

according to Regulation (EC) No 1907/2006

Revision date: 01.08.2019

**smartseal® & loc/ & loc F**

Product code: 10679

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

#### 1.1. Product identifier

smartseal® &amp; loc/ &amp; loc F

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### **Use of the substance/mixture**

Ligth curing fissure sealant for use in dentistry.

#### 1.3. Details of the supplier of the safety data sheet

Company name:	DETAX GmbH & Co. KG	
Street:	Carl-Zeiss-Strasse	
Place:	D-76275 Ettlingen	
Telephone:	+49 7243/510-0	Telefax: +49 7243/510-100
e-mail:	post@detax.de	
Internet:	www.detax.de	
Responsible Department:	Emergency number:	

+49 7243/510-0

This number is only obtainable during office hours (Monday - Thursday 8.00 a.m. - 5.00 p.m., Friday 8.00 a.m. - 4.00 p.m.)

#### 1.4. Emergency telephone number:

+49 7243/510-0

This number is only obtainable during office hours (Monday - Thursday 8.00 a.m. - 5.00 p.m., Friday 8.00 - 4.00 p.m.)

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### **Regulation (EC) No. 1272/2008**

Hazard categories:

Skin corrosion/irritation: Skin Corr. 1B

Serious eye damage/eye irritation: Eye Dam. 1

Respiratory or skin sensitisation: Skin Sens. 1

Reproductive toxicity: Repr. 1B

Hazardous to the aquatic environment: Aquatic Chronic 3

Hazard Statements:

Causes severe skin burns and eye damage.

Causes serious eye damage.

May cause an allergic skin reaction.

May damage fertility or the unborn child.

Harmful to aquatic life with long lasting effects.

#### 2.2. Label elements

##### **Regulation (EC) No. 1272/2008**

##### **Hazard components for labelling**

2-propenoic acid, 2-methyl-, 2-hydroxyethyl ester, phosphate

2-dimethylaminoethyl methacrylate

2-Ethylhexyl 4-(dimethylamino)benzoate

Triethylene glycol dimethacrylate

**Signal word:** Danger

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#### Pictograms:



#### Hazard statements

- |      |  |
|------|--|
| H314 | Causes severe skin burns and eye damage.           |
| H317 | May cause an allergic skin reaction.               |
| H360 | May damage fertility or the unborn child.          |
| H412 | Harmful to aquatic life with long lasting effects. |

#### Precautionary statements

- |                |  |
|----------------|--|
| P260           | Do not breathe dust/fume/gas/mist/vapours/spray.   |
| P264           | Wash hands thoroughly after handling.  |
| P280           | Wear protective gloves/protective clothing/eye protection/face protection.   |
| P303+P361+P353 | IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.                           |
| P305+P351+P338 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| P310           | Immediately call a POISON CENTER/doctor.   |

#### Additional advice on labelling

According to Regulation (EC) 1272/2008, art.1 No. 5 (d) this product as a medical product must not be labelled!

#### 2.3. Other hazards

No information available.

### SECTION 3: Composition/information on ingredients

#### 3.2. Mixtures

##### Chemical characterization

Mixture of methacrylic resins with auxiliary matters.

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#### Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
32435-46-4	bis(methacryloxyethyl) hydrogen phosphate			10 - < 15 %
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335			
24599-21-1	2-propenoic acid, 2-methyl-, 2-hydroxyethyl ester, phosphate			5 - < 10 %
	Skin Corr. 1B, Skin Sens. 1, STOT SE 3; H314 H317 H335			
2867-47-2	2-dimethylaminoethyl methacrylate			1 - < 5 %
	220-688-8	607-132-00-3		
	Acute Tox. 4, Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1; H312 H302 H315 H319 H317			
3290-92-4	trimethylolpropane trimethacrylate			1 - < 5 %
	221-950-4			
	Aquatic Chronic 2; H411			
21245-02-3	2-Ethylhexyl 4-(dimethylamino)benzoate			< 1 %
	244-289-3		01-2120766649-35	
	Repr. 1B; H360			
109-16-0	Triethylene glycol dimethacrylate			< 1 %
	203-652-6		01-2119969287-21	
	Skin Sens. 1B; H317			

Full text of H and EUH statements: see section 16.

#### SECTION 4: First aid measures

##### 4.1. Description of first aid measures

###### General information

First aider: Pay attention to self-protection! Remove affected person from the danger area and lay down.

###### After inhalation

Provide fresh air. When in doubt or if symptoms are observed, get medical advice.

###### After contact with skin

After contact with skin, wash immediately with plenty of water and soap. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary.

###### After contact with eyes

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.

###### After ingestion

Rinse mouth immediately and drink plenty of water. Do NOT induce vomiting. Adverse human health effects and symptoms: Gastric perforation. Call a physician immediately. Do not allow a neutralisation agent to be drunk.

##### 4.2. Most important symptoms and effects, both acute and delayed

No information available.

##### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

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### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

##### **Suitable extinguishing media**

Co-ordinate fire-fighting measures to the fire surroundings.

#### 5.2. Special hazards arising from the substance or mixture

Non-flammable.

#### 5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

#### **Additional information**

Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately.  
Do not allow entering drains or surface water.

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

#### 6.2. Environmental precautions

Do not allow to enter into surface water or drains.

#### 6.3. Methods and material for containment and cleaning up

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

#### 6.4. Reference to other sections

Safe handling: see section 7  
Personal protection equipment: see section 8  
Disposal: see section 13

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

##### **Advice on safe handling**

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

##### **Advice on protection against fire and explosion**

No special fire protection measures are necessary.

#### 7.2. Conditions for safe storage, including any incompatibilities

##### **Requirements for storage rooms and vessels**

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaustion at critical locations.

##### **Hints on joint storage**

Do not store with strong oxidising materials. Keep away from strong acids and bases.

##### **Further information on storage conditions**

Keep only in the original container in a cool, dry and well-ventilated place, away from foodstuffs. Keep away from all kind of lighth.

#### 7.3. Specific end use(s)

Dental composite based material for sealing of fissures and enamel effects .  
For use by trained specialist staff.

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## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

### 8.2. Exposure controls

#### Appropriate engineering controls

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

#### Protective and hygiene measures

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat, drink, smoke, sniff.

#### Eye/face protection

Suitable eye protection: goggles.

#### Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Suitable are gloves of the following material: Butyl caoutchouc (butyl rubber)

#### Skin protection

Wear suitable protective clothing.

#### Respiratory protection

In case of inadequate ventilation wear respiratory protection.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state:	Paste , low-viscosity
Colour:	light yellow , opaque
Odour:	aromatic

#### Test method

pH-Value (at 20 °C):	1,6
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#### Changes in the physical state

Melting point:	not determined
Initial boiling point and boiling range:	not determined
Flash point:	>100 °C

#### Flammability

Solid:	not applicable
Gas:	not applicable

#### Explosive properties

The product is not: Explosive.

Lower explosion limits:	not determined
Upper explosion limits:	not determined

#### Auto-ignition temperature

Solid:	not applicable
Gas:	not applicable

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Decomposition temperature: not determined

**Oxidizing properties**

Not oxidizing.

Vapour pressure: <1 hPa  
(at 20 °C)

Density (at 20 °C): 1,54 g/cm<sup>3</sup> DIN 51757

Water solubility: insoluble

**Solubility in other solvents**

not determined

Partition coefficient: not determined

Vapour density: not determined

Evaporation rate: not determined

**9.2. Other information**

Solid content: not determined

**SECTION 10: Stability and reactivity**

**10.1. Reactivity**

No hazardous reaction when handled and stored according to provisions.

**10.2. Chemical stability**

The product is stable under storage at normal ambient temperatures.

**10.3. Possibility of hazardous reactions**

Reacts with : oxidising agents, radicals forming substances or heavy metal ions.

**10.4. Conditions to avoid**

Ultra-violet lighth and daylighth initiate polymerisation of the product. Therefore keep only in tightly closed containers away from any sources of light. Keep at temperature not exceeding 25°C/ 77°F.

**10.5. Incompatible materials**

No information available.

**10.6. Hazardous decomposition products**

In case of fire, acrid acrylic fumes may occur.

**SECTION 11: Toxicological information**

**11.1. Information on toxicological effects**

**Acute toxicity**

Based on available data, the classification criteria are not met.

For the product itself no toxicological data are available. In products with a comparable composition, a LD50 (orally, species rat) of > 5000 mg/kg has been found.

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CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
2867-47-2	2-dimethylaminoethyl methacrylate				
	oral	LD50 mg/kg	1750	Rat	GESTIS
	dermal	ATE mg/kg	1100		
	inhalation (4 h) vapour	LC50	0,62 mg/l	Rat	GESTIS
3290-92-4	trimethylolpropane trimethacrylate				
	oral	LD50 mg/kg	>2000	Rat	
	dermal	LD50 mg/kg	>2000	Rat	OECD 402
21245-02-3	2-Ethylhexyl 4-(dimethylamino)benzoate				
	oral	LD50 mg/kg	14,900	Rat	
109-16-0	Triethylene glycol dimethacrylate				
	oral	LD50 mg/kg	10800	Rat	GESTIS

#### Irritation and corrosivity

Causes severe skin burns and eye damage.

Causes serious eye damage.

#### Sensitising effects

May cause an allergic skin reaction. (2-propenoic acid, 2-methyl-, 2-hydroxyethyl ester, phosphate; 2-dimethylaminoethyl methacrylate; Triethylene glycol dimethacrylate)

#### Carcinogenic/mutagenic/toxic effects for reproduction

May damage fertility or the unborn child. (2-Ethylhexyl 4-(dimethylamino)benzoate)

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: 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.

#### Additional information on tests

This mixture is classified as hazardous according to regulation (EC) No. 1272/2008 [CLP]. Special hazards arising from the substance or mixture!

## SECTION 12: Ecological information

### 12.1. Toxicity

Harmful to aquatic life with long lasting effects.

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CAS No	Chemical name					
	Aquatic toxicity	Dose	[h]   [d]	Species	Source	Method
2867-47-2	2-dimethylaminoethyl methacrylate					
	Acute algae toxicity	ErC50 41,6 mg/l	72 h	Scenedesmus subspicatus	OECD 201	
	Acute crustacea toxicity	EC50 33 mg/l	48 h	Daphnia magna (Big water flea)	OECD 202	
3290-92-4	trimethylolpropane trimethacrylate					
	Acute fish toxicity	LC50 2 mg/l	96 h	Oncorhynchus mykiss (Rainbow trout)	OECD 203	
	Acute algae toxicity	ErC50 0,177 mg/l	72 h	Pseudokirchneriella subcapitata	OECD 201	
	Acute crustacea toxicity	EC50 >9,22 mg/l	48 h	Daphnia magna (Big water flea)	OECD 202	
	Acute bacteria toxicity	(>1000 mg/l)	3 h		OECD 209	
21245-02-3	2-Ethylhexyl 4-(dimethylamino)benzoate					
	Acute fish toxicity	LC50 0,235 mg/l	96 h	QSAR		
	Acute algae toxicity	ErC50 <0,015 mg/l	72 h	Pseudokirchneriella subcapitata		
	Acute crustacea toxicity	EC50 >0,031 mg/l	48 h	Daphnia magna (Big water flea)		
	Acute bacteria toxicity	(1000 mg/l)	3 h	Activated sludge		

### 12.2. Persistence and degradability

The product has not been tested.

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
2867-47-2	2-dimethylaminoethyl methacrylate			
		95,3%	28	
	Readily biodegradable (according to OECD criteria).			
3290-92-4	trimethylolpropane trimethacrylate			
	OECD 301B/ ISO 9439/ EEC 92/69/V, C.4-C	53%	28	
	Not readily biodegradable (according to OECD criteria)			

### 12.3. Bioaccumulative potential

The product has not been tested.

### 12.4. Mobility in soil

The product has not been tested.

### 12.5. Results of PBT and vPvB assessment

Not identified as PBT/ vPvB substances

### 12.6. Other adverse effects

No information available.

### Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods



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#### Advice on disposal

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation.

#### Contaminated packaging

@1301.B130039 Handle contaminated packages in the same way as the substance itself.

### SECTION 14: Transport information

#### Land transport (ADR/RID)

<b>14.1. UN number:</b>	UN 3265
<b>14.2. UN proper shipping name:</b>	CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. 2-Propenoic acid, 2-Methyl-, 2-Hydroxyethylester-phosphate.
<b>14.3. Transport hazard class(es):</b>	8
<b>14.4. Packing group:</b>	II
Hazard label:	8
Classification code:	C3
Limited quantity:	1 L/ 30 kg
Transport category:	2
Hazard No:	80
Tunnel restriction code:	E

#### Other applicable information (land transport)

Contains:: 2-Propenoic acid, 2-Methyl-, 2-Hydroxyethylester-phosphate.

#### Marine transport (IMDG)

<b>14.1. UN number:</b>	UN 3265
<b>14.2. UN proper shipping name:</b>	CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. 2-propenoic acid, 2-methyl-, 2-hydroxyethyl ester, phosphate
<b>14.3. Transport hazard class(es):</b>	8
<b>14.4. Packing group:</b>	II
Hazard label:	8
Special Provisions:	274
Limited quantity:	1 L/ 30 kg
Excepted quantity:	E2
EmS:	F-A, S-B

#### Other applicable information (marine transport)

Contains: 2-propenoic acid, 2-methyl-, 2-hydroxyethyl ester, phosphate

#### Air transport (ICAO-TI/IATA-DGR)

<b>14.1. UN number:</b>	UN 3265
<b>14.2. UN proper shipping name:</b>	CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. 2-propenoic acid, 2-methyl-, 2-hydroxyethyl ester, phosphate
<b>14.3. Transport hazard class(es):</b>	8
<b>14.4. Packing group:</b>	II
Hazard label:	8
Special Provisions:	A3 A803
Limited quantity Passenger:	0.5 L/ 30 kg
Passenger LQ:	Y840
Excepted quantity:	E2
IATA-packing instructions - Passenger:	851
IATA-max. quantity - Passenger:	1 L
IATA-packing instructions - Cargo:	855

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IATA-max. quantity - Cargo: 30 L

#### Other applicable information (air transport)

Contains: 2-propenoic acid, 2-methyl-, 2-hydroxyethyl ester, phosphate

#### 14.6. Special precautions for user

Warning: strongly corrosive.

#### 14.7. Transport in bulk according to Annex II of Marpol 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 regulatory information

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

##### National regulatory information

Employment restrictions: Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

Water contaminating class (D): 3 - highly water contaminating

Skin resorption/Sensitization: Causes allergic hypersensitivity reactions.

#### 15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

### SECTION 16: Other information

#### Abbreviations and acronyms

ADR: Accord européen sur le transport 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 Harmonized 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  
 LC50: Lethal concentration, 50%  
 LD50: Lethal dose, 50%  
 CLP: Classification, labelling and Packaging  
 REACH: Registration, Evaluation and Authorization of Chemicals  
 GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals  
 UN: United Nations  
 DNEL: Derived No Effect Level  
 DMEL: Derived Minimal Effect Level  
 PNEC: Predicted No Effect Concentration  
 ATE: Acute toxicity estimate  
 LL50: Lethal loading, 50%  
 EL50: Effect loading, 50%  
 EC50: Effective Concentration 50%  
 ErC50: Effective Concentration 50%, growth rate  
 NOEC: No Observed Effect Concentration  
 BCF: Bio-concentration factor

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PBT: persistent, bioaccumulative, toxic  
 vPvB: very persistent, very bioaccumulative  
 RID: Regulations concerning the international carriage of dangerous goods by rail  
 EmS: Emergency Schedules  
 MFAG: Medical First Aid Guide  
 ICAO: International Civil Aviation Organization  
 MARPOL: International Convention for the Prevention of Marine Pollution from Ships  
 IBC: Intermediate Bulk Container  
 SVHC: Substance of Very High Concern  
 @1602.B016012

#### Classification for mixtures and used evaluation method according to Regulation (EC) No. 1272/2008 [CLP]

Classification	Classification procedure
Skin Corr. 1B; H314	Calculation method
Eye Dam. 1; H318	Calculation method
Skin Sens. 1; H317	Calculation method
Repr. 1B; H360	Calculation method
Aquatic Chronic 3; H412	Calculation method

#### Relevant H and EUH statements (number and full text)

H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H360	May damage fertility or the unborn child.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

#### Further Information

The information is based on present level of our knowledge. It does not, however, give assurances of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

#### Identified uses

No	Short title	LCS	SU	PC	PROC	ERC	AC	TF	Specification
1	Gewerblich	-	-	-	-	-	-	-	2

LCS: Life cycle stages

SU: Sectors of use

PC: Product categories

PROC: Process categories

ERC: Environmental release categories

AC: Article categories

TF: Technical functions

*(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)*