
	H319 Causes serious eye irritation. PRECAUTIONARY STATEMENTS			
	P261 Avoid breathing dust/fume/gas/mist/vapour s/spray.			
	P280 Wear protective gloves/protective clothing/eye protection/face			
	protection.			
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(Contd. of page1) P302+P352 IF ON SKIN: Wash with plenty of soap and water. P332+P313 If skin irritation occurs: Get medical advice/attention. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. 2.3 Other hazards Results of PBT and vPvB assessment PBT: Not applicable. vPvB: Not applicable. SECTION 3. **Composition/information on ingredients** Chemical characterization: Mixtures 3.1 3.2 Description: Mixture of substances listed below with nonhazardous additions. 3.3 Dangerous components: UDMA Cas: 72869-86-4 Skin Irrit. 2, H315; Skin Sens. 1, H317 1-5 % EINECS: 276-957-5 Eye Irrit. 2, H319 Others: Bis-GMA [Cas No. 1565-94-2, EINECS 216-367-7] 5-10 % 3.4 Additional information: For the wording of the listed risk phrases refer to section 2. SECTION 4. **First-aid measures** 4.1 Description of first aid measures Rinse cautiously with water for several minutes. Remove contact lenses, if Eve contact: 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. Get medical advice/attention. Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. If symptom concerning breath goes out, call a POISON CENTER or 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. **Fire-fighting measures** 5.1 Extinguishing Media: CO₂, Dry chemical, Foam, Dry sand 5.2 Special hazards arising from the substance or mixture: In case of fire, do not breath fumes and gases. (Irritation gases and fumes may emit.)

5.3 Advice for firefighters:

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Wear fire protective cloth and self-contained breathing apparatus,	if necessary.
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SECTION 6. Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures: Avoid contact with eyes and skin.
- 6.2 Environmental Precautions:

Send to approved treatment/disposal company or dispose according to local, state and federal regulations.

- 6.3 Methods and material for containment and cleaning Up: Wipe up and discard in a suitable container.
- 6.4 Reference to other section:
 - 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:
 - Avoid inhalation of grindings and prolonged skin contact with uncured resin.
- 7.2 Conditions for safe storage, including any incompatibilities:
- Store in a cool and dark fire proof area with container tightly closed.
- 7.3 Specific end use(s):

No further relevant information available.

SECTION 8. Exposure controls/personal protection

8.1	Control parameters	5:			
	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 m	nonitored at the workplace.			
8.2	Exposure controls:				
	Respiratory Protection:				
		Not required.			
	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.			
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	· 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 o					
	the following materials are suitable:					
	Butyl rubbe	er, BR				
	Nitrile rubb	er, NBR				
E	Eye Protection: Safety goggles					
SECTION						
	nformation on basic physical and chemical p	-				
A	Appearance/Odor/Colour:	Non- or yellowish- colored putty-like paste with				
		sweet odor.				
C	Ddour threshold	Not determined.				
· ·	рН	Not determined.				
	Melting point/freezing point	Not determined.				
	Boiling Point:	Not determined.				
	Flash point:	Not determined.				
E	Evaporation rate	Not determined.				
F	Flammability (solid, gas)	Not applicable.				
U	Jpper/lower flammability or explosive limits	Not determined.				
V	/apour pressure	Not determined.				
V	/apour density	Not determined.				
R	Relative Density:	2.0 (water=1)				
S	Solubility: water solubility	Insoluble				
P	Partition coefficient: n-octanol/water	Not determined.				
A	Auto-ignition temperature	Not determined.				
D	Decomposition temperature	Not determined.				
V	/iscosity	Not determined.				
E	Explosive properties	Not applicable.				
	Dxidising properties	Not applicable.				
	Other information					
	No further relevant information available	le.				
	10. Stability and reactivity					
10.1 R	Reactivity:					
	Polymerization will occur with heat, ligh	nt.				
10.2 C	Chemical stability:					
	Stable under normal temperatures and	pressures.				
10.3 P	Possibility of hazardous reactions:					
	No dangerous reactions known.					
10.4 C	Condition to Avoid:					
	Protect from exposure to the light.					
	Keep away from heat and direct sunlig	ht.				
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10.5 Incompatible materials:			
No further relevant information available.			
10.6 Hazardous Decomposition Products:			
None under norm	al conditions of storage and use.		
SECTION 11. Toxicological in	formation		
11.1 Information on toxicolog			
Acute toxicity:	Based on available data, the classification criteria are not met		
Skin corrosion/irritation:			
Eye damage/irritation:	Eye Irrit. 2; H319 Causes serious eye irritation.		
Sensitization to the resp			
	Based on available data, the classification criteria are not met.		
Skin sensitization:	Skin Sens. 1; H317 May cause an allergic skin reaction.		
Germ cell mutagenicity/			
Cerim cen matagementy/	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.		
Effects on or via lactation			
Specific target organ to			
	Based on available data, the classification criteria are not met.		
Specific target organ to	xicity (repeated exposure):		
	Based on available data, the classification criteria are not met.		
SECTION 12. Ecological infor	mation		
12.1 Toxicity:	nt information available.		
12.2 Persistence and degrad	•		
	nt information available.		
12.3 Bioaccumulative potent			
	nt information available.		
12.4 Mobility in soil:			
	nt information available.		
12.5 Results of PBT and vPv	'B assessment:		
Not applicable.			
12.6 Other adverse effects:			
No further relevan	nt information available.		
SECTION 13. Disposal consid			
13.1 Waste treatment metho			
	nts/container to in accordance with local/regional/national/international		
regulations.			
SECTION 14. Transport inform	nation		
14.1 UN number:	Void		
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- 14.2 UN proper shipping name:
- 14.3 Transport hazard class(es):
- Void Void

Void

- 14.4 Packing group: 14.5 Environmental hazards:
- No further relevant information available.
- 14.6 Special precautions for user:
- 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:

Not applicable.

Not applicable.

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)

Relevant phrases:

- H315 Causes skin irritation.
- May cause an allergic skin reaction. H317
- H319 Causes serious eye irritation.

Abbreviations and acronyms:

EINESC: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative