

## Safety Data Sheet

according to UK REACH Regulation

### VITA VM LC OPAQUE PASTE und VM LC GINGIVA OPAQUE PASTE

Revision date: 18.11.2022

Product code: 218

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

##### 1.1. Product identifier

VITA VM LC OPAQUE PASTE und VM LC GINGIVA OPAQUE PASTE

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

###### Use of the substance/mixture

Use as laboratory reagent

##### 1.3. Details of the supplier of the safety data sheet

Company name:	VITA Zahnfabrik H.Rauter GmbH & Co.KG	
Street:	Spitalgasse 3	
Place:	D-79713 Bad Säckingen	
Post-office box:	1338	
	D-79704 Bad Säckingen	
Telephone:	+49(0)7761-562-0	Telefax: +49(0)7761-562-299
e-mail:	info@vita-zahnfabrik.com	
Contact person:	regulatory affairs	
e-mail:	info@vita-zahnfabrik.com	
Internet:	www.vita-zahnfabrik.com	
Responsible Department:	Regulatory Affairs	

##### 1.4. Emergency telephone number:

+49-(0)761-19240

##### Further Information

medical device

#### 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.

##### 2.2. Label elements

###### GB CLP Regulation

###### Hazard components for labelling

2-hydroxyethyl methacrylate  
7,7,9-Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadecan-1,16-diol-dimethacrylat (mixture of isomers)  
2-dimethylaminoethyl methacrylate  
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

**Signal word:** Warning**Pictograms:****Hazard statements**

H315 Causes skin irritation.

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

#### Precautionary statements

- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
 P273 Avoid release to the environment.  
 P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.  
 P302+P352 IF ON SKIN: Wash with plenty of water.  
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

#### 2.3. Other hazards

No information available.

### SECTION 3: Composition/information on ingredients

#### 3.2. Mixtures

##### Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
72869-86-4	7,7,9-Trimethyl-4,13-dioxo-3,14-dioxo-5,12-diaza-hexadecan-1,16-diol-dimethacrylat (mixture of isomers)			15 - < 20 %
	276-957-5		01-2120751202-68	
	Skin Sens. 1B, Aquatic Chronic 3; H317 H412			
94108-97-1	Ditrimethylolpropane Tetraacrylate			5 - < 10 %
	302-434-9		01-2119977121-41	
	Eye Irrit. 2, Aquatic Chronic 2; H319 H411			
2867-47-2	2-dimethylaminoethyl methacrylate			5 - < 10 %
	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			
10373-78-1	Camphorquinone			1 - < 5 %
	233-814-1			
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335			
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide			1 - < 5 %
	278-355-8			
	Repr. 2, Skin Sens. 1, Aquatic Chronic 2; H361f H317 H411			
79-41-4	Methacrylsäure			< 1 %
	201-204-4		01-2119463884-26	
	Acute Tox. 3, Acute Tox. 4, Acute Tox. 4, Skin Corr. 1A, STOT SE 3; H311 H332 H302 H314 H335			

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	
2867-47-2	220-688-8	2-dimethylaminoethyl methacrylate	5 - < 10 %
		dermal: ATE = 1100 mg/kg; oral: ATE = 500 mg/kg	
79-41-4	201-204-4	Methacrylsäure	< 1 %
		inhalation: ATE = 11 mg/l (vapours); inhalation: ATE = 1.5 mg/l (dusts or mists); dermal: ATE = 300 mg/kg; oral: ATE = 500 mg/kg	

#### SECTION 4: First aid measures

##### 4.1. Description of first aid measures

###### **After inhalation**

Provide fresh air. When in doubt or if symptoms are observed, get medical advice.

###### **After contact with skin**

After contact with skin, wash immediately with plenty of water and soap. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary.

###### **After contact with eyes**

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

###### **After ingestion**

Rinse mouth immediately and drink plenty of water.

##### 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

Treat symptomatically.

#### SECTION 5: Firefighting measures

##### 5.1. Extinguishing media

###### **Suitable extinguishing media**

Co-ordinate fire-fighting measures to the fire surroundings.

##### 5.2. Special hazards arising from the substance or mixture

Non-flammable.

##### 5.3. Advice for firefighters

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

##### **Additional information**

Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

#### SECTION 6: Accidental release measures

##### 6.1. Personal precautions, protective equipment and emergency procedures

###### **General advice**

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

##### 6.2. Environmental precautions

Do not allow to enter into surface water or drains.

##### 6.3. Methods and material for containment and cleaning up

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#### Other information

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal.

#### 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

No special measures are necessary.

##### Advice on protection against fire and explosion

No special fire protection measures are necessary.

##### Advice on general occupational hygiene

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat, drink, smoke, sniff.

#### 7.2. Conditions for safe storage, including any incompatibilities

##### Requirements for storage rooms and vessels

Keep container tightly closed.

##### Hints on joint storage

No special measures are necessary.

#### 7.3. Specific end use(s)

Use as laboratory reagent

### 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
79-41-4	Methacrylic acid	20	72		TWA (8 h)	WEL
		40	143		STEL (15 min)	WEL
13463-67-7	Titanium dioxide, total inhalable	-	10		TWA (8 h)	WEL

#### 8.2. Exposure controls



#### Individual protection measures, such as personal protective equipment

##### Eye/face protection

Suitable eye protection: goggles.

##### Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the

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supplier of these gloves. Recommended glove articles KCL DermatriIP NBR (Nitrile rubber) Breakthrough time: 480 min

#### Skin protection

Use of protective clothing.

#### Respiratory protection

Provide adequate ventilation as well as local exhaustion at critical locations. Technical ventilation of workplace

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state:

Colour:

#### Changes in the physical state

Melting point/freezing point: not determined

Boiling point or initial boiling point and boiling range: ?

Flash point: 151 °C

Flash point: 151 °C

#### Flammability

Solid/liquid: not determined

Gas: not applicable

#### Explosive properties

The product is not: Explosive.

Lower explosion limits: not determined

Upper explosion limits: not determined

#### Self-ignition temperature

Solid: not determined

Gas: not applicable

Decomposition temperature: not determined

pH-Value: not determined

Water solubility: No

#### Solubility in other solvents

not determined

Partition coefficient n-octanol/water: not determined

Vapour pressure: <=1100 hPa

(at 50 °C)

Density: not determined

Relative vapour density: not determined

### 9.2. Other information

#### Information with regard to physical hazard classes

Oxidizing properties

Not oxidising.

#### Other safety characteristics

Solid content: 49,4 %

Evaporation rate: not determined

#### Further Information

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#### SECTION 10: Stability and reactivity

##### 10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

##### 10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

##### 10.3. Possibility of hazardous reactions

No known hazardous reactions.

##### 10.4. Conditions to avoid

none

##### 10.5. Incompatible materials

No information available.

##### 10.6. Hazardous decomposition products

No known hazardous decomposition products.

#### 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.

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
2867-47-2	2-dimethylaminoethyl methacrylate				
	oral	ATE 500 mg/kg			
	dermal	ATE 1100 mg/kg			
79-41-4	Methacrylsäure				
	oral	ATE 500 mg/kg			
	dermal	ATE 300 mg/kg			
	inhalation vapour	ATE 11 mg/l			
	inhalation dust/mist	ATE 1.5 mg/l			

###### Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

###### Sensitising effects

May cause an allergic skin reaction.

(7,7,9-Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadecan-1,16-diol-dimethacrylat (mixture of isomers);

2-dimethylaminoethyl methacrylate; Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide)

###### Carcinogenic/mutagenic/toxic effects for reproduction

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.

#### Additional information on tests

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

### SECTION 12: Ecological information

#### 12.1. Toxicity

Harmful to aquatic life with long lasting effects.

#### 12.2. Persistence and degradability

The product has not been tested.

#### 12.3. Bioaccumulative potential

The product has not been tested.

#### 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.

The product has not been tested.

#### 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 to enter into surface water or drains. Do not allow to enter into soil/subsoil.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

##### Disposal recommendations

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation.

##### Contaminated packaging

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself. Waste codes/waste designations according to EWC/AVV

### SECTION 14: Transport information

#### Land transport (ADR/RID)

##### 14.1. UN number or ID number:

UN 3243

##### 14.2. UN proper shipping name:

SOLIDS CONTAINING TOXIC LIQUID, N.O.S.  
(7,7,9-Trimethyl-4,13-dioxo-3,14-dioxo-5,12-diaza-hexadecan-1,16-diol-dime  
thacrylat (mixture of isomers), 2-Propenoic acid, 2-methyl-,  
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)]  
ester)

##### 14.3. Transport hazard class(es):

6.1

##### 14.4. Packing group:

II

Hazard label:

6.1

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Classification code: T9  
 Special Provisions: 217 274 601  
 Limited quantity: 500 g  
 Excepted quantity: E4  
 Transport category: 2  
 Hazard No: 60  
 Tunnel restriction code: D/E

#### Inland waterways transport (ADN)

**14.1. UN number or ID number:** UN 3243  
**14.2. UN proper shipping name:** SOLIDS CONTAINING TOXIC LIQUID, N.O.S.  
 (7,7,9-Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadecan-1,16-diol-dime  
 thacrylat (mixture of isomers), 2-Propenoic acid, 2-methyl-,  
 (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)]  
 ester)  
**14.3. Transport hazard class(es):** 6.1  
**14.4. Packing group:** II  
 Hazard label: 6.1



Classification code: T9  
 Special Provisions: 217 274 601 802  
 Limited quantity: 500 g  
 Excepted quantity: E4

#### Marine transport (IMDG)

**14.1. UN number or ID number:** UN 3243  
**14.2. UN proper shipping name:** SOLIDS CONTAINING TOXIC LIQUID, N.O.S.  
 (7,7,9-Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadecan-1,16-diol-dime  
 thacrylat (mixture of isomers), 2-Propenoic acid, 2-methyl-,  
 (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)]  
 ester)  
**14.3. Transport hazard class(es):** 6.1  
**14.4. Packing group:** II  
 Hazard label: 6.1



Special Provisions: 217, 274  
 Limited quantity: 500 g  
 Excepted quantity: E4  
 EmS: F-A, S-A

#### Air transport (ICAO-TI/IATA-DGR)

**14.1. UN number or ID number:** UN 3243



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**14.2. UN proper shipping name:**

SOLIDS CONTAINING TOXIC LIQUID, N.O.S.  
(7,7,9-Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadecan-1,16-diol-dime  
thacrylat (mixture of isomers), 2-Propenoic acid, 2-methyl-,  
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)]  
ester)

**14.3. Transport hazard class(es):**

6.1

**14.4. Packing group:**

II

Hazard label:

6.1



Special Provisions:

A50

Limited quantity Passenger:

1 kg

Passenger LQ:

Y644

Excepted quantity:

E4

IATA-packing instructions - Passenger:

669

IATA-max. quantity - Passenger:

25 kg

IATA-packing instructions - Cargo:

676

IATA-max. quantity - Cargo:

100 kg

**14.5. Environmental hazards**

ENVIRONMENTALLY HAZARDOUS: No

**14.6. Special precautions for user**

No information available.

**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 75

2010/75/EU (VOC): 0,102 %

2004/42/EC (VOC): 0,102 %

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

**National regulatory information**

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).

Water hazard class (D): 3 - highly hazardous to water

Skin resorption/Sensitization: Causes allergic hypersensitivity reactions.

**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): 7,8,14.

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#### Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route  
(European Agreement concerning the International Carriage of Dangerous Goods by Road)  
IMDG: International Maritime Code for Dangerous Goods  
IATA: International Air Transport Association  
GHS: Globally Harmonized System of Classification and Labelling of Chemicals  
EINECS: European Inventory of Existing Commercial Chemical Substances  
ELINCS: European List of Notified Chemical Substances  
CAS: Chemical Abstracts Service  
LC50: Lethal concentration, 50%  
LD50: Lethal dose, 50%  
CLP: Classification, labelling and Packaging  
REACH: Registration, Evaluation and Authorization of Chemicals  
GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals  
UN: United Nations  
DNEL: Derived No Effect Level  
DMEL: Derived Minimal Effect Level  
PNEC: Predicted No Effect Concentration  
ATE: Acute toxicity estimate  
LL50: Lethal loading, 50%  
EL50: Effect loading, 50%  
EC50: Effective Concentration 50%  
ErC50: Effective Concentration 50%, growth rate  
NOEC: No Observed Effect Concentration  
BCF: Bio-concentration factor  
PBT: persistent, bioaccumulative, toxic  
vPvB: very persistent, very bioaccumulative  
RID: Regulations concerning the international carriage of dangerous goods by rail  
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways  
(Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)  
EmS: Emergency Schedules  
MFAG: Medical First Aid Guide  
ICAO: International Civil Aviation Organization  
MARPOL: International Convention for the Prevention of Marine Pollution from Ships  
IBC: Intermediate Bulk Container  
VOC: Volatile Organic Compounds  
SVHC: Substance of Very High Concern  
For abbreviations and acronyms, see table at <http://abbrev.esdscom.eu>

#### 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.
H311	Toxic in contact with skin.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.

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H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H361f	Suspected of damaging fertility.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

#### Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

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