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Revision: 17.11.2022

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

Printing date 17.11.2022

Version number 4 (replaces version 3)

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

- · 1.1 Product identifier
 - · Trade name: Signum composite flow
- · 1.2 Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
 - · Application of the substance / the mixture Veneering resin
- · 1.3 Details of the supplier of the safety data sheet
 - Manufacturer/Supplier:

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany) Tel.: +49 (0)800 4372522

- · Informing department: E-Mail: msds@kulzer-dental.com
- · 1.4 Emergency telephone number: Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
 - · Classification according to Regulation (EC) No 1272/2008

Skin Sens. 1 H317 May cause an allergic skin reaction.

- · 2.2 Label elements
 - · Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the GB CLP regulation.

· Hazard pictograms



GHS07

- · Signal word Warning
- · Hazard-determining components of labelling:

triethylen glycol dimethacrylate

methyl methacrylate

· Hazard statements

H317 May cause an allergic skin reaction.

Precautionary statements

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

· 2.3 Other hazards -

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

SECTION 3: Composition/information on ingredients

- · 3.2 Mixtures
 - · Description: -
 - · Dangerous components:

CAS: 109-16-0

EINECS: 203-652-6

triethylen glycol dimethacrylate

Skin Sens. 1B, H317

Reg.nr.: 01-2119969287-21-xxx

≥10-*≤*25%

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_		(C	ontd. of page 1)
	CAS: 41637-38-1 EC number: 609-946-4	bisphenol a polyethylene glycol diether dimethacrylate Aquatic Chronic 4, H413	≥0-≤5%
	CAS: 131-57-7 EINECS: 205-031-5	Oxybenzone Aquatic Acute 1, H400; Aquatic Chronic 2, H411	≥0.25-<1%
	CAS: 80-62-6 EINECS: 201-297-1	methyl methacrylate Flam. Lig. 2, H225 Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	≥0.1-<1%

[·] Additional information For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
 - · After inhalation Supply fresh air; consult doctor in case of symptoms.
 - · After skin contact

Instantly wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

· After eye contact

Rinse opened eye for several minutes under running water. Then consult doctor.

After swallowing

Rinse out mouth and then drink plenty of water.

In case of persistent symptoms consult 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: Firefighting measures

- · 5.1 Extinguishing media
 - · Suitable extinguishing agents

CO2, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam. Use fire fighting measures that suit the environment.

5.2 Special hazards arising from the substance or mixture

No further relevant information available.

- · 5.3 Advice for firefighters
 - · Protective equipment: No special measures required.
 - Additional information -

SECTION 6: Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures Wear protective clothing.
- · 6.2 Environmental precautions:

Do not allow product to reach sewage system or water bodies.

Do not allow to enter the ground/soil.

· 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues). Send for recovery or disposal in suitable containers.

6.4 Reference to other sections

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

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See Section 13 for information on disposal.

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SECTION 7: Handling and storage

- · 7.1 Precautions for safe handling Wear protective equipment. Keep unprotected persons away. Information about protection against explosions and fires: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities Storage
 - Requirements to be met by storerooms and containers: No special requirements. Information about storage in one common storage facility: Not required.

 - · Further information about storage conditions: None.
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

٠,	8.1	Control	parameters
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· Comp	onents with cri	tical values that require	monitoring at the workplace:			
	62-6 methyl methacrylate					
WEL (Great Britain) Short-term value: 416			g/m³, 100 ppm			
			Long-term value: 208 mg/m³, 50 ppm Short-term value: 100 ppm Long-term value: 50 ppm			
IOELV (Eu	ıropean Union)	Short-term value: 100 pp Long-term value: 50 ppn				
· DNI	ELs					
109-16-0	riethylen glyce	ol dimethacrylate				
Oral	general popula	tion, long term, systemic	8.33 mg/Kg (not defined)			
Dermal	worker industri	al, long term, systemic	13.9 mg/Kg/d (not defined)			
	general popula	tion, long term, systemic	8.33 mg/Kg/d (not defined)			
Inhalative	worker industri	al, long term, systemic	48.5 mg/m3 (not defined)			
	general popula	tion, long term, systemic	14.5 mg/m3 (not defined)			
41637-38-	1 bisphenol a	polyethylene glycol die	ther dimethacrylate			
Oral general population, long term, systemic		tion, long term, systemic	5 mg/Kg (not defined)			
Dermal	worker industri	al, long term, systemic	140 mg/Kg/d (not defined)			
	general popula	tion, long term, systemic	50 mg/Kg/d (not defined)			
Inhalative	worker industri	al, long term, systemic	98.7 mg/m3 (not defined)			
	general popula	tion, long term, systemic	17.4 mg/m3 (not defined)			
131-57-7	Oxybenzone					
Oral	general popula	tion, long term, systemic	2 mg/Kg (not defined)			
Dermal	worker industrial, long term, systemic		39 mg/Kg/d (not defined)			
	general population, long term, systemic		20 mg/Kg/d (not defined)			
Inhalative	worker industri	al, long term, systemic	27.7 mg/m3 (not defined)			
	general popula	tion, long term, systemic	6.8 mg/m3 (not defined)			
80-62-6 m	ethyl methacr	ylate				
Oral	general popula	tion, long term, systemic	8.2 mg/Kg (not defined)			
Dermal	worker industri	al, long term, systemic	13.67 mg/Kg/d (not defined)			
	general popula	tion, long term, systemic	8.2 mg/Kg/d (not defined)			



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Inhalative	worker industrial, acute,	local	416 mg/m3 (not defined)	(Samuel Page 6)
	worker industrial, long tern		348.4 mg/m3 (not defined)	
	worker industrial, long te	rm, local	208 mg/m3 (not defined)	
	general population, acute	e, local	208 mg/m3 (not defined)	
	general population, long	term, systemic	74.3 mg/m3 (not defined)	
· PNI	ECs			
109-16-0	triethylen glycol dimetha	acrylate		
freshwate	r	0.016 mg/l (no	t defined)	
marine wa	nter	0.002 mg/l (no	t defined)	
sewage tr	eatment plant	1.7 mg/l (not d	lefined)	
sediment,	dry weight, freshwater	0.185 mg/Kg (not defined)	
sediment,	dry weight, marine water	0.018 mg/Kg (not defined)	
soil, dry w	eight	0.027 mg/Kg (not defined)	
131-57-7	Oxybenzone			
freshwate	r	0.00067 mg/l ((not defined)	
marine wa	nter	0.000067 mg/l	(not defined)	
sewage tr	eatment plant	10 mg/l (not defined)		
sediment,	dry weight, freshwater	0.066 mg/Kg (not defined)	
sediment,	dry weight, marine water	0.007 mg/Kg (not defined)	
soil, dry w	eight	0.013 mg/Kg (not defined)	
80-62-6 m	ethyl methacrylate			
freshwate	r	0.94 mg/l (not defined)		
marine wa	nter	0.094 mg/l (no	t defined)	
sewage tr	eatment plant	10 mg/l (not de	efined)	
sediment,	dry weight, freshwater	10.2 mg/Kg (n	ot defined)	
sediment,	dry weight, marine water	0.102 mg/Kg (not defined)	
soil, dry w	eight	1.48 mg/Kg (n	ot defined)	

Additional information: The lists that were valid during the compilation were used as basis.

· 8.2 Exposure controls

- · Individual protection measures, such as personal protective equipment
 - General protective and hygienic measures

Wash hands during breaks and at the end of the work.

- · Breathing equipment: Not necessary if room is well-ventilated.
- Hand protection

Check protective gloves prior to each use for their proper condition. recommended

· 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 trough 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

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· Eye/face protection Safety glasses

· Body protection: Light weight protective clothing

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

General Information

· Physical state Fluid · Colour: Brown White

VVnite
Pink
Colourless
Odourless

· Smell: Odourless

· Odour threshold: Not determined. Not determined. Not determined

Boiling point or initial boiling point and

boiling range 255 °C Flammability Not applicable.

· Lower and upper explosion limit

Lower: Not determined.Upper: Not determined.

· Flash point: >100 °C (109-16-0 triethylen glycol

dimethacrylate)

Decomposition temperature: Not determined.

·SADT

• **pH** Mixture is non-soluble (in water).

· Viscosity:

· Kinematic viscosity
· dynamic:

Not determined.

Not determined.

Solubility

• Water: Not miscible or difficult to mix

· Partition coefficient n-octanol/water (log

value) Not determined. Steam pressure: Not determined.

Density and/or relative density

Density
 Relative density
 Vapour density
 Not determined.
 Not determined.

• **9.2 Other information** No further relevant information available.

· Appearance:

Fluid

Important information on protection of health and environment, and on safety.

• Self-inflammability: Product is not selfigniting.
• Explosive properties: Product is not explosive.

Not determined.

· Solvent content:

Water: 1.3 % Solids content: 9.6 %

· Change in condition · Evaporation rate Not determined.

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Information with regard to physical hazard classes	
	Maid
Explosives	Void
· Flammable gases	Void
Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
Flammable liquids	Void
Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
Pyrophoric solids	Void
Self-heating substances and mixtures	Void
· Substances and mixtures, which emit	
flammable gases in contact with water	Void
· Oxidising liquids	Void
Oxidising solids	Void
· Organic peroxides	Void
Corrosive to metals	Void
· Desensitised explosives	Void

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
- Conditions to be avoided: No decomposition if used and stored according to specifications. 10.3 Possibility of hazardous reactions No dangerous reactions known
- · 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available. 10.6 Hazardous decomposition products: None
- - Additional information: -

SECTION 11: Toxicological information

· 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008 Acute toxicity Based on available data, the classification criteria are not met.

7.00.0	react textery based on available adia, the statement of terms are not met.				
· LD/	· LD/LC50 values that are relevant for classification:				
109-16-0	109-16-0 triethylen glycol dimethacrylate				
Oral	LD50	8,300 mg/kg (rat)			
Dermal	LD50	>2,000 mg/kg (mouse)			
68611-44	9 Silane,	dichlorodimethyl-, reaction products with silica			
Oral	LD50	>5,000 mg/kg (rat)			
Inhalative	LC0/4h	0.477 mg/L (rat)			
41637-38-	1 bisphe	nol a polyethylene glycol diether dimethacrylate			
Oral	LD50	>2,000 mg/kg (rat) (OECD 423)			
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)			
131-57-7	Oxybenzo	one			
Oral	LD50	>12,800 mg/kg (rat) (OECD 401)			
Dermal	LD50	>16,000 mg/kg (rabbit) (OECD 402)			
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80-	-62-6	methy	met	hacry	ate
_			_		

~7,900 mg/kg (rat) Oral LD50

LD50 >5,000 mg/kg (guinea pig) (OECD 402)

Inhalative LC50/4 h 29.8 mg/l (rat)

- Skin corrosion/irritation Based on available data, the classification criteria are not met.
- Serious eye damage/irritation Based on available data, the classification criteria are not met.
- Respiratory or skin sensitisation

May cause an allergic skin reaction.

- Germ cell mutagenicity 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.

- STOT-single exposure Based on available data, the classification criteria are not met.
- STOT-repeated exposure Based on available data, the classification criteria are not met.
- Aspiration hazard Based on available data, the classification criteria are not met.
- 11.2 Information on other hazards
 - · Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

12.	1	Toxici	ty
	Λ	auatia	tovioity

· Aquatic to				
65997-17-3 G	Glaspulver			
EC50/72h	EC50/72h >1,000 mg/l (daphnia)			
LC50/96h	>1,000 mg/l (fish)			
ErC50 / 72 h	>1,000 mg/l (algae)			
NOEC / 72h	1,000 mg/l (algae)			
	1,000 mg/l (daphnia)			
109-16-0 trie	thylen glycol dimethacrylate			
EC50/21d	51.9 mg/L (daphnia) (OECD 211)			
LC50/96h	16.4 mg/l (fish) (OECD 203)			
NOEC / 21d	32 mg/l (daphnia) (OECD 211)			
ErC50 / 72 h	>100 mg/l (algae) (OECD 201)			
NOEC / 72h	18.6 mg/l (algae) (OECD 201)			
	72.8 mg/l (algae) (OECD 201)			
68611-44-9 S	ilane, dichlorodimethyl-, reaction products with silica			
LC50/96h	>10,000 mg/l (fish) (OECD 203)			
ErC50 / 72 h	>10,000 mg/l (algae) (OECD 201)			
	>10,000 mg/l (daphnia) (OECD 202)			
41637-38-1 b	isphenol a polyethylene glycol diether dimethacrylate			
LL50/96h	>100 mg/L (fish) (OECD 203)			
EL50/48h	>100 mg/L (daphnia) (OECD 202)			
EL50/72h	>100 mg/L (algae) (OECD 201)			
NOEC / 21d	≥0.00224 mg/l (daphnia) (OECD 211)			
131-57-7 Oxy				
EC50/48h	1.87 mg/l (daphnia) (OECD 202)			
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I CEO	/96h 3	(Contd. of page 7)
		2.8 mg/l (fish) (OECD 203)
		0.67 mg/l (algae) (OECD 201)
		1.18 mg/l (algae) (OECD 201)
		7.72 mg/l (fish) (OECD 203)
		.15 mg/l (daphnia) (OECD 202)
		l methacrylate
EC50		9 mg/L (daphnia) (OECD 211)
EC50,	/48h 6	9 mg/l (daphnia) (EPA OTS 797.1300)
NOEC	C/21d 3	7 mg/l (daphnia) (OECD 211)
ErC50)/72 h >	110 mg/l (algae) (OECD 201)
NOEC	C/72h 1	10 mg/l (algae) (OECD 201)
NOEC	C/48h 4	8 mg/l (daphnia) (EPA OTS 797.1300)
EbC5	0 / 72h >	110 mg/l (algae) (OECD 201)
NOEC	C/ 35d 9	0.4 mg/L (fish) (OECD 210)
LC50/	/ 35d 3	3.7 mg/L (fish) (OECD 210)
· 12.2 F	Persisten	ce and degradability
109-1	6-0 trieth	ylen glycol dimethacrylate
Biode	gradation	85 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)
41637	7-38-1 bis	sphenol a polyethylene glycol diether dimethacrylate
Biode	gradation	24 % /28d (not defined) (OECD 301D)
	7-7 Oxyb	
		60-70 % /28d (not defined)
		l methacrylate
Biode	gradation	94 % /14d (not defined) (OECD 301C)

- · 12.3 Bioaccumulative potential
- 131-57-7 Oxybenzone

Bloconcentration factor (BCF) | >33-<160 (fish) (OECD 305)

- · 12.4 Mobility in soil No further relevant information available.
- 12.5 Results of PBT and vPvB assessment
 - · PBT: Not applicable.
 - · **vPvB:** Not applicable.
- 12.6 Endocrine disrupting properties

For information on endocrine disrupting properties see section 11.

- 12.7 Other adverse effects
 - · Remark: Harmful to fish
 - Additional ecological information:
 - · General notes:

Avoid transfer into the environment. Harmful to aquatic organisms

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
 - · Recommendation

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

Disposal must be made according to official regulations.

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· Uncleaned packagings:

· Recommendation:

Disposal must be made according to official regulations. Non contaminated packagings can be used for recycling.

SECTION 14: Transport informati	on	
14.1 UN number or ID number ADR, ADN, IMDG, IATA	Void	
14.2 UN proper shipping name ADR, ADN, IMDG, IATA	Void	
· 14.3 Transport hazard class(es)		
ADR, ADN, IMDG, IATA Class	Void	
14.4 Packing group ADR, IMDG, IATA	Void	
· 14.5 Environmental hazards:	Not applicable.	
· 14.6 Special precautions for user	Not applicable.	
· 14.7 Maritime transport in bulk accordin IMO instruments	g to Not applicable.	
· Transport/Additional information:	-	
· UN "Model Regulation":	Void	

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
 - · Directive 2012/18/EU
 - · Named dangerous substances ANNEX I None of the ingredients is listed.
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Relevant phrases

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

H400 Very toxic to aquatic life.

H411 Toxic to aquatic life with long lasting effects.

H413 May cause long lasting harmful effects to aquatic life.

Abbreviations and acronyms:

SADT: Self Accelerating Decomposition Temperature

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

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IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chamical Abstracts Society (division of the American Chemical Society)

CAS: Chemical Abstracts Service (division of the American Chemical Society)
DNEL: Derived No-Effect Level (UK REACH)

DNEL: Derived No-Effect Level (UK REACH)
PNEC: Predicted No-Effect Concentration (UK REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Flam. Liq. 2: Flammable liquids — Category 2
Skin Irrit. 2: Skin corrosion/irritation — Category 2
Skin Sens. 1: Skin sensitisation — Category 1
Skin Sens. 1B: Skin sensitisation — Category 1B
STOT SE 3: Specific target organ toxicity (single exposure) — Category 3
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard — Category 1
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard — Category 4
** Data compared to the previous version altered.