

Safety Data Sheet

according to UK REACH Regulation

Visalys® Temp One:One

Revision date: 18.06.2025

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

1.1. Product identifier

Visalys® Temp One:One

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 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

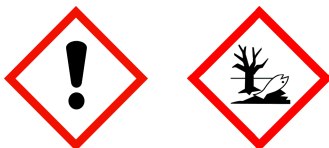
GB CLP Regulation

Hazard components for labelling

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate
1,12-DODECANEDIOL DIMETHACRYLATE
dibenzoyl peroxide; benzoyl peroxide

Signal word: Warning

Pictograms:



Hazard statements

H317 May cause an allergic skin reaction.

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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.

2.3. Other hazards

Due to the physical form (paste), classification with H372 and H373 is not indicated. Inhalation is not possible.

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)			
14464-46-1	Cristobalite			15 - <40% (*)
	238-455-4			
	STOT RE 1; H372			
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazaheptadecane-1,16-diyl bismethacrylate			15 - <40% (*)
	276-957-5		01-2120751202-68	
	Skin Sens. 1, Aquatic Chronic 2; H317 H411			
72829-09-5	1,12-DODECANEDIOL DIMETHACRYLATE			3 - <7% (*)
	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]))			3 - <7% (*)
	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			

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

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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	15 - <40% (*)
		STOT RE 1; H372: >= - 100	
72869-86-4	276-957-5	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate	15 - <40% (*)
		inhalation: Data lacking (gases); dermal: LD50 = >2000 mg/kg; oral: LD50 = >5000 mg/kg	
72829-09-5	276-900-4	1,12-DODECANEDIOL DIMETHACRYLATE	3 - <7% (*)
		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	3 - <7% (*)
		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	

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

First Aid, decontamination, treatment of symptoms.

SECTION 5: Firefighting measures

5.1. Extinguishing media

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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.

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.

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

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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
13463-67-7	Titanium dioxide, respirable	-	4		TWA (8 h)	WEL
13463-67-7	Titanium dioxide, 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.

Environmental exposure controls

Do not allow to enter into surface water or drains.

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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):		~1.42 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:
(at 23 °C) ~10000 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)

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10.5. Incompatible materials

No data available

10.6. Hazardous decomposition products

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) > 50 mg/l; ATE (inhalation dust/mist) > 5 mg/l

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-diazahexadecane-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			
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		

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.

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-diazahexadecane-1,16-diyl bismethacrylate; 1,12-DODECANEDIOL DIMETHACRYLATE; dibenzoyl peroxide; benzoyl peroxide)

Sensitization through skin contact possible..

Carcinogenic/mutagenic/toxic effects for reproduction

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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

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

Further information

May cause an allergic skin reaction.

SECTION 12: Ecological information

12.1. Toxicity

Toxic to aquatic life with long lasting effects.

The product has not been tested.

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 10,1 mg/l	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 0,21 mg/l	72 d			
72829-09-5	1,12-DODECANEDIOL DIMETHACRYLATE					
	Acute crustacea toxicity	EC50 >100 mg/l	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 0.06 mg/l	96 h	Oncorhynchus mykiss (Rainbow trout)		
	Acute algae toxicity	ErC50 0.0711 mg/l	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		

12.2. Persistence and degradability

The product has not been tested.

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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-diazahehexadecane-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).			

12.3. Bioaccumulative potential

The product has not been tested.

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-diazahehexadecane-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

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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. (7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate)
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, (7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl 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.
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.
14.3. Transport hazard class(es):	9
14.4. Packing group:	III
Hazard label:	9

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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, (7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl 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.
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, (7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate), III.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: Yes



Danger releasing substance: This product contains a chemical which is listed as a marine pollutant according to IMDG/IMO.

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

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

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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: 18/06/2025

Version number: 1,00

Replaces version number: -- (--/--/20--)

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
Skin Sens. 1; H317	Calculation method
Aquatic Chronic 2; H411	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.
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.

Safety Data Sheet

according to UK REACH Regulation

Visalys® Temp One:One

Revision date: 18.06.2025

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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.)