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

· **1.1 Product identifier**

· **Trade name: Signum opaque F**

· **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** Auxiliary for manufacture of dental prothesis

· **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

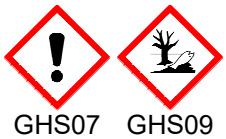
· **Informing department:** E-Mail: msds@kulzer-dental.com
· **1.4 Emergency telephone number:** Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

SECTION 2: Hazards identification

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

Eye Irrit. 2	H319 Causes serious eye irritation.
Skin Sens. 1	H317 May cause an allergic skin reaction.
Aquatic Chronic 2	H411 Toxic to aquatic life with long lasting effects.

· **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 GHS09

· **Signal word** Warning

· **Hazard-determining components of labelling:**
Bisphenol A Diglycidylether Diacrylate (BADGE-DA)
propylidynetrimethanol, ethoxylated, esters with acrylic acid
methacrylic acid, monoester with propane-1,2-diol
triethylen glycol dimethacrylate
diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide
· **Hazard statements**
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
H411 Toxic to aquatic life with long lasting effects.
· **Precautionary statements**
P273 Avoid release to the environment.
P280 Wear protective gloves / eye protection.
· **2.3 Other hazards** -
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

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SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**
· **Description:** Product based on methacrylates

· **Dangerous components:**

CAS: 55818-57-0 NLP: 500-130-2 Reg.nr.: 01-2119490020-53-XXXX	Bisphenol A Diglycidylether Diacrylate (BADGE-DA) Aquatic Chronic 2, H411 Skin Sens. 1, H317	≥25-≤50%
CAS: 28961-43-5	propylidynetrimethanol, ethoxylated, esters with acrylic acid Eye Irrit. 2, H319; Skin Sens. 1, H317 Aquatic Chronic 3, H412	≥10-≤25%
CAS: 27813-02-1 EINECS: 248-666-3 Reg.nr.: 01-2119490226-37-xxxx	methacrylic acid, monoester with propane-1,2-diol Eye Irrit. 2, H319; Skin Sens. 1, H317	≥1-≤5%
CAS: 109-16-0 EINECS: 203-652-6 Reg.nr.: 01-2119969287-21-xxxx	triethylen glycol dimethacrylate Skin Sens. 1B, H317	≥1-≤5%
CAS: 75980-60-8 EINECS: 278-355-8 Reg.nr.: 01-2119972295-29-xxxx	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Repr. 2, H361f Aquatic Chronic 2, H411 Skin Sens. 1B, H317	≥0.25-<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 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**
Formation of toxic gases is possible during heating or in case of fire.

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· **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**
Avoid contact with eyes and skin.
· **6.2 Environmental precautions:** Prevent material from reaching sewage system, holes and cellars.
· **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).
· **6.4 Reference to other sections**
No dangerous materials are released.
See Section 8 for information on personal protection equipment.
-

SECTION 7: Handling and storage

· **7.1 Precautions for safe handling** Keep containers tightly sealed.
· **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:** Store cool (not above 25 °C).
· **7.3 Specific end use(s)** No further relevant information available.

*
SECTION 8: Exposure controls/personal protection

· **8.1 Control parameters**
· **Components with critical 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.
Not required.

· **DNELs**		
55818-57-0 Bisphenol A Diglycidylether Diacrylate (BADGE-DA)		
Dermal	worker industrial, long term, systemic	17.5 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	122.5 mg/m3 (not defined)
27813-02-1 methacrylic acid, monoester with propane-1,2-diol		
Oral	general population, long term, systemic	2.5 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	4.2 mg/Kg/d (not defined)
	general population, long term, systemic	2.5 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	14.7 mg/m3 (not defined)
	general population, long term, systemic	8.8 mg/m3 (not defined)
109-16-0 triethylen glycol dimethacrylate		
Oral	general population, long term, systemic	8.33 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	13.9 mg/Kg/d (not defined)
	general population, long term, systemic	8.33 mg/Kg/d (not defined)

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Inhalative	worker industrial, long term, systemic	48.5 mg/m3 (not defined)
	general population, long term, systemic	14.5 mg/m3 (not defined)
75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide		
Oral	general population, long term, systemic	0.0833 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	0.233 mg/Kg/d (not defined)
	general population, long term, systemic	0.0833 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	0.822 mg/m3 (not defined)
	general population, long term, systemic	0.145 mg/m3 (not defined)

· **PNECs**	
55818-57-0 Bisphenol A Diglycidylether Diacrylate (BADGE-DA)	
freshwater	0.1 mg/l (not defined)
marine water	0.01 mg/l (not defined)
intermediate water release	1 mg/l (not defined)
sewage treatment plant	10 mg/l (not defined)
sediment, dry weight, freshwater	35.8 mg/Kg (not defined)
soil, dry weight	71 mg/Kg (not defined)
27813-02-1 methacrylic acid, monoester with propane-1,2-diol	
freshwater	0.904 mg/l (not defined)
marine water	0.904 mg/l (not defined)
sewage treatment plant	10 mg/l (not defined)
sediment, dry weight, freshwater	6.28 mg/Kg (not defined)
sediment, dry weight, marine water	6.28 mg/Kg (not defined)
soil, dry weight	0.727 mg/Kg (not defined)
109-16-0 triethylen glycol dimethacrylate	
freshwater	0.016 mg/l (not defined)
marine water	0.002 mg/l (not defined)
sewage treatment plant	1.7 mg/l (not defined)
sediment, dry weight, freshwater	0.185 mg/Kg (not defined)
sediment, dry weight, marine water	0.018 mg/Kg (not defined)
soil, dry weight	0.027 mg/Kg (not defined)
75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	
freshwater	0.0014 mg/l (not defined)
marine water	0.00014 mg/l (not defined)
sediment, dry weight, freshwater	0.115 mg/Kg (not defined)
sediment, dry weight, marine water	0.0115 mg/Kg (not defined)
soil, dry weight	0.0222 mg/Kg (not defined)

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

· **8.2 Exposure controls**
· **Appropriate engineering controls** No further data; see item 7.
· **Individual protection measures, such as personal protective equipment**
· **General protective and hygienic measures**
Avoid contact with the eyes.
Keep away from foodstuffs, beverages and food.
Instantly remove any soiled and impregnated garments.
Wash hands during breaks and at the end of the work.

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Avoid contact with the eyes and skin.
· **Breathing equipment:**
Not neccessary with efficient local exhaust. If exposition to vapours is possible, use breathing protective mask (filter A).
· **Hand protection**
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.
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
· **Eye/face protection** Tightly sealed 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 Pink White Colourless
· **Smell:**	Ester-like
· **Odour threshold:**	Not determined.
· **Melting point/freezing point:**	Not determined
· **Boiling point or initial boiling point and boiling range**	100 °C
· **Flammability**	Not applicable.
· **Lower and upper explosion limit**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Flash point:**	111 °C (27813-02-1 methacrylic acid, monoester with propane-1,2-diol)
· **Decomposition temperature:**	Not determined.
· **SADT**	
· **pH**	Not determined.
· **Viscosity:**	
· **Kinematic viscosity**	Not determined.
· **dynamic:**	Not determined.

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· **Solubility**	
· **Water:**	Not miscible or difficult to mix
· **Partition coefficient n-octanol/water (log value)**	Not determined.
· **Steam pressure at 20 °C:**	40 mbar
· **Density and/or relative density**	
· **Density at 20 °C**	1.360 g/cm³
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **9.2 Other information**	No further relevant information available.
· **Appearance:**	
· **Form:**	Pasty
· **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:**	
· **VOC EU**	g/l
· **Change in condition**	
· **Evaporation rate**	Not determined.
· **Information with regard to physical hazard classes**	
· **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

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· ***Additional information:***
If stored longer than recommended and/or above recommended temperature, product may polymerize generating heat.

*

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.*

· ***LD/LC50 values that are relevant for classification:***		
55818-57-0 Bisphenol A Diglycidylether Diacrylate (BADGE-DA)		
Oral	*LD0*	*>2,000 mg/kg (rat) (OECD 401)*
Dermal	*LD0*	*>2,000 mg/kg (rat) (OECD 402)*
Sensitisation	*sensitization*	*(human)*
		(mouse) (LLNA)
28961-43-5 propylidynetrimethanol, ethoxylated, esters with acrylic acid		
Oral	*LD50*	*>2,000 mg/kg (rat) (OECD 401)*
Dermal	*LD50*	*>13,200 mg/kg (rabbit)*
27813-02-1 methacrylic acid, monoester with propane-1,2-diol		
Oral	*LD50*	*>2,000 mg/kg (rat) (OECD 401)*
Dermal	*LD50*	*>5,000 mg/kg (rabbit)*
109-16-0 triethylen glycol dimethacrylate		
Oral	*LD50*	*8,300 mg/kg (rat)*
Dermal	*LD50*	*>2,000 mg/kg (mouse)*
75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide		
Oral	*LD50*	*>5,000 mg/kg (rat) (OECD 401)*
Dermal	*LD50*	*>2,000 mg/kg (rat) (OECD 402)*

· ***Skin corrosion/irritation*** *Based on available data, the classification criteria are not met.*
· ***Serious eye damage/irritation***
Causes serious eye irritation.
· ***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 Toxicity***

· ***Aquatic toxicity:***	
65997-17-3 Glaspulver	
EC50/72h	*>1,000 mg/l (daphnia)*

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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)
55818-57-0 Bisphenol A Diglycidylether Diacrylate (BADGE-DA)	
EC50/72h	>110 mg/l (algae) (OECD 201)
LC50/96h	>79 mg/l (fish) (OECD 203)
27813-02-1 methacrylic acid, monoester with propane-1,2-diol	
EC50/72h	>97.2 mg/l (algae)
EC50/48h	>143 mg/l (daphnia) (OECD 202)
NOEC / 21d	45.2 mg/l (daphnia) (OECD 211)
ErC50 / 72 h	>97.2 mg/l (algae) (OECD 201)
NOEC / 72h	>97.2 mg/l (algae) (OECD 201)
LC50/48h	483 mg/L (fish)
109-16-0 triethylen 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)
EbC50 / 72h	72.8 mg/l (algae) (OECD 201)
75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	
EC50/48h	10,100 mg/l (algae)
	3.53 mg/l (daphnia) (OECD 202)
LC50/96h	1.4 mg/l (fish) (OECD 203)
ErC50 / 72 h	>2.01 mg/l (algae) (OECD 201)
ErC10/72h	1.56 mg/L (algae) (OECD 201)

· **12.2 Persistence and degradability**

27813-02-1 methacrylic acid, monoester with propane-1,2-diol	
Biodegradation	81 % /28d (not defined) (OECD 301C)
109-16-0 triethylen glycol dimethacrylate	
Biodegradation	85 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)
75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	
Biodegradation	0-10 % /28d (not defined) (OECD 301F; ISO 9408/ EEC 92/69/V, C.4-D)

· **12.3 Bioaccumulative potential**

75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	
Bioconcentration factor (BCF)	47-55 (not defined)

· **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.

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· **12.7 Other adverse effects**
· **Additional ecological information:**
· **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.
Do not allow product to reach ground water, water bodies or sewage system.
Danger to drinking water if even small quantities leak into soil.

*
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.

· **Uncleaned packagings:**
· **Recommendation:**
Disposal must be made according to official regulations.
Non contaminated packagings can be used for recycling.

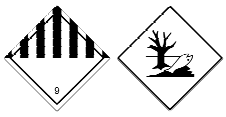
*
SECTION 14: Transport information

· **14.1 UN number or ID number**
· **ADR, IMDG, IATA** UN3082

· **14.2 UN proper shipping name**
· **IMDG, IATA** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Bisphenol A Diglycidylether Diacrylate (BADGE-DA))

· **14.3 Transport hazard class(es)**

· **ADR**



· **Class** 9 (M6) Miscellaneous dangerous substances and articles.
· **Label** 9

· **IMDG**



· **Class** 9 Miscellaneous dangerous substances and articles.

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· **Label**	9
· **IATA**	
	
· **Class**	9 Miscellaneous dangerous substances and articles.
· **Label**	9
· **14.4 Packing group**	
· **ADR, IMDG, IATA**	III
· **14.5 Environmental hazards:**	
· **Marine pollutant:**	No
· **Special marking (ADR):**	Symbol (fish and tree)
· **Special marking (IATA):**	Symbol (fish and tree)
· **14.6 Special precautions for user**	Warning: Miscellaneous dangerous substances and articles.
· **Kemler Number:**	90
· **EMS Number:**	F-A,S-F
· **Stowage Category**	A
· **14.7 Maritime transport in bulk according to IMO instruments**	Not applicable.
· **Transport/Additional information:**	-
· **ADR**	
· **Limited quantities (LQ)**	5L
· **Excepted quantities (EQ)**	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· **Transport category**	3
· **Tunnel restriction code**	(-)
· **IMDG**	
· **Limited quantities (LQ)**	5L
· **Excepted quantities (EQ)**	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· **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**

· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 200 t

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· ***Qualifying quantity (tonnes) for the application of upper-tier requirements*** *500 t*
· ***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***
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H361f Suspected of damaging fertility.
H411 Toxic to aquatic life with long lasting effects.
H412 Harmful to aquatic life with long lasting effects.

· ***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)
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: Chemical Abstracts Service (division of the American Chemical Society)
VOCV: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweiz (Swiss Ordinance on volatile organic compounds)
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
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
Skin Sens. 1B: Skin sensitisation – Category 1B
Repr. 2: Reproductive toxicity – Category 2
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

· **** Data compared to the previous version altered.***