

Safety Data Sheet

according to UK REACH Regulation

smartseal® & loc/ & loc F

Revision date: 05.05.2022

Product code: 10679

Page 1 of 11

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

1.1. Product identifier

smartseal® & loc/ & 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	
Street:	Carl-Zeiss-Straße 4	
Place:	D-76275 Ettlingen	
Telephone:	+49 7243/510-0	Telefax: +49 7243/510-100
e-mail:	post@detax.com	
Internet:	www.detax.com	
Responsible Department:	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.)	
	+1-800-424-9300 (CHEMTREC worldwide)	

1.4. Emergency telephone number:

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GB CLP Regulation

Skin Corr. 1B; H314
Eye Dam. 1; H318
Skin Sens. 1; H317
Aquatic Chronic 2; H411

Full text of hazard statements: see SECTION 16.

2.2. Label elements

GB CLP Regulation

Hazard components for labelling

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate
2-dimethylaminoethyl methacrylate
2-propenoic acid, 2-methyl-, 2-hydroxyethyl ester, phosphate
Triethylene glycol dimethacrylate
1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with oxirane, 4-(dimethylamino)benzoate

Signal word: Danger

Pictograms:



Hazard statements

H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H411	Toxic 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/hearing

Safety Data Sheet

according to UK REACH Regulation

smartseal® & loc/ & loc F

Revision date: 05.05.2022

Product code: 10679

Page 2 of 11

- P303+P361+P353 protection.
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.

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate			20 - < 40 %
	276-957-5		01-2120751202-68	
	Skin Sens. 1B, Aquatic Chronic 2; H317 H411			
32435-46-4	bis(methacryloxyethyl) hydrogen phosphate			5 - < 20 %
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335			
2867-47-2	2-dimethylaminoethyl methacrylate			0.1 - < 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			0.1 - < 5 %
	221-950-4			
	Aquatic Chronic 2; H411			
24599-21-1	2-propenoic acid, 2-methyl-, 2-hydroxyethyl ester, phosphate			0.1 - < 5 %
	Skin Corr. 1B, Skin Sens. 1, STOT SE 3; H314 H317 H335			
109-16-0	Triethylene glycol dimethacrylate			0.1 - < 5 %
	203-652-6		01-2119969287-21	
	Skin Sens. 1B; H317			
2067275-86-7	1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)-,polymer with oxirane, 4-(dimethylamino)benzoate			0.1 - < 5 %
	Skin Sens. 1B, Aquatic Chronic 4; H317 H413			

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

Safety Data Sheet

according to UK REACH Regulation

smartseal® & loc/ & loc F

Revision date: 05.05.2022

Product code: 10679

Page 3 of 11

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
72869-86-4	276-957-5	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate	20 - < 40 %
		dermal: LD50 = >2000 mg/kg; oral: LD50 = >5000 mg/kg	
2867-47-2	220-688-8	2-dimethylaminoethyl methacrylate	0.1 - < 5 %
		dermal: ATE = 1100 mg/kg; oral: LD50 = 1750 mg/kg	
3290-92-4	221-950-4	trimethylolpropane trimethacrylate	0.1 - < 5 %
		dermal: LD50 = >2000 mg/kg; oral: LD50 = >2000 mg/kg	
24599-21-1		2-propenoic acid, 2-methyl-, 2-hydroxyethyl ester, phosphate	0.1 - < 5 %
		Skin Corr. 1B; H314: >= 2 - 100	
109-16-0	203-652-6	Triethylene glycol dimethacrylate	0.1 - < 5 %
		oral: LD50 = 10800 mg/kg	

SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

Provide fresh air. If breathing is irregular or stopped, administer artificial respiration. Medical treatment necessary.

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

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

After ingestion

Rinse mouth immediately and drink 1 glass of water.

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.

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

General advice

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and

Safety Data Sheet

according to UK REACH Regulation

smartseal® & loc/ & loc F

Revision date: 05.05.2022

Product code: 10679

Page 4 of 11

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

For cleaning up

Absorb with liquid-binding material (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.

Advice on general occupational hygiene

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.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed.

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.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls

Individual protection measures, such as personal protective equipment

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)

Safety Data Sheet

according to UK REACH Regulation

smartseal® & loc/ & loc F

Revision date: 05.05.2022

Product code: 10679

Page 5 of 11

Skin protection

Use of protective clothing. 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

Changes in the physical state

Melting point/freezing point:	not determined
Boiling point or initial boiling point and boiling range:	not determined
Flash point:	>100 °C

Flammability

Solid/liquid:	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:	not determined
Decomposition temperature:	not determined
pH-Value (at 20 °C):	1,6
Water solubility:	The study does not need to be conducted because the substance is known to be insoluble in water.

Solubility in other solvents

not determined

Partition coefficient n-octanol/water:	not determined
Vapour pressure: (at 20 °C)	<1 hPa
Density (at 20 °C):	1,54 g/cm³ DIN 51757
Relative vapour density:	not determined

9.2. Other information

Information with regard to physical hazard classes

Oxidizing properties

The product is not: oxidising.

Other safety characteristics

Solid content:	not determined
Evaporation rate:	not determined

Further Information

SECTION 10: Stability and reactivity

Safety Data Sheet

according to UK REACH Regulation

smartseal® & loc/ & loc F

Revision date: 05.05.2022

Product code: 10679

Page 6 of 11

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 light and daylight 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 hazard classes as defined in GB CLP Regulation

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.

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate				
	oral	LD50 mg/kg	>5000	Rat	OECD 401
	dermal	LD50 mg/kg	>2000	Rat	OECD 402
2867-47-2	2-dimethylaminoethyl methacrylate				
	oral	LD50 mg/kg	1750	Rat	Lieferanten SDB
	dermal	ATE mg/kg	1100		
3290-92-4	trimethylolpropane trimethacrylate				
	oral	LD50 mg/kg	>2000	Rat	
	dermal	LD50 mg/kg	>2000	Rat	OECD 402
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. (7,7,9(or 7,9,9)

-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate; 2-dimethylaminoethyl methacrylate; 2-propenoic acid, 2-methyl-, 2-hydroxyethyl ester, phosphate; Triethylene glycol dimethacrylate; 1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with oxirane, 4-(dimethylamino)benzoate)

Safety Data Sheet

according to UK REACH Regulation

smartseal® & loc/ & loc F

Revision date: 05.05.2022

Product code: 10679

Page 7 of 11

Carcinogenic/mutagenic/toxic effects for reproduction

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.

Further information

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 12: Ecological information

12.1. Toxicity

Toxic to aquatic life with long lasting effects.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate					
	Acute crustacea toxicity	EC50 mg/l	>1,2	48 h	Daphnia magna (Big water flea)	OECD 202
2867-47-2	2-dimethylaminoethyl methacrylate					
	Acute fish toxicity	LC50 mg/l	19,1	96 h	Oryzias latipes	Lieferanten SDB
	Acute algae toxicity	ErC50 mg/l	69,7	72 h	Scenedesmus subspicatus	OECD 201
	Acute crustacea toxicity	EC50 mg/l	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 mg/l	0,177	72 h	Pseudokirchneriella subcapitata	OECD 201
	Acute crustacea toxicity	EC50 mg/l	>9,22	48 h	Daphnia magna (Big water flea)	OECD 202
	Acute bacteria toxicity	(EC50 mg/l)	>1000	3 h		OECD 209

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.

Safety Data Sheet

according to UK REACH Regulation

smartseal® & loc/ & loc F

Revision date: 05.05.2022

Product code: 10679

Page 8 of 11

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH.

Not identified as PBT/ vPvB substances

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. 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

Disposal recommendations

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

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number or ID number:	UN 3082
14.2. UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
14.3. Transport hazard class(es):	9
14.4. Packing group:	III
Hazard label:	9
Classification code:	M6
Special Provisions:	274 335 375 601
Limited quantity:	5 L
Excepted quantity:	E1
Transport category:	3
Hazard No:	90
Tunnel restriction code:	-

Other applicable information (land transport)

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

Inland waterways transport (ADN)

14.1. UN number or ID number:	UN 3082
14.2. UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
14.3. Transport hazard class(es):	9
14.4. Packing group:	III
Hazard label:	9
Classification code:	M6
Special Provisions:	274 335 375 601
Limited quantity:	5 L
Excepted quantity:	E1

Marine transport (IMDG)

14.1. UN number or ID number:	UN 3082
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Safety Data Sheet

according to UK REACH Regulation

smartseal® & loc/ & loc F

Revision date: 05.05.2022

Product code: 10679

Page 9 of 11

14.2. UN proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

14.3. Transport hazard class(es): 9

14.4. Packing group: III

Hazard label: 9

Special Provisions: 274, 335, 969

Limited quantity: 5 L

Excepted quantity: E1

EmS: F-A, S-F

Other applicable information (marine transport)

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

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number: UN 3082

14.2. UN proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

14.3. Transport hazard class(es): 9

14.4. Packing group: III

Hazard label: 9

Special Provisions: A97 A158 A197 A215

Limited quantity Passenger: 30 kg G

Passenger LQ: Y964

Excepted quantity: E1

IATA-packing instructions - Passenger: 964

IATA-max. quantity - Passenger: 450 L

IATA-packing instructions - Cargo: 964

IATA-max. quantity - Cargo: 450 L

Other applicable information (air transport)

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

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: Yes

14.6. Special precautions for user

No information available.

14.7. Maritime transport in bulk according to IMO instruments

not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 75

Information according to 2012/18/EU (SEVESO III): E2 Hazardous to the Aquatic Environment

National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).

Water hazard class (D): 3 - highly hazardous to water

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

Safety Data Sheet

according to UK REACH Regulation

smartseal® & loc/ & loc F

Revision date: 05.05.2022

Product code: 10679

Page 10 of 11

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
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
For abbreviations and acronyms, see table at <http://abbrev.esdscom.eu>
For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

Classification for mixtures and used evaluation method according to GB CLP Regulation

Classification	Classification procedure
Skin Corr. 1B; H314	Calculation method
Eye Dam. 1; H318	Calculation method
Skin Sens. 1; H317	Calculation method
Aquatic Chronic 2; H411	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.
H411 Toxic to aquatic life with long lasting effects.

Safety Data Sheet

according to UK REACH Regulation

smartseal® & loc/ & loc F

Revision date: 05.05.2022

Product code: 10679

Page 11 of 11

H413

May cause long lasting harmful effects to aquatic life.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance 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

PC: Product categories

ERC: Environmental release categories

TF: Technical functions

SU: Sectors of use

PROC: Process categories

AC: Article categories

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