

Safety Data Sheet

according to UK REACH Regulation

Visalys® CemCore

Revision date: 05.03.2026

Page 1 of 14

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

1.1. Product identifier

Visalys® CemCore

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

Use of the substance/mixture

Medical device for use in dentistry, observe instructions for use.

Uses advised against

Observe instructions for use.

1.3. Details of the supplier of the safety data sheet

Company name:	Kettenbach GmbH & Co. KG	
Street:	Im Heerfeld 7	
Place:	D-35713 Eschenburg	
Telephone:	+ 49(0) 2774/705-0	Telefax: +49 (0)2774/705-66
E-mail:	info@kettenbach.com	
Internet:	www.kettenbach.com	
Responsible Department:	R&D	

Further Information

The product is intended for professional use.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GB CLP Regulation

Eye Irrit. 2; H319
Skin Sens. 1; H317
STOT SE 3; H335
Aquatic Chronic 3; H412

Full text of hazard statements: see SECTION 16.

Safety Information Sheet for Medical Devices The particulars given in the Safety Information Sheet only apply to the described product in connection with its appropriate utilization. These particulars are based on the latest state of our knowledge and information. They serve the purpose of describing our product under the aspect of hazards caused by such product and pertaining safety actions. They do not constitute any guarantee of product quality and/or quality features. The particulars given in this Safety Information Sheet are not required according to the Article 31 and Annex II of Regulation (EC) No 1907/2006 (REACH Regulation). This product is classified as a medical device. Medical devices are exempt from the labelling provisions. They merely serve the purpose of providing sufficient information on the voluntary basis with a view to ensure the safe utilization of such substance/mixture/product.

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
Ytterbium trifluoride
dibenzoyl peroxide; benzoyl peroxide
2-(2-Hydroxy-5-methylphenyl)benzotriazole

Signal word: Warning

Safety Data Sheet

according to UK REACH Regulation

Visalys® CemCore

Revision date: 05.03.2026

Page 2 of 14

Pictograms:



Hazard statements

- | | |
|------|--|
| H317 | May cause an allergic skin reaction. |
| H319 | Causes serious eye irritation. |
| H335 | May cause respiratory irritation. |
| H412 | Harmful to aquatic life with long lasting effects. |

Precautionary statements

- | | |
|----------------|--|
| P260 | Do not breathe dust/fume/gas/mist/vapours/spray. |
| P280 | Wear protective gloves and 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. |
| P333+P313 | If skin irritation or rash occurs: Get medical advice/attention. |
| P501 | Dispose of contents/container in accordance with local/regional/national international regulations. |

2.3. Other hazards

Due to the physical form (paste), classification with H372 and H373 is not indicated. Inhalation is not possible. The fillers are not bioavailable and accordingly these substances are not considered in the classification of this product for inhalation hazards according to Article 12, note (b) of CLP Directive 1272/2008.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Preparation of multifunctional methacrylates, filler materials and additives.

Safety Data Sheet

according to UK REACH Regulation

Visalys® CemCore

Revision date: 05.03.2026

Page 3 of 14

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
14464-46-1	Cristobalite			30 - < 60% (*)
	238-455-4			
	STOT RE 1; H372			
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate			10 - < 30% (*)
	276-957-5		01-2120751202-68	
	Skin Sens. 1, Aquatic Chronic 2; H317 H411			
13760-80-0	Ytterbium trifluoride (nanoform: Nanoform: (100 ± 30) nm [D50, number distribution])			10 - < 30% (*)
	237-354-2		01-2120754122-65	
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335			
72829-09-5	1,12-DODECANEDIOL DIMETHACRYLATE			5 - < 10% (*)
	276-900-4		01-2120756306-53	
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3, Aquatic Acute 1, Aquatic Chronic 1; H315 H319 H317 H335 H400 H410			
68909-20-6	silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica (nanoform: Nanoform: 2.5 - 50 nm [D50, number distribution]))			1 - < 5% (*)
	272-697-1	014-052-00-7		
	STOT RE 2; H373 EUH066			
94-36-0	dibenzoyl peroxide; benzoyl peroxide			0.1 - < 1% (*)
	202-327-6	617-008-00-0		
	Org. Perox. B, Eye Irrit. 2, Skin Sens. 1, Aquatic Acute 1; H241 H319 H317 H400			
2440-22-4	2-(2-Hydroxy-5-methylphenyl)benzotriazole			0.1 - < 1% (*)
	219-470-5		01-2119583811-34	
	Skin Sens. 1, Aquatic Chronic 1; H317 H410			

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

Safety Data Sheet

according to UK REACH Regulation

Visalys® CemCore

Revision date: 05.03.2026

Page 4 of 14

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
14464-46-1	238-455-4	Cristobalite	30 - < 60% (*)
		STOT RE 1; H372: >= - 100	
72869-86-4	276-957-5	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	10 - < 30% (*)
		inhalation: Data lacking (gases); dermal: LD50 = >2000 mg/kg; oral: LD50 = >5000 mg/kg	
13760-80-0	237-354-2	Ytterbium trifluoride	10 - < 30% (*)
		inhalation: Data lacking (gases); dermal: LD50 = >2000 mg/kg; oral: LD50 = 3160 mg/kg Skin Irrit. 2; H315: >= - 100	
72829-09-5	276-900-4	1,12-DODECANEDIOL DIMETHACRYLATE	5 - < 10% (*)
		inhalation: Data lacking (gases); dermal: Data lacking; oral: LD50 = 2000 mg/kg Aquatic Acute 1; H400: M=1 Aquatic Chronic 1; H410: M=1	
68909-20-6	272-697-1	silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	1 - < 5% (*)
		inhalation: Data lacking (gases); dermal: Data lacking; oral: LD50 = >5000 mg/kg	
94-36-0	202-327-6	dibenzoyl peroxide; benzoyl peroxide	0.1 - < 1% (*)
		inhalation: LC50 = 24.3 mg/l (vapours); dermal: Data lacking; oral: LD50 = >2000 mg/kg	
2440-22-4	219-470-5	2-(2-Hydroxy-5-methylphenyl)benzotriazole	0.1 - < 1% (*)
		inhalation: LC50 = 590 mg/l (dusts or mists); dermal: LD50 = 1000 mg/kg; oral: LD50 = 10000 mg/kg	

Further Information

(*) The actual concentration is withheld as a trade secret.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

After inhalation

Provide fresh air.

After contact with skin

After contact with skin, wash immediately with: Water and soap.

After contact with eyes

If product gets into the eye, keep eyelid open and rinse immediately with large quantities of water, for at least 5 minutes. Subsequently consult an ophthalmologist.

After ingestion

If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention. Do NOT induce vomiting.

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

Inhalation: Not expected to present a significant inhalation hazard under anticipated conditions of normal use.

In case of skin contact: Symptoms may be delayed. Narcotic effect. Vapor concentrations above recommended exposure levels are irritating to the eyes and the respiratory tract, may cause headaches and dizziness, are anesthetic and may have other severe central nervous system effects. Drowsiness, dizziness, disorientation, vertigo.

Following eye contact: Not expected to present a significant eye contact hazard under anticipated conditions of normal use.

In case of ingestion: Not expected to present a significant ingestion hazard under anticipated conditions of normal use.

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

Safety Data Sheet

according to UK REACH Regulation

Visalys® CemCore

Revision date: 05.03.2026

Page 5 of 14

First Aid, decontamination, treatment of symptoms.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

All standard extinguishing agents are suitable.

Unsuitable extinguishing media

None known.

5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to the escape of irritating gases and vapours.

hydrofluoric acid

Carbon monoxide

Carbon dioxide (CO₂)

5.3. Advice for firefighters

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

Additional information

Fire fighting water forms corrosive acid solutions.

Suppress gases/vapours/mists with water spray jet.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Use personal protection equipment.

For non-emergency personnel

Do not breathe mist/vapours/spray.

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 containment

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

Other information

Take up mechanically.

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

Keep away from heat, flame and direct sunlight.

Wear personal protection equipment (refer to section 8).

Advice on protection against fire and explosion

No special fire protection measures are necessary.

Usual measures for fire prevention.

Advice on general occupational hygiene

Contaminated work clothing should not be allowed out of the workplace.

When using do not eat, drink, smoke, sniff.

Avoid contact with skin, eyes and clothes.

Safety Data Sheet

according to UK REACH Regulation

Visalys® CemCore

Revision date: 05.03.2026

Page 6 of 14

Protect skin by using skin protective cream.

Further information on handling

Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed and store in a cool place.

Store in the original container only.

Hints on joint storage

Keep away from food and drink.

Further information on storage conditions

Please pay attention to the information on the package!

7.3. Specific end use(s)

Apart from the uses mentioned in section 1.2, no other specific uses are foreseen.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m ³	fibres/ml	Category	Origin
128-37-0	2,6-Di-tert-butyl-p-cresol	-	10		TWA (8 h)	WEL
94-36-0	Dibenzoyl peroxide	-	5		TWA (8 h)	WEL
1309-37-1	Rouge, total inhalable	-	10		TWA (8 h)	WEL

Additional advice on limit values

None.

8.2. Exposure controls



Individual protection measures, such as personal protective equipment

Eye/face protection

Safety glasses.

Hand protection

Protective gloves.

Suitable material:

Butyl caoutchouc (butyl rubber), NR (Natural rubber (Caoutchouc), Natural latex), PVC (Polyvinyl chloride).

Unsuitable material:

NBR (Nitrile rubber).

Skin protection

Protective clothing.

Respiratory protection

Not required.

Thermal hazards

None.

Safety Data Sheet

according to UK REACH Regulation

Visalys® CemCore

Revision date: 05.03.2026

Page 7 of 14

Environmental exposure controls

Do not allow to enter into surface water or drains.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Paste	
Colour:	tooth-coloured	
Odour:	almost odourless, ester-like	
Melting point/freezing point:		No data available
Boiling point or initial boiling point and boiling range:		No data available
Flammability:		No data available
Lower explosion limits:		No data available
Upper explosion limits:		No data available
Flash point:		>100 °C
Auto-ignition temperature:		>300 °C
Decomposition temperature:		No data available
pH-Value:		No data available
Viscosity / kinematic:		No data available
Water solubility:		practically insoluble
Solubility in other solvents:		No data available
Dissolution rate:		No data available
Partition coefficient n-octanol/water:		No data available
Vapour pressure:		No data available
Density (at 23 °C):		~1.75 g/cm ³
Relative density:		No data available
Bulk density:		not applicable
Relative vapour density:		No data available
Particle characteristics:		not applicable

9.2. Other information

Information with regard to physical hazard classes

Explosive properties

not applicable

Oxidizing properties

not applicable

Other safety characteristics

Viscosity / dynamic: ~12000 mPa·s
(at 23 °C)

Further Information

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: Stability and reactivity

10.1. Reactivity

None by intended use.

10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3. Possibility of hazardous reactions

Safety Data Sheet

according to UK REACH Regulation

Visalys® CemCore

Revision date: 05.03.2026

Page 8 of 14

No known hazardous reactions.

10.4. Conditions to avoid

Storage outside of the predetermined storage conditions (see packaging)

10.5. Incompatible materials

No data available

10.6. Hazardous decomposition products

hydrofluoric acid

Carbon monoxide

Carbon dioxide (CO₂)

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.

Toxicological data are not available.

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

Safety Data Sheet

according to UK REACH Regulation

Visalys® CemCore

Revision date: 05.03.2026

Page 9 of 14

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-dioxa-5,12-diazahehexadecane-1,16-diyl bismethacrylate				
	oral	LD50 >5000 mg/kg	Rat		OECD-Test-Nr. 40
	dermal	LD50 >2000 mg/kg	Rat		OECD-Test-Nr. 402
	inhalation	Data lacking			
13760-80-0	Ytterbium trifluoride				
	oral	LD50 3160 mg/kg	Rat		
	dermal	LD50 >2000 mg/kg	Rabbit		
	inhalation	Data lacking			
72829-09-5	1,12-DODECANEDIOL DIMETHACRYLATE				
	oral	LD50 2000 mg/kg	Rat	ECHA	
	dermal	Data lacking			
	inhalation	Data lacking			
68909-20-6	silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica				
	oral	LD50 >5000 mg/kg	Rat		
	dermal	Data lacking			
	inhalation	Data lacking			
94-36-0	dibenzoyl peroxide; benzoyl peroxide				
	oral	LD50 >2000 mg/kg	Mouse		
	dermal	Data lacking			
	inhalation (4 h) vapour	LC50 24.3 mg/l	Rat		
2440-22-4	2-(2-Hydroxy-5-methylphenyl)benzotriazole				
	oral	LD50 10000 mg/kg	Rat	ECHA	
	dermal	LD50 1000 mg/kg	Rat	ECHA	
	inhalation (4 h) dust/mist	LC50 590 mg/l	Rat	ECHA	

Irritation and corrosivity

Serious eye damage/eye irritation: Causes serious eye irritation.

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Irritant effect on the skin: .

Irritant effect on the eye:..

Sensitising effects

May cause an allergic skin reaction. (7,7,9(or

7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahehexadecane-1,16-diyl bismethacrylate;

1,12-DODECANEDIOL DIMETHACRYLATE; dibenzoyl peroxide; benzoyl peroxide; 2-

(2-Hydroxy-5-methylphenyl)benzotriazole)

Sensitization trough skin contact possible..

Carcinogenic/mutagenic/toxic effects for reproduction

Safety Data Sheet

according to UK REACH Regulation

Visalys® CemCore

Revision date: 05.03.2026

Page 10 of 14

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.

No experimental indications of mutagenicity in-vitro exist.

STOT-single exposure

May cause respiratory irritation. (Ytterbium trifluoride)

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.

Practical experience

No data available

11.2. Information on other hazards

Further information

May cause an allergic skin reaction.

SECTION 12: Ecological information

12.1. Toxicity

Harmful to aquatic life with long lasting effects.

The product has not been tested.

Safety Data Sheet

according to UK REACH Regulation

Visalys® CemCore

Revision date: 05.03.2026

Page 11 of 14

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 fish toxicity	LC50 mg/l	10,1	96 h	Carassius auratus (goldfish)	OECD-Test-Nr. 203
	Acute algae toxicity	ErC50	100 mg/l	72 h		OECD-Test-Nr. 201
	Acute crustacea toxicity	EC50	1.2 mg/l	48 h	Daphnia magna (Big water flea)	OECD Test No. 202
	Algae toxicity	NOEC mg/l	0,21	72 d		
13760-80-0	Ytterbium trifluoride					
	Acute fish toxicity	LC50 mg/l	5000	96 h		
72829-09-5	1,12-DODECANEDIOL DIMETHACRYLATE					
	Acute crustacea toxicity	EC50 mg/l	>100	48 h	Daphnia	ECHA
68909-20-6	silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica					
	Aquatic toxicity	Data lacking				
94-36-0	dibenzoyl peroxide; benzoyl peroxide					
	Acute fish toxicity	LC50 mg/l	0.06	96 h	Oncorhynchus mykiss (Rainbow trout)	
	Acute algae toxicity	ErC50 mg/l	0.0711	72 h	Pseudokirchneriella subcapitata	
	Acute crustacea toxicity	EC50	0.11 mg/l	48 h	Daphnia magna (Big water flea)	
	Acute bacteria toxicity	EC50	35 mg/l ()	0,5 h	Activated sludge	
2440-22-4	2-(2-Hydroxy-5-methylphenyl)benzotriazole					
	Acute fish toxicity	LC50 mg/l	> 0,17	96 h	Oncorhynchus mykiss	OECD 203
	Fish toxicity	NOEC mg/l	0,013	21 d		

12.2. Persistence and degradability

The product has not been tested.

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate			
	OECD-Test-Nr. 301B	22%	28	
	Not readily biodegradable (according to OECD criteria)			
72829-09-5	1,12-DODECANEDIOL DIMETHACRYLATE			
	OECD 301B	97.3%	28	
	Readily biodegradable (according to OECD criteria).			
2440-22-4	2-(2-Hydroxy-5-methylphenyl)benzotriazole			
	OECD 301 B	0%	28	
	Poorly biodegradable.			

12.3. Bioaccumulative potential

The product has not been tested.

Safety Data Sheet

according to UK REACH Regulation

Visalys® CemCore

Revision date: 05.03.2026

Page 12 of 14

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate	3,39
72829-09-5	1,12-DODECANEDIOL DIMETHACRYLATE	6.5

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.

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

None known.

Further information

Do not allow to enter into surface water or drains.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Do not remove with domestic waste.

List of Wastes Code - residues/unused products

180106 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE); wastes from natal care, diagnosis, treatment or prevention of disease in humans; chemicals consisting of or containing hazardous substances; hazardous waste

List of Wastes Code - used product

150110 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); packaging containing residues of or contaminated by hazardous substances; hazardous waste

List of Wastes Code - contaminated packaging

150110 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); packaging containing residues of or contaminated by hazardous substances; hazardous waste

Contaminated packaging

Non-contaminated packages may be recycled.

SECTION 14: Transport information

Land transport (ADR/RID)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.

Safety Data Sheet

according to UK REACH Regulation

Visalys® CemCore

Revision date: 05.03.2026

Page 13 of 14

14.4. Packing group:

No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

14.1. UN number or ID number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous good in sense of this transport regulation.

Other applicable information

No dangerous good in sense of these transport regulations.

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 75

National regulatory information

Water hazard class (D):

1 - slightly hazardous to water

15.2. Chemical safety assessment

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

SECTION 16: Other information

Changes

This data sheet contains changes from the previous version in section(s): 1,2,3,9,14,16.

Date of preparation / Revised on: 05/03/2026

Version number: 2,01

Replaces version number: 2,0 (05/03/2021)

Abbreviations and acronyms

ATE: Acute toxicity estimate. CAS: Chemical abstracts service. CFR: Code of Federal Regulations. DNEL: Derived No Effect Level EC50: 50% of maximal effective concentration. FDA: Food and Drug Administration. GHS: Globally Harmonised System. IATA: International air transport association. ICAO: Technical instructions for the safe transport of dangerous goods by air. IMDG: International maritime dangerous goods. LC50: Lethal concentration to 50 % of a test population. LD50: Lethal dose to 50% of a test population (median lethal dose). NOAEL: No Observed Adverse Effect Level. PBT: Persistent, bioaccumulative and toxic substance. PEL: Permissible Exposure Limit. PNEC: Predicted No Effect Concentration. REL: Recommended exposure limit. STOT RE: Specific Target Organ Toxicity – Single Exposure. STOT SE: Specific Target Organ Toxicity – Repeated Exposure. TWA: 8-hour Time Weighted Averages (long-term exposure limit). US OSHA: US Occupational Safety and Health Administration. vPvB: Very persistent and very bioaccumulative.

Key literature references and sources for data

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

Safety Data Sheet

according to UK REACH Regulation

Visalys® CemCore

Revision date: 05.03.2026

Page 14 of 14

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

Classification	Classification procedure
Eye Irrit. 2; H319	Calculation method
Skin Sens. 1; H317	Calculation method
STOT SE 3; H335	Calculation method
Aquatic Chronic 3; H412	Calculation method

Relevant H and EUH statements (number and full text)

H241	Heating may cause a fire or explosion.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H372	Causes damage to organs through prolonged or repeated exposure.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
EUH066	Repeated exposure may cause skin dryness or cracking.

Further Information

Training instructions: Use only by personnel trained in dentistry.

Disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions.

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

Safety Data Sheet

according to UK REACH Regulation

Visalys Restorative Primer

Revision date: 09.02.2024

Page 1 of 10

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

1.1. Product identifier

Visalys Restorative Primer

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

Use of the substance/mixture

Restorative Primer

Medical device for use in dentistry, observe instructions for use.

Uses advised against

Observe instructions for use.

1.3. Details of the supplier of the safety data sheet

Company name: Kettenbach GmbH & Co. KG

Street: Im Heerfeld 7

Place: D-35713 Eschenburg

Telephone: + 49(0) 2774/705-0

Telefax: +49 (0)2774/705-66

E-mail: info@kettenbach.com

Internet: www.kettenbach.com

Responsible Department: R&D

Further Information

The product is intended for professional use.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GB CLP Regulation

Flam. Liq. 2; H225

Full text of hazard statements: see SECTION 16.

Safety Information Sheet for Medical Devices The particulars given in the Safety Information Sheet only apply to the described product in connection with its appropriate utilization. These particulars are based on the latest state of our knowledge and information. They serve the purpose of describing our product under the aspect of hazards caused by such product and pertaining safety actions. They do not constitute any guarantee of product quality and/or quality features. The particulars given in this Safety Information Sheet are not required according to the Article 31 and Annex II of Regulation (EC) No 1907/2006 (REACH Regulation). This product is classified as a medical device. Medical devices are exempt from the labelling provisions. They merely serve the purpose of providing sufficient information on the voluntary basis with a view to ensure the safe utilization of such substance/mixture/product.

2.2. Label elements

GB CLP Regulation

Signal word:

Danger

Pictograms:



Hazard statements

H225

Highly flammable liquid and vapour.

Precautionary statements

P280

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

P305+P351+P338

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

Safety Data Sheet

according to UK REACH Regulation

Visalys Restorative Primer

Revision date: 09.02.2024

Page 2 of 10

P241	present and easy to do. Continue rinsing.
P233	Use explosion-proof electrical/ventilating/lighting equipment.
P210	Keep container tightly closed.
	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Special labelling of certain mixtures

EUH208	Contains 2-dimethylaminoethyl methacrylate. May produce an allergic reaction.
	Contains 1 - < 5 % of components with unknown hazards to the aquatic environment.
	1 - < 5 per cent of the mixture consists of component(s) of unknown acute toxicity.

2.3. Other hazards

Vapours can form explosive mixtures with air.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Mixture based on methacrylates in ethanolic solution.

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
64-17-5	ethanol; ethyl alcohol			95 - < 100 %
	200-578-6	603-002-00-5		
	Flam. Liq. 2; H225			
85590-00-7	10-(Phosphonooxy)decyl methacrylate			1 - < 5 %
	874-929-2			
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335			
2867-47-2	2-dimethylaminoethyl methacrylate			< 1 %
	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			

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

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
64-17-5	200-578-6	ethanol; ethyl alcohol	95 - < 100 %
		inhalation: LC50 = 95,6 mg/l (vapours); oral: LD50 = 6200 mg/kg	
85590-00-7	874-929-2	10-(Phosphonooxy)decyl methacrylate	1 - < 5 %
		inhalation: Data lacking (gases); dermal: Data lacking; oral: Data lacking	
2867-47-2	220-688-8	2-dimethylaminoethyl methacrylate	< 1 %
		dermal: ATE = 1100 mg/kg; oral: ATE = 500 mg/kg	

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

After inhalation

Provide fresh air.

Safety Data Sheet

according to UK REACH Regulation

Visalys Restorative Primer

Revision date: 09.02.2024

Page 3 of 10

After contact with skin

After contact with skin, wash immediately with plenty of water and soap.

After contact with eyes

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

After ingestion

If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention. Do NOT induce vomiting.

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

Wash off promptly and flush contaminated skin with water. Promptly remove clothing if soaked through and flush skin with water. If swallowed, do NOT induce vomiting. Give a glass of water. Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

All standard extinguishing agents are suitable.

Unsuitable extinguishing media

Avoid water in straight hose stream; will scatter and spread fire.

5.2. Special hazards arising from the substance or mixture

Carbon dioxide (CO₂).

Combustible.

Vapours are heavier than air, spread along floors and form explosive mixtures with air.

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

Additional information

Move undamaged containers from immediate hazard area if it can be done safely.

Do not allow run-off from fire-fighting to enter drains or water courses.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Remove all sources of ignition.

Use personal protection equipment.

For non-emergency personnel

Do not breathe mist/vapours/spray.

Provide adequate ventilation.

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

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 containment

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

6.4. Reference to other sections

No release of hazardous substances.

Personal protection equipment: see section 8

Safety Data Sheet

according to UK REACH Regulation

Visalys Restorative Primer

Revision date: 09.02.2024

Page 4 of 10

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Keep away from sources of ignition - No smoking.
Wear personal protection equipment (refer to section 8).

Advice on protection against fire and explosion

Take precautionary measures against static discharges.

Advice on general occupational hygiene

Avoid contact with skin, eyes and clothes. Change contaminated clothing.
Wash hands before breaks and after work.
Protect skin by using skin protective cream.
When using do not eat, drink, smoke, sniff.

Further information on handling

Keep locked up and out of reach of children.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed and store in a cool place.
Store only in original container.

Hints on joint storage

Keep away from food and drink.

Further information on storage conditions

Protect against: heat.

7.3. Specific end use(s)

Apart from the uses mentioned in section 1.2, no other specific uses are foreseen.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m ³	fibres/ml	Category	Origin
128-37-0	2,6-Di-tert-butyl-p-cresol	-	10		TWA (8 h)	WEL
64-17-5	Ethanol	1000	1920		TWA (8 h)	WEL

8.2. Exposure controls

Appropriate engineering controls

not applicable

Individual protection measures, such as personal protective equipment

Eye/face protection

Safety glasses.

Hand protection

Disposable gloves
Hand protection: Suitable material: Butyl caoutchouc (butyl rubber)
Wash hands before breaks and after work.
Protect skin by using skin protective cream.

Skin protection

Protective clothing.
Avoid contact with skin, eyes and clothes.

Safety Data Sheet

according to UK REACH Regulation

Visalys Restorative Primer

Revision date: 09.02.2024

Page 5 of 10

Take off contaminated clothing and wash it before reuse.

Respiratory protection

With correct and proper use, and under normal conditions, breathing protection is not required.

Provide adequate ventilation.

Environmental exposure controls

Do not allow to enter into surface water or drains.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	colourless
Odour:	after alcohol
Melting point/freezing point:	-114 °C
Boiling point or initial boiling point and boiling range:	78 °C
Flammability:	No data available
Lower explosion limits:	3,1 vol. %
Upper explosion limits:	27,7 vol. %
Flash point:	13 °C
Auto-ignition temperature:	363-425 °C
Decomposition temperature:	No data available
pH-Value (at 25 °C):	2
Viscosity / kinematic:	No data available
Water solubility:	No data available
Dissolution rate:	No data available
Partition coefficient n-octanol/water:	No data available
Dispersion stability:	No data available
Vapour pressure:	No data available
Vapour pressure:	No data available
Density:	0,81 g/cm ³
Relative density:	No data available
Bulk density:	not applicable
Relative vapour density:	No data available
Particle characteristics:	not applicable

9.2. Other information

Information with regard to physical hazard classes

Explosive properties

Formation of potentially explosive vapor/air mixtures is possible.

Sustaining combustion:

No data available

Self-ignition temperature

Solid:

not applicable

Gas:

not applicable

Oxidizing properties

none

Further Information

No information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

Vapours can form explosive mixtures with air.

Safety Data Sheet

according to UK REACH Regulation

Visalys Restorative Primer

Revision date: 09.02.2024

Page 6 of 10

10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3. Possibility of hazardous reactions

None by intended use.

10.4. Conditions to avoid

Keep away from sources of heat (e.g. hot surfaces), sparks and open flames.

10.5. Incompatible materials

Alkali metals.

10.6. Hazardous decomposition products

No data available

Further information

Highly flammable. Vapours may form explosive mixtures with air.

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.

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
64-17-5	ethanol; ethyl alcohol				
	oral	LD50 6200 mg/kg	Rat	IUCLID	
	inhalation (4 h) vapour	LC50 95,6 mg/l	Rat	RTECS	
85590-00-7	10-(Phosphonooxy)decyl methacrylate				
	oral	Data lacking			
	dermal	Data lacking			
	inhalation	Data lacking			
2867-47-2	2-dimethylaminoethyl methacrylate				
	oral	ATE 500 mg/kg			
	dermal	ATE 1100 mg/kg			

Irritation and corrosivity

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation: Based on available data, the classification criteria are not met.

Sensitising effects

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

Contains 2-dimethylaminoethyl methacrylate. May produce an allergic reaction.

Carcinogenic/mutagenic/toxic effects for reproduction

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.

Safety Data Sheet

according to UK REACH Regulation

Visalys Restorative Primer

Revision date: 09.02.2024

Page 7 of 10

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.

SECTION 12: Ecological information

12.1. Toxicity

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

No information available.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
64-17-5	ethanol; ethyl alcohol					
	Acute crustacea toxicity	EC50 9268 - 14221 mg/l	48 h	Daphnia magna	IUCLID	
85590-00-7	10-(Phosphonooxy)decyl methacrylate					
	Aquatic toxicity	Data lacking				

12.2. Persistence and degradability

No information available.

12.3. Bioaccumulative potential

No information available.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
64-17-5	ethanol; ethyl alcohol	-0,31
85590-00-7	10-(Phosphonooxy)decyl methacrylate	3,53

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

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

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 uncontrolled discharge of product into the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Do not remove with domestic waste.

List of Wastes Code - residues/unused products

180106 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE); wastes from natal care, diagnosis, treatment or prevention of disease in humans; chemicals consisting of or containing hazardous substances; hazardous waste

List of Wastes Code - used product

Safety Data Sheet

according to UK REACH Regulation

Visalys Restorative Primer

Revision date: 09.02.2024

Page 8 of 10

150110 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); packaging containing residues of or contaminated by hazardous substances; hazardous waste

List of Wastes Code - contaminated packaging

150110 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); packaging containing residues of or contaminated by hazardous substances; hazardous waste

Contaminated packaging

Non-contaminated packages may be recycled.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number or ID number: UN 1170
14.2. UN proper shipping name: Ethanol
14.3. Transport hazard class(es): 3
14.4. Packing group: II
Hazard label: 3



Classification code: F1
Hazard No: 33
Tunnel restriction code: D/E

Inland waterways transport (ADN)

14.1. UN number or ID number: UN 1170
14.2. UN proper shipping name: Ethanol
14.3. Transport hazard class(es): 3
14.4. Packing group: II
Hazard label: 3



Marine transport (IMDG)

14.1. UN number or ID number: UN 1170
14.2. UN proper shipping name: Ethanol
14.3. Transport hazard class(es): 3
14.4. Packing group: II
Hazard label: 3



Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number: UN 1170
14.2. UN proper shipping name: Ethanol
14.3. Transport hazard class(es): 3
14.4. Packing group: II
Hazard label: 3

Safety Data Sheet

according to UK REACH Regulation

Visalys Restorative Primer

Revision date: 09.02.2024

Page 9 of 10



14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

The usual precautions when handling chemicals have to be obtained.

14.7. Maritime transport in bulk according to IMO instruments

not relevant

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 40, Entry 75

National regulatory information

15.2. Chemical safety assessment

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

SECTION 16: Other information

Changes

This data sheet contains changes from the previous version in section(s): 4,16.

Date of preparation / Revised on: 09/02/2024

Version number: 3,00

Replaces version number: 2,00 (07/04/2020)

Abbreviations and acronyms

ATE: Acute toxicity estimate. CAS: Chemical abstracts service. CFR: Code of Federal Regulations. DNEL: Derived No Effect Level EC50: 50% of maximal effective concentration. FDA: Food and Drug Administration. GHS: Globally Harmonised System. IATA: International air transport association. ICAO: Technical instructions for the safe transport of dangerous goods by air. IMDG: International maritime dangerous goods. LC50: Lethal concentration to 50 % of a test population. LD50: Lethal dose to 50% of a test population (median lethal dose). NOAEL: No Observed Adverse Effect Level. PBT: Persistent, bioaccumulative and toxic substance. PEL: Permissible Exposure Limit. PNEC: Predicted No Effect Concentration. REL: Recommended exposure limit. STOT RE: Specific Target Organ Toxicity – Single Exposure. STOT SE: Specific Target Organ Toxicity – Repeated Exposure. TWA: 8-hour Time Weighted Averages (long-term exposure limit). US OSHA: US Occupational Safety and Health Administration. vPvB: Very persistent and very bioaccumulative.

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

Classification	Classification procedure
Flam. Liq. 2; H225	On basis of test data

Relevant H and EUH statements (number and full text)

H225	Highly flammable liquid and vapour.
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
EUH208	Contains 2-dimethylaminoethyl methacrylate. May produce an allergic reaction.

Safety Data Sheet

according to UK REACH Regulation

Visalys Restorative Primer

Revision date: 09.02.2024

Page 10 of 10

Further Information

Training instructions: Use only by personnel trained in dentistry.

Disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions.

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

Safety Data Sheet

according to UK REACH Regulation

Visalys Tooth Primer

Revision date: 19.02.2024

Page 1 of 9

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

1.1. Product identifier

Visalys Tooth Primer

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

Use of the substance/mixture

Medical device for use in dentistry, observe instructions for use.

Uses advised against

Observe instructions for use.

1.3. Details of the supplier of the safety data sheet

Company name:	Kettenbach GmbH & Co. KG	
Street:	Im Heerfeld 7	
Place:	D-35713 Eschenburg	
Telephone:	+ 49(0) 2774/705-0	Telefax: +49 (0)2774/705-66
E-mail:	info@kettenbach.com	
Internet:	www.kettenbach.com	
Responsible Department:	R&D	

Further Information

The product is intended for professional use.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GB CLP Regulation

Skin Irrit. 2; H315
Eye Irrit. 2; H319
Skin Sens. 1; H317
Aquatic Chronic 3; H412

Full text of hazard statements: see SECTION 16.

Safety Information Sheet for Medical Devices The particulars given in the Safety Information Sheet only apply to the described product in connection with its appropriate utilization. These particulars are based on the latest state of our knowledge and information. They serve the purpose of describing our product under the aspect of hazards caused by such product and pertaining safety actions. They do not constitute any guarantee of product quality and/or quality features. The particulars given in this Safety Information Sheet are not required according to the Article 31 and Annex II of Regulation (EC) No 1907/2006 (REACH Regulation). This product is classified as a medical device. Medical devices are exempt from the labelling provisions. They merely serve the purpose of providing sufficient information on the voluntary basis with a view to ensure the safe utilization of such substance/mixture/product.

2.2. Label elements

GB CLP Regulation

Hazard components for labelling

2-hydroxyethyl methacrylate
2-dimethylaminoethyl methacrylate

Signal word: Warning

Pictograms:



Safety Data Sheet

according to UK REACH Regulation

Visalys Tooth Primer

Revision date: 19.02.2024

Page 2 of 9

Hazard statements

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H412	Harmful to aquatic life with long lasting effects.

Precautionary statements

P280	Wear protective gloves/protective clothing and eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of water and soap.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P501	Dispose of contents/container in accordance with local/regional/national international regulations.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Mixture based on methacrylates in aqueous solution.

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
868-77-9	2-hydroxyethyl methacrylate			25-50 %
	212-782-2	607-124-00-X		
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1; H315 H319 H317			
85590-00-7	10-(Phosphonooxy)decyl methacrylate			10-25 %
	874-929-2			
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335			
2867-47-2	2-dimethylaminoethyl methacrylate			< 1 %
	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			

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

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
	Specific Conc. Limits, M-factors and ATE		
868-77-9	212-782-2	2-hydroxyethyl methacrylate	25-50 %
	oral: LD50 = 5050 mg/kg		
85590-00-7	874-929-2	10-(Phosphonooxy)decyl methacrylate	10-25 %
	inhalation: Data lacking (gases); dermal: Data lacking; oral: Data lacking		
2867-47-2	220-688-8	2-dimethylaminoethyl methacrylate	< 1 %
	dermal: ATE = 1100 mg/kg; oral: ATE = 500 mg/kg		

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

Safety Data Sheet

according to UK REACH Regulation

Visalys Tooth Primer

Revision date: 19.02.2024

Page 3 of 9

After inhalation

Provide fresh air.

After contact with skin

After contact with skin, wash immediately with plenty of water and soap.

After contact with eyes

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

After ingestion

If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention. Do NOT induce vomiting.

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

No information available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

All standard extinguishing agents are suitable.

Unsuitable extinguishing media

Avoid water in straight hose stream; will scatter and spread fire.

5.2. Special hazards arising from the substance or mixture

Carbon dioxide (CO₂)

Combustible.

Vapours are heavier than air and will spread at floor level.

5.3. Advice for firefighters

No information available.

Additional information

Move undamaged containers from immediate hazard area if it can be done safely.

Do not allow run-off from fire-fighting to enter drains or water courses.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Use personal protection equipment.

For non-emergency personnel

Do not breathe mist/vapours/spray.

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 containment

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

Other information

Take up mechanically.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

Safety Data Sheet

according to UK REACH Regulation

Visalys Tooth Primer

Revision date: 19.02.2024

Page 4 of 9

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

- Keep away from sources of ignition - No smoking.
- Wear personal protection equipment (refer to section 8).

Advice on general occupational hygiene

- Avoid contact with skin, eyes and clothes.
- Wash hands before breaks and after work.
- Protect skin by using skin protective cream.
- When using do not eat, drink, smoke, sniff.

Further information on handling

- Keep locked up and out of reach of children.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

- Keep container tightly closed and store in a cool place.
- Keep/Store only in original container.

Hints on joint storage

- Keep away from food and drink.

Further information on storage conditions

- Protect against: Heat

7.3. Specific end use(s)

- Apart from the uses mentioned in section 1.2, no other specific uses are foreseen.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Additional advice on limit values

- not applicable

8.2. Exposure controls

Appropriate engineering controls

- not applicable

Individual protection measures, such as personal protective equipment

Eye/face protection

- Safety glasses.

Hand protection

- Single-use gloves.
- Hand protection Suitable material: Butyl caoutchouc (butyl rubber)
- Wash hands before breaks and after work.
- Protect skin by using skin protective cream.

Skin protection

- Protective clothing.
- Avoid contact with skin, eyes and clothes.
- Take off contaminated clothing and wash it before reuse.

Respiratory protection

- With correct and proper use, and under normal conditions, breathing protection is not required.
- Provide adequate ventilation.

Environmental exposure controls

- Do not allow to enter into surface water or drains.

Safety Data Sheet

according to UK REACH Regulation

Visalys Tooth Primer

Revision date: 19.02.2024

Page 5 of 9

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	light yellow
Odour:	ester-like

Test method

Melting point/freezing point:	No data available
Boiling point or initial boiling point and boiling range:	No data available
Flammability:	No data available
Lower explosion limits:	No data available
Upper explosion limits:	No data available
Flash point:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
pH-Value (at 25 °C):	>2
Viscosity / kinematic:	No data available
Water solubility:	easily soluble
Solubility in other solvents	No data available
Dissolution rate:	No data available
Partition coefficient n-octanol/water:	No data available
Dispersion stability:	No data available
Vapour pressure:	No data available
Density:	1.25 g/cm ³
Relative density:	No data available
Bulk density:	not applicable
Relative vapour density:	No data available
Particle characteristics:	not applicable

9.2. Other information

Information with regard to physical hazard classes

Explosive properties	No data available
Sustaining combustion:	No data available
Self-ignition temperature	No data available
Solid:	No data available
Gas:	No data available
Oxidizing properties	No data available
No data available	

Other safety characteristics

Evaporation rate:	DIN 53170
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SECTION 10: Stability and reactivity

10.1. Reactivity

No information available.

10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3. Possibility of hazardous reactions

Safety Data Sheet

according to UK REACH Regulation

Visalys Tooth Primer

Revision date: 19.02.2024

Page 6 of 9

None by intended use.

10.4. Conditions to avoid

Heat
Light

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

Decomposition products in case of fire: see section 5.

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.

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
868-77-9	2-hydroxyethyl methacrylate				
	oral	LD50 5050 mg/kg	Rat		
85590-00-7	10-(Phosphonooxy)decyl methacrylate				
	oral	Data lacking			
	dermal	Data lacking			
	inhalation	Data lacking			
2867-47-2	2-dimethylaminoethyl methacrylate				
	oral	ATE 500 mg/kg			
	dermal	ATE 1100 mg/kg			

Irritation and corrosivity

Skin corrosion/irritation: Causes skin irritation.

Serious eye damage/eye irritation: Causes serious eye irritation.

Sensitising effects

May cause an allergic skin reaction. (2-hydroxyethyl methacrylate; 2-dimethylaminoethyl methacrylate)

Carcinogenic/mutagenic/toxic effects for reproduction

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.

SECTION 12: Ecological information

Safety Data Sheet

according to UK REACH Regulation

Visalys Tooth Primer

Revision date: 19.02.2024

Page 7 of 9

12.1. Toxicity

Harmful to aquatic life with long lasting effects.

No information available.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
868-77-9	2-hydroxyethyl methacrylate					
	Acute fish toxicity	LC50	227 mg/l	96 h	Pimephales promelas	
85590-00-7	10-(Phosphonooxy)decyl methacrylate					
	Aquatic toxicity	Data lacking				

12.2. Persistence and degradability

No information available.

12.3. Bioaccumulative potential

No information available.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
868-77-9	2-hydroxyethyl methacrylate	0,47
85590-00-7	10-(Phosphonooxy)decyl methacrylate	3,53

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

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

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 uncontrolled discharge of product into the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Do not remove with domestic waste.

List of Wastes Code - residues/unused products

180106 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE); wastes from natal care, diagnosis, treatment or prevention of disease in humans; chemicals consisting of or containing hazardous substances; hazardous waste

List of Wastes Code - used product

150110 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); packaging containing residues of or contaminated by hazardous substances; hazardous waste

List of Wastes Code - contaminated packaging

Safety Data Sheet

according to UK REACH Regulation

Visalys Tooth Primer

Revision date: 19.02.2024

Page 8 of 9

150110 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); packaging containing residues of or contaminated by hazardous substances; hazardous waste

Contaminated packaging

Non-contaminated packages may be recycled.

SECTION 14: Transport information

Land transport (ADR/RID)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

not applicable

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

Additional information

National regulations

National regulatory information

15.2. Chemical safety assessment

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

SECTION 16: Other information

Changes

Safety Data Sheet

according to UK REACH Regulation

Visalys Tooth Primer

Revision date: 19.02.2024

Page 9 of 9

This data sheet contains changes from the previous version in section(s):

1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16.

Date of preparation / Revised on: 19/02/2024

Version number: 2,00

Replaces version number: 1,00 (14/03/2019)

Abbreviations and acronyms

ATE: Acute toxicity estimate. CAS: Chemical abstracts service. CFR: Code of Federal Regulations. DNEL: Derived No Effect Level EC50: 50% of maximal effective concentration. FDA: Food and Drug Administration. GHS: Globally Harmonised System. IATA: International air transport association. ICAO: Technical instructions for the safe transport of dangerous goods by air. IMDG: International maritime dangerous goods. LC50: Lethal concentration to 50 % of a test population. LD50: Lethal dose to 50% of a test population (median lethal dose). NOAEL: No Observed Adverse Effect Level. PBT: Persistent, bioaccumulative and toxic substance. PEL: Permissible Exposure Limit. PNEC: Predicted No Effect Concentration. REL: Recommended exposure limit. STOT RE: Specific Target Organ Toxicity – Single Exposure. STOT SE: Specific Target Organ Toxicity – Repeated Exposure. TWA: 8-hour Time Weighted Averages (long-term exposure limit). US OSHA: US Occupational Safety and Health Administration. vPvB: Very persistent and very bioaccumulative.

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

Classification	Classification procedure
Skin Irrit. 2; H315	Calculation method
Eye Irrit. 2; H319	Calculation method
Skin Sens. 1; H317	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.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H412 Harmful to aquatic life with long lasting effects.

Further Information

Training instructions: Use only by personnel trained in dentistry.

Disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions.

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