

## Safety Data Sheet

according to UK REACH Regulation

### Visalys Restorative Primer

Revision date: 09.02.2024

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## 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

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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.

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#### 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 (CO<sub>2</sub>).

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

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**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 <sup>3</sup>	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.

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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 <sup>3</sup>
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.

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#### 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.

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#### 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

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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



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#### 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.

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#### 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.

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