

Safety Data Sheet

according to 29 CFR 1910.1200(g)

Visalys Restorative Primer

Revision date: 02/09/2024

Product code: 13581

Page 1 of 8

1. Identification

Product identifier

Visalys Restorative Primer

Recommended use of the chemical and restrictions on use

Use of the substance/mixture

Restorative Primer

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

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.

2. Hazard(s) identification

Classification of the chemical

29 CFR Part 1910.1200

Flammable liquids: Flam. Liq. 2

Respiratory or skin sensitization: Skin Sens. 1

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. In particular, 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 in accordance with FDA regulations. This product is classified as a medical device. Medical devices are exempt from the labelling provisions of GHS according to the Hazard Communication Standard (29 CFR § 1910.1200). 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.

Label elements

29 CFR Part 1910.1200

Signal word: Danger

Pictograms:



Hazard statements

Highly flammable liquid and vapor
May cause an allergic skin reaction

Precautionary statements

Keep away from heat. - No Smoking.
Keep container tightly closed.
Take precautionary measures against static discharge.
Wear protective gloves/protective clothing/eye protection/face protection.
If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

Safety Data Sheet

according to 29 CFR 1910.1200(g)

Visalys Restorative Primer

Revision date: 02/09/2024

Product code: 13581

Page 2 of 8

Special labelling of certain mixtures

1 % of the mixture consists of ingredient(s) of unknown acute toxicity.

Hazards not otherwise classified

Vapors may form explosive mixtures with air.

3. Composition/information on ingredients

Mixtures

Chemical characterization

Mixture based on methacrylates in ethanolic solution.

Hazardous components

CAS No	Components	Quantity
64-17-5	ethanol; ethyl alcohol	98.25 %
85590-00-7	10-(Phosphonooxy)decyl methacrylate	1 %
2867-47-2	2-dimethylaminoethyl methacrylate	0.2 %

4. First-aid measures

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 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.

Most important symptoms and effects, both acute and delayed

No information available.

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.

5. Fire-fighting measures

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.

Specific hazards arising from the chemical

Carbon dioxide (CO₂).

Combustible.

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

Safety Data Sheet

according to 29 CFR 1910.1200(g)

Visalys Restorative Primer

Revision date: 02/09/2024

Product code: 13581

Page 3 of 8

Special protective equipment and precautions for fire-fighters

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.

6. Accidental release measures

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/vapors/spray.

Provide adequate ventilation.

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

Environmental precautions

Do not allow to enter into surface water or drains.

Methods and material for containment and cleaning up

For containment

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

Reference to other sections

No release of hazardous substances.

Personal protection equipment (PPE): see section 8

7. Handling and storage

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.

Wash hands before breaks and after work.

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

Further information on handling

Keep locked up and out of reach of children.

Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed and store in a cool place.

Hints on joint storage

Keep away from food and drink.

Further information on storage conditions

Protect against:

8. Exposure controls/personal protection

Control parameters

Safety Data Sheet

according to 29 CFR 1910.1200(g)

Visalys Restorative Primer

Revision date: 02/09/2024

Product code: 13581

Page 4 of 8

Exposure limits

CAS No	Substance	ppm	mg/m ³	f/cc	Category	Origin
128-37-0	2,6-Di-tert-butyl-p-cresol	-	10		TWA (8 h)	REL
64-17-5	Ethyl alcohol (Ethanol)	1000	1900		TWA (8 h)	REL
64-17-5	Ethyl alcohol	1000	1900		TWA (8 h)	REL

Exposure controls

Appropriate engineering controls

not applicable

Individual protection measures, such as personal protective equipment

Eye/face protection

Safety glasses.

Hand protection

Disposable gloves

Suitable material: Butyl caoutchouc (butyl rubber)

Wash hands before breaks and after work.

Skin protection

Protective clothing.

Avoid contact with skin, eyes and clothes.

Take off contaminated clothing and wash it before reuse.

Respiratory protection

Respiratory protection is not required when used properly and under normal conditions.

Provide adequate ventilation.

Environmental exposure controls

Do not allow to enter into surface water or drains.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state:	Liquid
Color:	colorless
Odor:	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
Vapor pressure:	No data available
Vapor pressure:	No data available
Density:	0,81 g/cm ³

Safety Data Sheet

according to 29 CFR 1910.1200(g)

Visalys Restorative Primer

Revision date: 02/09/2024

Product code: 13581

Page 5 of 8

Relative density:	No data available
Bulk density:	not applicable
Relative vapour density:	No data available
Particle characteristics:	not applicable

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.

10. Stability and reactivity

Reactivity

Vapors may form explosive mixtures with air.

Chemical stability

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

Possibility of hazardous reactions

None by intended use.

Conditions to avoid

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

Hazardous decomposition products

No data available

11. Toxicological information

Information on toxicological effects

Acute toxicity

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

Safety Data Sheet

according to 29 CFR 1910.1200(g)

Visalys Restorative Primer

Revision date: 02/09/2024

Product code: 13581

Page 6 of 8

CAS No	Components				
	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

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

Sensitizing effects

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

Carcinogenic/mutagenic/toxic effects for reproduction

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

Specific target organ toxicity (STOT) - single exposure

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

Specific target organ toxicity (STOT) - repeated exposure

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

Carcinogenicity (IARC): Ethanol in alcoholic beverages (CAS 64-17-5) is listed in group 1. Butylated hydroxytoluene (BHT) (CAS 128-37-0) is listed in group 3.

Aspiration hazard

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

12. Ecological information

Ecotoxicity

No information available.

Persistence and degradability

No information available.

Bioaccumulative potential

No information available.

Mobility in soil

No information available.

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.

Other adverse effects

No information available.

Further information

Do not allow uncontrolled discharge of product into the environment.

Safety Data Sheet

according to 29 CFR 1910.1200(g)

Visalys Restorative Primer

Revision date: 02/09/2024

Product code: 13581

Page 7 of 8

13. Disposal considerations

Waste treatment methods

Disposal recommendations

Do not remove with domestic waste. Do not allow to enter drains or watercourses.
Dispose in accordance with official regulations.

Contaminated packaging

Non-contaminated packages may be recycled.

14. Transport information

Marine transport (IMDG)

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



Air transport (ICAO-TI/IATA-DGR)

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



Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

Special precautions for user

The usual precautions when handling chemicals have to be obtained.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

not relevant

15. Regulatory information

U.S. Regulations

National regulatory information

SARA Section 311/312 Hazards:
ethanol; ethyl alcohol (64-17-5): Fire hazard
10-(Phosphonooxy)decyl methacrylate (85590-00-7): Immediate (acute) health hazard
2-dimethylaminoethyl methacrylate (2867-47-2): Immediate (acute) health hazard

State Regulations

Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65, State of California)

This product can not expose you to chemicals known to the State of California to cause cancer, birth defects or other reproductive harm.

16. Other information

Safety Data Sheet

according to 29 CFR 1910.1200(g)

Visalys Restorative Primer

Revision date: 02/09/2024

Product code: 13581

Page 8 of 8

Changes

Revision date: 02/09/2024

Revision No: 3,00

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.

Other data

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