

## Safety Data Sheet

according to UK REACH Regulation

### VITAVM LC BASE DENTINE\_ENAMEL\_EFFECT-ENAMEL\_NEUTRAL\_GINGIVA

Revision date: 10.07.2023

Product code: 161

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

##### 1.1. Product identifier

VITAVM LC BASE DENTINE\_ENAMEL\_EFFECT-ENAMEL\_NEUTRAL\_GINGIVA

##### 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	

##### Further Information

medical device

#### SECTION 2: Hazards identification

##### 2.1. Classification of the substance or mixture

###### GB CLP Regulation

Skin Sens. 1B; H317

Full text of hazard statements: see SECTION 16.

##### 2.2. Label elements

###### GB CLP Regulation

###### Hazard components for labelling

2,2'-ethylenedioxydiethyl dimethacrylate

2-hydroxyethyl methacrylate

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

Signal word: Warning

###### Pictograms:



###### Hazard statements

H317 May cause an allergic skin reaction.

###### Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

##### 2.3. Other hazards

No information available.

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## 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			
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate			15 - < 20 %
	203-652-6		01-2119969287-21	
	Skin Sens. 1B; H317			

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

## 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. IF ON SKIN: Wash with plenty of soap and water.

#### 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.

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#### 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

###### 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

##### 8.2. Exposure controls

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#### 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 Dermatril P Breakthrough time: 10 min NBR (Nitrile rubber)

##### Skin protection

Use of protective clothing.

##### Respiratory protection

Provide adequate ventilation as well as local exhaust 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:	
Odour:	characteristic
Melting point/freezing point:	not determined
Boiling point or initial boiling point and boiling range:	139 °C
Flammability:	not determined not applicable
Lower explosion limits:	not determined
Upper explosion limits:	not determined
Flash point:	151 °C
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

### 9.2. Other information

#### Information with regard to physical hazard classes

##### Explosive properties

The product is not: Explosive.

##### Self-ignition temperature

Solid:

not determined

Gas:

not applicable

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Oxidizing properties  
Not oxidising.

#### Other safety characteristics

Evaporation rate: not determined  
Solid content: 59,1 %

## 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.

#### 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

#### Irritation and corrosivity

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

#### 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); 2,2'-ethylenedioxydiethyl dimethacrylate)

#### 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.

#### 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

The product is not: Ecotoxic.

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#### 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

Handle contaminated packages in the same way as the substance itself.

### SECTION 14: Transport information

#### Land transport (ADR/RID)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

#### Inland waterways transport (ADN)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

#### Marine transport (IMDG)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

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

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

#### 14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

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#### 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): 0,103 %

2004/42/EC (VOC): 0,103 %

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): 1 - slightly 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): 1.

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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>

Acute Tox: Acute toxicity

Skin Corr: Skin corrosion

Skin Sens: Skin sensitisation

STOT SE: Specific target organ toxicity - single exposure

Aquatic Chronic: Chronic aquatic hazard

#### Classification for mixtures and used evaluation method according to GB CLP Regulation

Classification	Classification procedure
Skin Sens. 1B; H317	Calculation method

#### Relevant H and EUH statements (number and full text)

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

#### Further Information



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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.

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