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

1.1. Product identifier

Visalys® Bulk Flow

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

Use by untrained dental personnel and/or unapproved areas of application.

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	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GB CLP Regulation

Eye Irrit. 2; H319
Skin Sens. 1; H317
Aquatic Chronic 2; H411

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

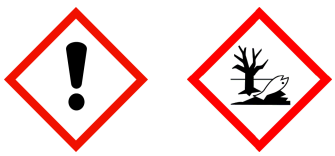
GB CLP Regulation

Hazard components for labelling

(octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate
phenyl bis(2,4,6-trimethylbenzoyl)phosphine oxide

Signal word: Warning

Pictograms:



Hazard statements

H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H411	Toxic to aquatic life with long lasting effects.

Precautionary statements

P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P273	Avoid release to the environment.
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.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Preparation of multifunctional methacrylates, filler materials and additives.

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
43048-08-4	(octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate			10 - < 30 (*) %
	256-062-6			
	Skin Sens. 1, Aquatic Chronic 2; H317 H411			
13760-80-0	Ytterbium trifluoride (nanoform: Nanoform: (100 ± 30) nm [D50, number distribution])			7 - < 13 (*) %
	237-354-2		01-2120754122-65	
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335			
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)phosphine oxide			0.1 - <1 (*) %
	423-340-5	015-189-00-5		
	Skin Sens. 1A, Aquatic Chronic 4; H317 H413			

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		
43048-08-4	256-062-6	(octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate	10 - < 30 (*) %
	inhalation: Data lacking (gases); dermal: LD50 = >2000 mg/kg; oral: LD50 = >2000 mg/kg		
13760-80-0	237-354-2	Ytterbium trifluoride	7 - < 13 (*) %
	inhalation: Data lacking (gases); dermal: LD50 = >2000 mg/kg; oral: LD50 = 3160 mg/kg Skin Irrit. 2; H315: >= - 100		
162881-26-7	423-340-5	phenyl bis(2,4,6-trimethylbenzoyl)phosphine oxide	0.1 - <1 (*) %
	inhalation: Data lacking (gases); dermal: LD50 = >2000 mg/kg; oral: LD50 = >2000 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 plenty of 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 SWALLOWED: rinse mouth. 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.
After skin contact: Not expected to present a significant skin 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

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.
Hydrogen fluoride, Carbon dioxide (CO_2), Silicon dioxide (SiO_2)

5.3. Advice for firefighters

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

Additional information

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

Allow stiffening. 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.
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.

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/m³	fibres/ml	Category	Origin
128-37-0	2,6-Di-tert-butyl-p-cresol	-	10		TWA (8 h)	WEL

8.2. Exposure controls





Individual protection measures, such as personal protective equipment

Eye/face protection

Safety glasses.

Hand protection

Protective gloves.

Suitable material:
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.

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-colored
Odour:	almost odourless
Odour threshold:	No data available

		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:	>100 °C	
Auto-ignition temperature:	No data available	
Decomposition temperature:	>300 °C	
pH-Value:	No data available	
Viscosity / kinematic:	No data available	
Water solubility:	practically insoluble	
Dissolution rate:	No data available	
Partition coefficient n-octanol/water:	No data available	
Dispersion stability:	No data available	
Vapour pressure:	No data available	DIN 51640
Vapour pressure:	No data available	
Density (at 20 °C):	~2.0 g/cm³	
Relative density:	No data available	
Bulk density:	No data available	
Relative vapour density:	Not applicable.	
Particle characteristics:	Not applicable.	

9.2. Other information

Information with regard to physical hazard classes

Explosive properties

Not applicable.

Sustained combustibility:	No data available

Oxidizing properties

Not applicable.

Other safety characteristics

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

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

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 (CO_2)

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

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
43048-08-4	(octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate				
	oral	LD50 >2000 mg/kg	Rat		
	dermal	LD50 >2000 mg/kg	Rat		
	inhalation	Data lacking			
13760-80-0	Ytterbium trifluoride				
	oral	LD50 3160 mg/kg	Rat		
	dermal	LD50 >2000 mg/kg	Rabbit		
	inhalation	Data lacking			
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)phosphine oxide				
	oral	LD50 >2000 mg/kg	Rat		
	dermal	LD50 >2000 mg/kg	Rat		
	inhalation	Data lacking			

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.

Sensitising effects

May cause an allergic skin reaction. ((octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate; phenyl bis(2,4,6-trimethylbenzoyl)phosphine oxide)

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.

Practical experience

No data available

11.2. Information on other hazards

Endocrine disrupting properties

Keine Daten verfügbar

SECTION 12: Ecological information

12.1. Toxicity

Toxic to aquatic life with long lasting effects.
Do not allow uncontrolled leakage of product into the environment.

CAS No	Chemical name						
	Aquatic toxicity	Dose		[h] | [d]	Species	Source	Method
43048-08-4	(octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate						
	Acute fish toxicity	LC50	1.65 mg/l	96 h	Danio rerio (zebrafish)		
	Acute algae toxicity	ErC50	1.6 mg/l	72 h	Pseudokirchneriella subcapitata		
	Acute crustacea toxicity	EC50	2.36 mg/l	48 h	Daphnia magna		
13760-80-0	Ytterbium trifluoride						
	Acute fish toxicity	LC50	5000 mg/l	96 h			
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)phosphine oxide						
	Acute fish toxicity	LC50	>0.09 mg/l	96 h	Danio rerio (zebrafish)		
	Acute algae toxicity	ErC50	>0.26 mg/l	72 h	Desmodesmus subspicatus		
	Acute crustacea toxicity	EC50	>1.175 mg/l	48 h	Daphnia magna		
	Fish toxicity	NOEC	>0.09 mg/l	96 d	Danio rerio (zebrafish)		
	Algae toxicity	NOEC	>0.26 mg/l	3 d	Desmodesmus subspicatus		

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
43048-08-4	(octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate	5.8

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.

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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)

14.1. UN number or ID number:	UN 3082
14.2. UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. ((Octahydro-4,7-methano-1H-indenediyl)bis(methylen)bismethacrylat)
14.3. Transport hazard class(es):	9
14.4. Packing group:	III
Hazard label:	9

Classification code:	M6
Special Provisions:	274 335 375 601
Limited quantity:	5 L
Excepted quantity:	E1
Transport category:	3
Hazard No:	90
Tunnel restriction code:	-

Other applicable information (land transport)

ADR/RID: UN3082, Not dangerous goods, fulfils special provision 375, Exception for environmentally hazardous substances, ((octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate), III, --. The special provision 375 applicable to UN number 3082 reads as follows: 'These substances, when carried in single packagings or combination packagings containing not more than 5 litres net quantity of liquids or not more than 5 kg net mass of solids per single or inner packaging, are not subject to the other provisions of RID/ADR, provided that the packagings comply with the general provisions of 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8.'

Inland waterways transport (ADN)

14.1. UN number or ID number:	UN 3082
14.2. UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. ((Octahydro-4,7-methano-1H-indenediyl)bis(methylen)bismethacrylat)
14.3. Transport hazard class(es):	9
14.4. Packing group:	III
Hazard label:	9

Classification code:	M6
Special Provisions:	274 335 375 601
Limited quantity:	5 L
Excepted quantity:	E1

Marine transport (IMDG)

14.1. UN number or ID number:	UN 3082
14.2. UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. ((octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate)
14.3. Transport hazard class(es):	9
14.4. Packing group:	III
Hazard label:	9

Special Provisions:	274 335 969
Limited quantity:	5 L
Excepted quantity:	E1
EmS:	F-A, S-F

Other applicable information (marine transport)

UN3082, NOT RESTRICTED AS PER IMDG CODE 2.10.2.7, MARINE POLLUTANT EXCEPTION, ((octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate), III, IMDG-Code segregation code: NONE, EMS: --.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number:	UN 3082

14.2. UN proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. ((octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate)

14.3. Transport hazard class(es): 9

14.4. Packing group: III

Hazard label: 9

Special Provisions:	A97 A158 A197 A215
Limited quantity Passenger:	30 kg G
Passenger LQ:	Y964
Excepted quantity:	E1
IATA-packing instructions - Passenger:	964
IATA-max. quantity - Passenger:	450 L
IATA-packing instructions - Cargo:	964
IATA-max. quantity - Cargo:	450 L

Other applicable information (air transport)

UN3082, NOT RESTRICTED AS PER SPECIAL PROVISION A197, ENVIRONMENTALLY HAZARDOUS SUBSTANCE EXCEPTION, (ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. ((octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate), III.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: Yes

Danger releasing substance: (octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate

14.6. Special precautions for user

No information available.

14.7. Maritime transport in bulk according to IMO instruments

Not applicable to product as supplied.

Other applicable information

Product may be shipped as non-hazardous in suitable packages containing a net quantity of 5 L or less under the provisions of various regulatory agencies: ADR, RID, ADN: Special Provision 375; IMDG: 2.10.2.7; IATA: A197; TDG: Special Provision 99(2); 49CFR: §171.4 (c) (2) and also the Special Provision 375 in Appendix B which is regulated in China "Regulations Concerning Road Transportation of Dangerous Goods Part 3: Index of dangerous goods name and transportation requirements" (JT/T 617.3)

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

Date of preparation / Revised on: 25/02/2025

Version number: 1,00
Replaces version number: -- (--)

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.

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
Aquatic Chronic 2; H411	Calculation method

Relevant H and EUH statements (number and full text)

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H411	Toxic to aquatic life with long lasting effects.
H413	May cause long lasting harmful effects to aquatic life.

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.)