

SECTIO	ON 1. Identification of the substance or mixture and of the supplier		
1.1	Product identifier		
	Trade Name:		
	ResiCem "PASTE"		
1.2	Relevant identified uses of the substance or mixture and uses advised against		
1.2	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: Am Brüll 17, 40878 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			
2.1	Classification of the substance or mixture		
	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		
	GHS07		
	HAZARD-DETERMINING COMPONENTS OF LABELLING		
	UDMA		
	2-hydroxyethyl methacrylate		
	Triethylenglycol dimethacrylate		
	SIGNAL WORD		
	Warning		
	HAZARD STATEMENTS		
	H315 Causes skin irritation.		
	H317 May cause an allergic skin reaction.		
	H319 Causes serious eye irritation.		
	PRECAUTIONARY STATEMENTS		
	P280 Wear protective gloves/protective clothing/eye protection/face		
	protection.		
	·		
	(Contd. on page2)		



	(Contd. of page1)
P302+P35	2
	IF ON SKIN: Wash with plenty of soap and water.
P305+P35	1+P338
	IF IN EYES: Rinse cautiously with water for several minutes.
	Remove contact lenses, if present and easy to do. Continue rinsing.
P501	Dispose of contents/container in accordance with
	local/regional/national/international regulation.
	-
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:

Cas: 72869-86-4	86-4 UDMA	
EINECS: 276-957-5	CS: 276-957-5 Skin Sens. 1 H317, Skin Irrit. 2 H315, Eye Irrit. 2 H319	
Cas: 868-77-9	2-hydroxyethyl methacrylate	1 5 0/
EINECS: 212-782-2	Skin Sens. 1 H317, Skin Irrit. 2 H315, Eye Irrit. 2 H319	1-5 %
Cas: 109-16-0	Triethylenglycol dimethacrylate	
EINECS: 203-652-6	Skin Sens. 1B H317	1-10 %

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
 - 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.
 - Rinse mouth. Get medical advice/attention. Ingestion:

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:
 - Powder, Alcohol-resistant foam, Carbon dioxide.
- 5.2 Special hazards arising from the substance or mixture: Irritation gases and fumes may emit.

(Contd. on page3)



(Contd. of page2)

5.3	Advice for firefighters: Wear fire protective cloth and self-contained breathing apparatus, if necessary.			
SECTIO		elease measures		
6.1	Personal precautions, protective equipment and emergency procedures: Avoid eye and skin contact.			
6.2	Environmental Prec	autions:		
	Send to approved to regulations.	reatment/disposal company or dispose according to local, state and federal		
6.3	•	ial for containment and cleaning up:		
0.0		d in a suitable container.		
6.4	Reference to other			
0.4		formation on safe handling.		
		formation on personal protection equipment.		
		disposal information.		
SECTIO	ON 7. Handling an	d storage		
7.1	Precautions for safe	handling:		
	Avoid prolonged ski	n contact with uncured resin.		
	Keep away from na	ked flames, sparks and sources of heat.		
7.2	Conditions for safe	storage, including any incompatibilities:		
	Store in a cool and	dark fire proof area with container tightly closed.		
	(Keep refrigerated v	vhen not in use.)		
7.3	Specific end use(s)			
	No further relevant	information available		
SECTIO		ontrols/personal protection		
8.1	Control parameters			
	-	it values that require monitoring at the workplace:		
	The produ	ct does not contain any relevant quantities of materials with critical values that		
	have to be	monitored at the workplace.		
8.2	Exposure controls:			
	Respiratory Protect	ion:		
		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		



	not be calc prior to the · Penetration time of The exact b manufactur · For the permanent o the following materia Butyl rubbe Nitrile rubb	break through time has to be found out by the rer of the protective gloves and has to be observed. contact of a maximum of 15 minutes gloves made of als are suitable: er, BR
	Eye Protection: Safety goggles	
SECTIO	ON 9. Physical and chemical properties	
9.1	Information on basic physical and chemical p Appearance/Odor/Colour: Odour threshold pH Melting point/freezing point Boiling Point: Flash point: Evaporation rate Flammability (solid, gas) Upper/lower flammability or explosive limits Vapour pressure Vapour density Relative Density: Solubility: water solubility Partition coefficient: n-octanol/water Auto-ignition temperature Decomposition temperature Viscosity Explosive properties Oxidising properties Other information	Non- or yellowish- colored putty-like paste with sweet odor Not determined. Not determined. Not determined. Not determined. Not determined. Not determined. Not determined. Not determined. Not determined. 1.8 (water=1) Insoluble Not determined. Not applicable.
	No further relevant information available.	
	ON 10. Stability and reactivity Reactivity:	
10.2	Polymerization will occur with heat, light. Chemical stability: Stable under normal temperatures and press Possibility of hazardous reactions: No dangerous reactions known.	sures.
		(Contd. on page5) Version Number 4



(Contd. of page4)

10.4	4 Condition to Avoid: Avoid direct sunlight and high temperature.	(Contd. of page4) Keep away from source of ignition. (-electric
	discharge and smoking etc.)	
10.5	5 Incompatible materials:	
	Strong oxidizing materials.	
10.6	6 Hazardous Decomposition Products:	
	None under normal conditions of storage ar	d use.
SECTIC	ION 11 Taxiaalagiaal information	
	ION 11. Toxicological information 1 Information on toxicological effects:	
	Acute toxicity: 2-Hydroxy Ethyl	Methacrylate:
	Oral	rat LD50 > 4000 mg/kg
		rabbit LD50 > 3000 mg/kg
	Skin corrosion/irritation: Skin Irrit. 2; H31	5 Causes skin irritation.
	Eye damage/irritation: Eye Irrit. 2; H319	O Causes serious eye irritation.
	Sensitization to the respiratory tract:	
	Based on availa	ble data, the classification criteria are not met.
	Skin sensitization: Skin Sens. 1; H3	317 May cause an allergic skin reaction.
	Germ cell mutagenicity/Genotoxicity:	
	Based on availa	ble data, the classification criteria are not met.
	o i	ble data, the classification criteria are not met.
		ble data, the classification criteria are not met.
	Effects on or via lactation: Lack of data.	
	Specific target organ toxicity (single exposu	-
		ble data, the classification criteria are not met.
	Specific target organ toxicity (repeated expo	
		ble data, the classification criteria are not met.
	Aspiration hazard: Based on availa	ble data, the classification criteria are not met.
SECTIC	ION 12. Ecological information	
	1 Toxicity:	
	No further relevant information available.	
12.2	2 Persistence and degradability:	
	No further relevant information available.	
12.3	3 Bioaccumulative potential:	
	No further relevant information available.	
12.4	4 Mobility in soil:	
	No further relevant information available.	
12.5	5 Results of PBT and vPvB assessment:	
	Not applicable.	
12.6	6 Other adverse effects:	
	No further relevant information available.	
		(Contd. on page6)



SECTIO	N 13. Disposal considerations		
13.1	Waste treatment methods: Dispose of contents/container to in accordance with local/regional/national/international regulations.		
SECTIO	N 14. Transport information		
14.1 14.2 14.3 14.4 14.5 14.6	UN number:VoidUN proper shipping name:VoidTransport hazard class(es):VoidPacking group:VoidEnvironmental hazards:No further relevant information available.Special precautions for user:Not applicable.Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Not applicable.		
SECTIO	N 15. Regulatory information		
15.2	 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. Chemical safety assessment: A Chemical Safety Assessment has not been carried out. 		
SECTIO	N 16. Other information		
	This product is intended for use by dental professionals. (instrument/material) Relevant phrases: H315 Causes skin irritation. H317 May cause an allergic skin reaction. 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) LD50: Lethal dose, 50 percent		
	PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative		



		Printing date: June 23, 2016	
SECTIO	N 1. Identification of th	e substance/mixture and of the company/undertaking	
1.1	Product identifier		
	Trade Name:		
	ResiCem "PRIMER	A''	
1.2	Relevant identified uses o	f the substance or mixture and uses advised against	
	Relevant identified uses: Dental material		
	Uses advised again		
1.3	Details of the supplier of the		
1.0	Company/Undertaking ide	-	
		e: SHOFU DENTAL GmbH	
		7, 40878 Ratingen, Germany	
	Phone: +49 (0) 2102		
	Fax: +49 (0) 2102-8		
	E-Mail: info@shofu.		
	•	Quality Management & Regulatory Affairs	
1.4	Emergency Telephone Nu		
	+49-2102-8664-53 (SHOFU DENTAL GmbH) 24 hours / 7 days	
SECTIO			
2.1	Classification of the substa		
	CLASSIFICATION (EC 12		
	1	Highly flammable liquid and vapour.	
	Eye Irrit. 2 H	319 Causes serious eye irritation.	
	STOT SE 3 H	336 May cause drowsiness or dizziness.	
2.2	Label elements		
	LABEL IN ACCORDANCE	EWITH (EC) NO.1272/2008	
		\wedge	
	(())		
		$\mathbf{\nabla}$	
	GHS02	GHS07	
	HAZARD-DETERMINING	COMPONENTS OF LABELLING	
	Acetone		
	SIGNAL WORD		
	Danger		
	HAZARD STATEMENTS.		
	H225	Highly flammable liquid and vapour.	
	H319	Causes serious eye irritation.	
	H336	May cause drowsiness or dizziness	
	1000	Way baddo diowoinicos of dizzinicos	
	PRECAUTIONARY STATE		
	PRECAUTIONANT STATE P202		
	rzuz	Do not handle until all safety precautions have been read and	
	Doto	understood.	
	P210	Keep away from heat/sparks/open flames/hot surfaces.	
		– No smoking.	
		(Contd. on page2)	



·			Finiting date. June 23, 2016
			(Contd. on page1)
		P233	Keep container tightly closed.
		P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
		P264	Wash hands thoroughly after handling.
		P280	Wear protective gloves/protective clothing/eye protection/face
			protection.
2.3	Other hazards	5	•
		-	vPvB assessment
	PBT:	Not applic	
	vPvB:	Not applic	
SECTIO	ON 3. Compo	osition/info	rmation on ingredients
3.1	Chemical cha		
3.2			ubstances listed below with nonhazardous additions.
3.3	Dangerous co		issiances listed below with nonnazardous additions.
5.5	Acetone	•	Cas: 67-64-1 5-15 %
	Acelone		
			EINECS: 200-662-2
		Flam. Liq.	2, H225; Eye Irrit. 2, H319; STOT SE 3, H336
		–	
3.4	Additional info	ormation: Fo	or the wording of the listed risk phrases refer to section 2.
SECTIO		id measure	
4.1	Description of		
	Eye contact:		tiously with water for several minutes. Remove contact lenses, if present
		•	to do. If eye irritation persists, get medical advice/attention.
	Skin contact:		nediately with soap and plenty of water. If on skin, skin irritation, get
		medical a	dvice/attention.
	Ingestion:	Rinse mo	uth. Get medical advice/attention.
	Inhalation:	Remove v	rictim to fresh air and keep at rest in a position comfortable for breathing.
		If symptor	n concerning breath goes out, call a POISON CENTER or doctor.
4.2	Most importar	nt symptom	s and effects, both acute and delayed
	No furth	ner relevant	information available.
4.3	Indication of a	any immedia	ate medical attention and special treatment needed
		-	information available.
SECTIO	ON 5. Fire-fic	phting mea	sures
5.1	Extinguishing	Media:	
	CO ₂ , Dry chemical, Foam		
5.2	· · · · · · · · · · · · · · · · · · ·		
	Easily flammable liquid in room temp.		
5.3	Advice for fire	•	
0.0		•	and self-contained breathing apparatus, if necessary.
	wear me prot		and sentonitanted breathing apparatus, it necessary.
SECTIO	ON 6 Accide	ntal releas	e measures
6.1			ptective equipment and emergency procedures:
0.1		autoris, pro	
			(Contd. on page3)



		(Contd. on page2)			
	Avoid contact with				
6.2	•				
	Send to approved treatment/disposal company or dispose according to local, state and federal regulations.				
6.3	•	rial for containment and cleaning Up:			
6.4	Wipe up and discard in a suitable container. Reference to other section:				
0.1		See Section 7 for information on safe handling.			
		nformation on personal protection equipment.			
		disposal information.			
		disposar mormation.			
SECTI	ON 7. Handling ar	nd storage			
7.1	Precautions for safe	e handling:			
l	Handle in a well ve	ntilated place.			
	Keep away from op	pen flames, sparks and sources of heat. No smoking.			
7.2	Conditions for safe	storage, including any incompatibilities:			
	Store in a cool and	dark area with container tightly closed.			
	Separated from stre	ong oxidants.			
7.3	Specific end use(s)	:			
	No further relevant	information available.			
		ontrols/personal protection			
8.1	Control parameters				
	Exposure limits	Acetone [Cas No.67-64-1]:			
		-OSHA Permissible Exposure Limit (PEL): 1000 ppm (TWA)			
		-ACGIH Threshold Limit Value (TLV): 500 ppm (TWA),			
		750 ppm (STEL) A4 - not classifiable as a human carcinogen			
8.2	Exposure controls:				
	Respiratory Protect	tion:			
		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.			

(Contd. on page4)



(Contd. on page3)

 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:			(Contd. on page3)
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: Buty Inubber, BR Nitrile rubber, BR Seve Protection: Satety goggles SECTION 9. Physical and chemical properties Appearance/Odor/Colour: Colorless liquid with sweet odor Odour threshold Not determined. pH Not determined. Bolling Point: Not determined. Bolling Point: 13 °C (closed) Evaporation rate Not determined. Flash point: 13 °C (closed) Evaporation rate Not determined. Wapour pressure Vapour furge subbility Solibab Bolling Vapour pressure Not determined. Relative Density: 1.01 (water=1) Solubility: water solubility Solibab Partition coefficient: n-cotanol/water Not determined. Explosive properties Not determined. Explosive properties Not determined. Explosive properties Not determined. Bolling Point: 1.01 (water=1) Solubility: water solubility Solibab Partition coefficient: n-cotanol/water Not determined. Explosive properties Not determined. Explosive properties Not determined. Explosive properties Not determined. Explosive properties Not determined. Becomposition temperature Not determined. Explosive properties Not determined. Becomposition temperatures Not determined. Explosive properties Not applicable. 9.2 Other information available. 9.2 Other information available. 9.2 Other information available. 9.3 Other relevant information available. 9.4 Condition to Avoid: Avoid direct sunight, excess heat, flame and other source of ignition. 9.5 Incompatible materials: Strong oxidizing materials.		· Penetration time of gl	ove material
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 chemical properties Appearance/Odor/Colour: Coloriess liquid with sweet odor Odour threshold Not determined. pH Not determined. Boiling Point: Not determined. Boiling Point: 13 °C (closed) Evaporation rate Not determined. Finamability (solid, gas) Not applicable. Upper/lower flammability or explosive limits Not determined. Vapour pressure Not determined. Vapour pressure Not determined. Vapour gressure Not determined. Patition coefficient: n-octanol/water Not determined. Auto-ignition temperature Not determined. Auto-ignition temperature Not determined. Auto-ignition temperature Not determined. Explosive properties Not applicable. Uscosity Not determined. Explosive properties Not applicable. 9.2 Other information No further relevant information available. 9.2 Other information No further relevant information available. 10.3 Possibility: Stable under normal temperatures and pressures. 10.3 Possibility: Stable under normal temperatures and pressures. 10.4 Condition to Avoid: Avoid direct sunlight, excess heat, flame and other source of ignition. 10.5 Incompatible materials: Strong oxidizing materials.		_	
 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 chemical properties Appearance/Odor/Colour: Coloriess liquid with sweet odor Odour threshold Not determined. pH Not determined. pH Not determined. Boiling Point: Not determined. Flash point: 13 °C (closed) Evaporation rate Not determined. Flash point: Not determined. Flash point: Not determined. Paperance/Viewer Bardia and Chemical properties Vapour density: Not determined. Flash point: Not determined. Flash point: Not determined. Flash point: Not determined. Flash point: Not determined. Vapour density: Not determined. Auto-ignition temperature Not determined. Explosive properties Not applicable. Oxidising properties Not applicable. Oxidising properties Not applicable. Section 10. Stability and reactivity Not applicable. Oxidising properties Not applicable. Oxidising properties and pressures. Possibility of hazardous reactions: No dangerous reactions known. Condition to Avoid: Avoid direct s			-
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Nitrile rubber, NBR Eye Protection: Safety goggles SECTION 9. Physical and chemical properties Appearance/Odor/Colur: Coloriess liquid with sweet odor Odour threshold Not determined. pH Not determined. Boiling Point/freezing point Not determined. Boiling Point: 13 °C (closed) Evaporation rate Not determined. Upper/lower flarmability or explosive limits Not determined. Vapour pressure Not determined. Vapour pressure Not determined. Vapour gensity Not determined. Vapour pressure Not determined. Vapour density 1.01 (water=1) Solubility: water solubility Soluble Partition coefficient: n-octanol/water Not determined. Auto-ignition temperature Not determined. Decomposition temperature Not determined. Discosity Not determined.		-	
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Appearance/Odor/Colour: Colorless liquid with sweet odor Odour threshold Not determined. pH Not determined. Melting point/freezing point Not determined. Boiling Point: Not determined. Flash point: 13 °C (closed) Evaporation rate Not determined. Flammability (solid, gas) Not applicable. Upper/lower flammability or explosive limits Not determined. Vapour pressure Not determined. Vapour pressure Not determined. Vapour density Not determined. Relative Density: 1.01 (water=1) Solubility: water solubility Soluble Partition coefficient: n-octanol/water Not determined. Auto-ignition temperature Not determined. Viscosity Not determined. Stable under normal temperatures Not applicable. 9.2 Other information available.			
Odour threshold Not determined. pH Not determined. Melting point/freezing point Not determined. Boiling Point: 13 °C (closed) Evaporation rate Not determined. Flash point: 13 °C (closed) Evaporation rate Not determined. Flammability (solid, gas) Not applicable. Upper/lower flammability or explosive limits Not determined. Vapour pressure Not determined. Vapour density Not determined. Vapour density Not determined. Relative Density: 1.01 (water=1) Solubility: water solubility Soluble Partition coefficient: n-octanol/water Not determined. Auto-ignition temperature Not determined. Viscosity Not determined. Explosive properties Not applicable. Oxidising properties Not applicable. Oxidising properties Not applicable. Oxidising properties Not applicable. 0.1 Reactivity: No further relevant information available. Io 10.2 Chemical stability:	9.1		
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Melting point/freezing point Not determined. Boiling Point: Not determined. Flash point: 13 °C (closed) Evaporation rate Not determined. Flammability (solid, gas) Not applicable. Upper/lower flammability or explosive limits Not determined. Vapour pressure Not determined. Vapour pressure Not determined. Vapour density Not determined. Relative Density: 1.01 (water=1) Solubility water solubility Soluble Partition coefficient: n-octanol/water Not determined. Auto-ignition temperature Not determined. Viscosity Not determined. Explosive properties Not applicable. Oxidising properties Not applicable. 9.2 Other information No further relevant information available. Ion 1 Reactivity: No tangerous reactions: No dangerous reactions: No dangerous reactions known. Io.4 Condition to Avoid: Avoid direct sunlight, excess heat, flame and other source of ignition. Io.5 Incompatible materials: Strong oxidizing materials. Strong oxidizing materials. <		Odour threshold	Not determined.
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Strong oxidizing materials.		-	a other source of ignition.
	10.5	•	
(Contd. on page5)		Strong oxidizing materials.	
			(Contd. on page5)



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SAFETY DATA SHEET

(Contd. on page4)

					(Contd. on page4)	
10.6	Hazardous Decomposition					
	None under normal condi	tions of storage and use.				
SECTIO	ON 11. Toxicological info	rmation				
	Information on toxicologic					
	Acute toxicity:					
	Acetone:	Inhalation toxicity; rat	LC50	75.8 mg/L		
		Oral toxicity; rat	LD50	> 5000 mg/kg		
		Dermal toxicity; rabbit	LD50	> 5000 mg/kg		
	Skin corrosion/irritation:	Based on available data,	the classi		e not met.	
	Eye damage/irritation:	Eye Irrit. 2; H319 Cause				
	Sensitization to the respiratory tract:					
		Based on available data,	the classi	fication criteria ar	e not met.	
	Skin sensitization:	Based on available data,	the classi	fication criteria ar	e not met.	
	Germ cell mutagenicity/G	-				
		Based on available data,				
	Carcinogenicity:	Based on available data,				
	Reproductive toxicity:	Based on available data,	the classi	fication criteria ar	e not met.	
	Effects on or via lactation					
	Specific target organ toxic					
	0	STOT SE 3; H336May ca	ause drow	siness or dizzine:	SS.	
	Specific target organ toxic		the elecsion	fication oritoria or		
	Aspiration hazard:	Based on available data, Based on available data,				
	Aspiration nazaru.	Dased off available data,		incation chiena ai	e not met.	
SECTIO	ON 12. Ecological inform	ation				
	Toxicity:					
	Acetone:					
	Fish toxicity: Fathead mi	nnow; LC50/96H >100 mg/	L			
12.2	Persistence and degradal					
	No further relevant inform					
12.3	Bioaccumulative potential					
	No further relevant inform	ation available.				
12.4	Mobility in soil:	- P 9 - 1 - 1 -				
105	No further relevant inform					
12.5	5 Results of PBT and vPvB assessment:					
106	Not applicable. 6 Other adverse effects:					
12.0	No further relevant inform	ation available				
SECTIO	ON 13. Disposal conside	rations				
	Waste treatment methods					
	Dispose of contents/conta	iner to in accordance with	local/regio	onal/national/inter	national	
	regulations.					
					(Contd. on page6)	
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	(Contd. on page5)
SECTION 14. Transport information	
14.1 UN number: 1090	
14.2 UN proper shipping name: Aceton, solution	
14.3 Transport hazard class(es): 3 Flammable liquids.	
14.4 Packing group: II	
14.5 Environmental hazards: No further relevant information available.	
14.6 Special precautions for user: Warning: Flammable liquids.	
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:	
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: H225 Highly flammable liquid and vapour. H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness Abbreviations and acronyms: EINESC: European Inventory of Existing Commercial Chemical Substance CAS: Chemical Abstracts Service (division of the American Chemical Soci LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative	



		Printing date: June 28, 2016			
SECTIO	ON 1. Identification of the su	bstance/mixture and of the company/undertaking			
1.1	Product identifier				
	Trade Name:				
	ResiCem "PRIMER B"				
1.2					
1.2	Relevant identified uses: Dental material				
10	Uses advised against: No further data				
1.3					
	Company/Undertaking identification				
	Manufacturer's Name: SHOFU DENTAL GmbH				
	Address: Am Brüll 17, 40878 Ratingen, Germany				
	Phone: +49 (0) 2102-866	64-0			
	Fax: +49 (0) 2102-8664-	64			
	E-Mail: info@shofu.de				
	Section in Charge: Quali	ty Management & Regulatory Affairs			
1.4	Emergency Telephone Number	r			
	+49-2102-8664-53 (SHC	FU DENTAL GmbH) 24 hours / 7 days			
SECTIO	ON 2. Hazards identification				
2.1	Classification of the substance	or mixture			
2.1	CLASSIFICATION (EC 1272/20				
	Flam.lig. 2 H225	Highly flammable liquid and vapour.			
	•	Causes skin irritation.			
	Skin Sens. 1 H317	May cause an allergic skin reaction.			
	Eye Irrit. 2 H319	Causes serious eye irritation.			
	STOT SE 3 H336	May cause drowsiness or dizziness.			
2.2	Label elements				
	LABEL IN ACCORDANCE WIT	H (EC) NO.1272/2008			
		$\mathbf{\hat{k}}$			
	GHS02 GH	S07			
	HAZARD-DETERMINING COM	/PONENTS OF LABELLING			
	Acetone				
	2-Hydroxy Ethy	l Methacrylate			
	SIGNAL WORD	,			
	Danger				
	2				
	HAZARD STATEMENTS				
		hly flammable liquid and vapour.			
	5	uses skin irritation.			
		y cause an allergic skin reaction.			
	H319 Causes serious eye irritation.				
	H336 Ma	y cause drowsiness or dizziness.			
		(Contd. on page2)			



(Contd. of page1)

PRECAUTIONARY STATEMENTS P202 Do not handle until all safety precautions have been read and understood. P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking. P233 Keep container tightly closed. P261 Avoid breathing dust/fume/gas/mist/vapour s/spray. P264 Wash hands thoroughly after handling. P280 Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P302+P352 IF ON SKIN: Wash with plenty of soap and water. 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. Dangerous components: 3.3 Cas: 67-64-1 Acetone 15-25 % EINECS: 200-662-2 Flam. Lig. 2 H225, Eye Irrit. 2 H319, STOT SE 3 H336 2-hydroxyethyl methacrylate Cas: 868-77-9 40-45 % Skin Sens. 1 H317, Skin Irrit. 2 H315, Eye Irrit. 2 H319 EINECS: 212-782-2 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 Eye 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. Rinse mouth. Get medical advice/attention. Ingestion: 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. (Contd. on page3)



(Contd. of page2)

		(Contd. of page2)			
SECTIO	ON 5. Fire-fighting	measures			
5.1	Extinguishing Media	:			
	CO ₂ , Dry chemical, Foam				
5.2	-				
	Easily flammable liquid in room temp.				
5.3					
	Wear fire protective cloth and self-contained breathing apparatus, if necessary.				
	•				
SECTIO	ON 6. Accidental re	elease measures			
6.1	1 Personal precautions, protective equipment and emergency procedures:				
	Avoid eye and skin o	contact.			
6.2					
	Send to approved treatment/disposal company or dispose according to local, state a				
	regulations.				
6.3	•	al for containment and cleaning up:			
		in a suitable container.			
6.4	Reference to other s				
	See Section 7 for inf	ormation on safe handling.			
	See Section 8 for information on personal protection equipment.				
	See Section 13 for c				
SECTIO	ON 7. Handling and	d storage			
7.1	Precautions for safe				
	Handle in a well ventilated place.				
	Keep away from open flames, sparks and sources of heat. No smoking.				
7.2		storage, including any incompatibilities:			
		dark fire proof area with container tightly closed.			
	(Keep refrigerated w	hen not in use.)			
7.3	· · ·	,			
	No further relevant in	nformation available			
SECTIO	ON 8. Exposure co	ntrols/personal protection			
8.1	Control parameters:				
	Exposure limits	Acetone [Cas No.67-64-1]:			
		-OSHA Permissible Exposure Limit (PEL): 1000 ppm (TWA)			
		-ACGIH Threshold Limit Value (TLV): 500 ppm (TWA),			
		750 ppm (STEL) A4 - not classifiable as a human carcinogen			
8.2	Exposure controls:				
	Respiratory Protection	on:			
	- -	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				
		(Contd. on page4)			
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		(Contd. of page3)				
	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					
	manufactur	rer 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					
	manufactur	rer 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 rubbe	ər, BR				
	Nitrile rubb	er, NBR				
	Eye Protection: Safety goggles					
1	ON 9. Physical and chemical properties					
9.1	Information on basic physical and chemical p	-				
	Appearance/Odor/Colour:	Colorless liquid with sweet odor				
	Odour threshold	Not determined.				
	pH	Not determined.				
	Melting point/freezing point	Not determined.				
	Boiling Point:	Not determined.				
	Flash point:	-12 °C (closed)				
	Evaporation rate	Not determined.				
	Flammability (solid, gas)	Not applicable.				
	Upper/lower flammability or explosive limits	Not determined.				
	Vapour pressure	Not determined.				
	Vapour density	Not determined.				
	Relative Density:	1.1 (water=1)				
	Solubility: water solubility	Soluble				
	Partition coefficient: n-octanol/water	Not determined.				
	Auto-ignition temperature	Not determined.				
	Decomposition temperature Viscosity	Not determined. Not determined.				
	Explosive properties	Not applicable.				
	Oxidising properties	Not applicable.				
9.2	Other information					
5.2	No further relevant information available.					
SECTIO	ON 10. Stability and reactivity					
	Reactivity:					



					i initing at	ate. June 20, 2010
						(Contd. of page4)
	No further relevant informa	ation available.				
10.2	.2 Chemical stability:					
	Stable under normal temperatures and pressures.					
10.3	3 Possibility of hazardous reactions:					
	No dangerous reactions known.					
10.4	0.4 Condition to Avoid:					
	Avoid direct sunlight, excess heat, flame and other source of ignition.					
10.5	0.5 Incompatible materials:					
	Strong oxidizing materials.					
10.6	Hazardous Decomposition					
	None under normal condition	ons of storage	and use.			
	ON 11. Toxicological info					
11.1	Information on toxicologica		la la da Maria			75.0
	Acute toxicity:	Acetone:	Inhalation	rat	LC50	75.8 mg/L
			Oral	rat	LD50	> 5000 mg/kg
			Dermal	rabbit	LD50	> 5000 mg/kg
		2-Hydroxy Etr	yl Methacrylate:			1000
			Oral	rat rabbit		4000 mg/kg
			Dermal	rabbit	LD50 >	3000 mg/kg
	Skin corrosion/irritation:		315 Causes skin irri		ion	
	Eye damage/irritation:	-	319 Causes serious	s eye imtat	ION.	
	Sensitization to the respire	-	ilable data the class	oification o	ritorio oro	not mot
	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/Genotoxicity: Based on available data, the classification criteria are not met.					
						not met
	Carcinogenicity:		ilable data, the class			
	Reproductive toxicity:					
	Reproductive toxicity: Based on available data, the classification criteria are not met. Effects on or via lactation: Lack of data.					not mot.
	Specific target organ toxic		sure).			
				wsiness or	dizzines	5.
	STOT SE 3; H336May cause drowsiness or dizziness. Specific target organ toxicity (repeated exposure):					
			ilable data, the class	sification c	riteria are	not met.
	Aspiration hazard:		ilable data, the class			
			,			
SECTIO	ON 12. Ecological information	ation				
	Toxicity:					
	Acetone:					
	Fish toxicity: Fathead mi	nnow; LC50/96	iH >100mg/L			
12.2	12.2 Persistence and degradability:					
	No further relevant information available.					
12.3	12.3 Bioaccumulative potential:					
	No further relevant information available.					
1						



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12.4 Mobility in soil: No further relevant information available. 12.5 Results of PBT and vPvB assessment: Not applicable. 12.6 Other adverse effects: No further relevant information available. **SECTION 13.** Disposal considerations 13.1 Waste treatment methods: Dispose of contents/container to in accordance with local/regional/national/international regulations. **SECTION 14.** Transport information 14.1 UN number: 1090 14.2 UN proper shipping name: Acetone, solution 14.3 Transport hazard class(es): 3 Flammable liquids. 14.4 Packing group: Ш 14.5 Environmental hazards: No further relevant information available. 14.6 Special precautions for user: Warning: Flammable liquids. 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: 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: Highly flammable liquid and vapour. H225 H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness. 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



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PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative