

according to UN GHS (ST/SG/AC.10/11/Rev.8)

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

Revision date: 12.08.2019

Product code: 218

Page 1 of 9

# 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

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	+49-(0)761-19240	
number:		

#### <u>number:</u>

Further Information

medical device

# **SECTION 2: Hazards identification**

# 2.1. Classification of the substance or mixture

## UN GHS (ST/SG/AC.10/11/Rev.8)

Hazard categories: Skin corrosion/irritation: Skin Irrit. 2 Serious eye damage/eye irritation: Eye Irrit. 2 Respiratory or skin sensitisation: Skin Sens. 1 Reproductive toxicity: Repr. 2 Hazardous to the aquatic environment: Aquatic Chronic 3 Hazard Statements: Causes skin irritation. Causes serious eye irritation. May cause an allergic skin reaction. Suspected of damaging fertility or the unborn child. Harmful to aquatic life with long lasting effects.

# 2.2. Label elements

#### UN GHS (ST/SG/AC.10/11/Rev.8)

#### Hazard components for labelling

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



according to UN GHS (ST/SG/AC.10/11/Rev.8)

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

Revision date: 12.08.2019

Product code: 218

Page 2 of 9

## Pictograms:



## Hazard statements

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H361	Suspected of damaging fertility or the unborn child.
H412	Harmful to aquatic life with long lasting effects.
	4-

#### **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			
	Classification (UN GHS (ST/SG/AC.10/11/Rev.8))			
72869-86-4	369-86-4 7,7,9-Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadecan-1,16-diol-dimethacrylat (mixture of isomers)			
	Skin Sens. 1B, Aquatic Chronic 3; H317 H412			
94108-97-1	8-97-1 Ditrimethylolpropane Tetraacrylate			
	Eye Irrit. 2, Aquatic Chronic 2; H319 H411			
2867-47-2	2-dimethylaminoethyl methacrylate	5 - < 10 %		
	Acute Tox. 4, Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1; H312 H302 H315 H319 H317			
10373-78-1	1 Camphorquinone			
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335			
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	1 - < 5 %		
	Repr. 2, Skin Sens. 1, Aquatic Chronic 2; H361f H317 H411			

# **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



according to UN GHS (ST/SG/AC.10/11/Rev.8)

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

Revision date: 12.08.2019

Product code: 218

Page 3 of 9

#### 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

# 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



according to UN GHS (ST/SG/AC.10/11/Rev.8)

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

Revision date: 12.08.2019

Product code: 218

Page 4 of 9

## Requirements for storage rooms and vessels

Keep container tightly closed.

# Hints on joint storage

No special measures are necessary.

# **SECTION 8: Exposure controls/personal protection**

#### 8.1. Control parameters

#### Exposure limits (EH40)

CAS No	Substance	ppm	mg/m³	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 supplier of these gloves. Recommended glove articles KCL DermatrilP 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
Flammability	
Solid/liquid:	not determined
Gas:	not applicable



according to UN GHS (ST/SG/AC.10/11/Rev.8)

VITA VM LC OPAQUE PA	STE und VM LC GINGIVA OPAQUE PAST	E
evision date: 12.08.2019	Product code: 218	Page 5 of
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: (at 50 °C)	<=1100 hPa	
Density:	not determined	
Relative vapour density:	not determined	
2. Other information		
Information with regard to physical hazard classes	i	
Oxidizing properties Not oxidising.		
Other safety characteristics		
Solid content:	49,4 %	
Evaporation rate:	not determined	

## 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.



according to UN GHS (ST/SG/AC.10/11/Rev.8)

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

Revision date: 12.08.2019

Product code: 218

Page 6 of 9

CAS No	Chemical name	Chemical name				
	Exposure route	Dose		Species	Source	Method
2867-47-2	2-dimethylaminoethyl methacrylate					
	oral	ATE mg/kg	500			
	dermal	ATE mg/kg	1100			

#### 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

Suspected of damaging fertility or the unborn child. (Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide) Germ cell mutagenicity: Based on available data, the classification criteria are not met. Carcinogenicity: 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.

#### 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.

#### 12.6. 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



according to UN GHS (ST/SG/AC.10/11/Rev.8)

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

Revision date: 12.08.2019

Product code: 218

Page 7 of 9

#### **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**

# Marine transport (IMDG)

14.1. UN number or ID number:	
14.2. UN proper shipping name:	SOLIDS CONTAINING TOXIC LIQUID, N.O.S.
14.3. Transport hazard class(es):	6.1 II
14.4. Packing group:	6.1
Hazard label:	0.1
	6
Special Provisions:	217, 274
Limited quantity:	500 g
Excepted quantity:	E4
EmS:	F-A, S-A
Air transport (ICAO-TI/IATA-DGR)	
<u>14.1. UN number or ID number:</u>	UN 3243
14.2. UN proper shipping name:	SOLIDS CONTAINING TOXIC LIQUID, N.O.S.
14.3. Transport hazard class(es):	6.1
14.4. Packing group:	II
Hazard label:	6.1
	6
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
<b>14.6. Special precautions for user</b> No information available.	
14.7. Maritime transport in bulk according to	IMO instruments
not applicable	
SECTION 15: Regulatory information	

# National regulatory information



according to UN GHS (ST/SG/AC.10/11/Rev.8)

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

Revision date: 12.08.2019

Product code: 218

Page 8 of 9

Employment restrictions:

Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC). Causes allergic hypersensitivity reactions.

Skin resorption/Sensitization:

# **SECTION 16: Other information**

# Changes

This data sheet contains changes from the previous version in section(s): 1,2,4,6,7,8,9,11,12,13,14,15,16.

#### 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

## **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.



according to UN GHS (ST/SG/AC.10/11/Rev.8)

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

Revision date: 12.08.2019

Product code: 218

Page 9 of 9

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