

Safety Data Sheet

according to Regulation (EC) No 1907/2006

VITAVM LC BASE DENTINE_ENAMEL_EFFECT-ENAMEL_NEUTRAL_GINGIVA

Revision date: 05.08.2019

Product code: 161

Page 1 of 8

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

Post-office box: 1338

79704 Bad Säckingen

Telephone: +49(0)7761-562-0

Telefax: +49(0)7761-562-299

e-mail: info@vita-zahnfabrik.com

Internet: www.vita-zahnfabrik.com

1.4. Emergency telephone

+49-(0)761-19240

number:

Further Information

medical device

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories:

Respiratory or skin sensitisation: Skin Sens. 1B

Hazard Statements:

May cause an allergic skin reaction.

2.2. Label elements

Regulation (EC) No. 1272/2008

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.

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

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

Safety Data Sheet

according to Regulation (EC) No 1907/2006

VITAVM LC BASE DENTINE_ENAMEL_EFFECT-ENAMEL_NEUTRAL_GINGIVA

Revision date: 05.08.2019

Product code: 161

Page 2 of 8

3.2. Mixtures

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
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.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and

Safety Data Sheet

according to Regulation (EC) No 1907/2006

VITAVM LC BASE DENTINE_ENAMEL_EFFECT-ENAMEL_NEUTRAL_GINGIVA

Revision date: 05.08.2019

Product code: 161

Page 3 of 8

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

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.

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

8.2. Exposure controls



Protective and hygiene measures

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.

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 (maximum wearing time) 10 min NBR (Nitrile rubber)

Skin protection

Use of protective clothing.

Respiratory protection

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

Safety Data Sheet

according to Regulation (EC) No 1907/2006

VITAVM LC BASE DENTINE_ENAMEL_EFFECT-ENAMEL_NEUTRAL_GINGIVA

Revision date: 05.08.2019

Product code: 161

Page 4 of 8

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:

Colour:

Odour: characteristic

pH-Value: not determined

Changes in the physical state

Melting point: not determined

Initial boiling point and boiling range: 139 °C

Flash point: 151 °C

Flammability

Solid: not determined

Gas: not applicable

Explosive properties

The product is not: Explosive.

Lower explosion limits: not determined

Upper explosion limits: not determined

Auto-ignition temperature

Solid: not determined

Gas: not applicable

Decomposition temperature: not determined

Oxidizing properties

Not oxidising.

Vapour pressure: <=1100 hPa
(at 50 °C)

Density: not determined

Water solubility: No

Solubility in other solvents

not determined

Partition coefficient: not determined

Vapour density: not determined

Evaporation rate: not determined

9.2. Other information

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

Safety Data Sheet

according to Regulation (EC) No 1907/2006

VITAVM LC BASE DENTINE_ENAMEL_EFFECT-ENAMEL_NEUTRAL_GINGIVA

Revision date: 05.08.2019

Product code: 161

Page 5 of 8

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 toxicological effects

Acute toxicity

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

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.

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 product has not been tested.

12.6. 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.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

VITAVM LC BASE DENTINE_ENAMEL_EFFECT-ENAMEL_NEUTRAL_GINGIVA

Revision date: 05.08.2019

Product code: 161

Page 6 of 8

Contaminated packaging

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

SECTION 14: Transport information

Land transport (ADR/RID)

- | | |
|--|--|
| 14.1. UN number: | No dangerous good in sense of this transport regulation. |
| 14.2. UN proper shipping name: | No dangerous good in sense of this transport regulation. |
| 14.3. Transport hazard class(es): | No dangerous good in sense of this transport regulation. |
| 14.4. Packing group: | No dangerous good in sense of this transport regulation. |

Inland waterways transport (ADN)

- | | |
|--|--|
| 14.1. UN number: | No dangerous good in sense of this transport regulation. |
| 14.2. UN proper shipping name: | No dangerous good in sense of this transport regulation. |
| 14.3. Transport hazard class(es): | No dangerous good in sense of this transport regulation. |
| 14.4. Packing group: | No dangerous good in sense of this transport regulation. |

Marine transport (IMDG)

- | | |
|--|--|
| 14.1. UN number: | No dangerous good in sense of this transport regulation. |
| 14.2. UN proper shipping name: | No dangerous good in sense of this transport regulation. |
| 14.3. Transport hazard class(es): | No dangerous good in sense of this transport regulation. |
| 14.4. Packing group: | No dangerous good in sense of this transport regulation. |

Air transport (ICAO-TI/IATA-DGR)

- | | |
|--|--|
| 14.1. UN number: | No dangerous good in sense of this transport regulation. |
| 14.2. UN proper shipping name: | No dangerous good in sense of this transport regulation. |
| 14.3. Transport hazard class(es): | No dangerous good in sense of this transport regulation. |
| 14.4. Packing group: | No dangerous good in sense of this transport regulation. |

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: no

14.6. Special precautions for user

No information available.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

- | | |
|---|--|
| 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.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

VITAVM LC BASE DENTINE_ENAMEL_EFFECT-ENAMEL_NEUTRAL_GINGIVA

Revision date: 05.08.2019

Product code: 161

Page 7 of 8

SECTION 16: Other information

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 Regulation (EC) No. 1272/2008 [CLP]

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

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.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

VITAVM LC BASE DENTINE_ENAMEL_EFFECT-ENAMEL_NEUTRAL_GINGIVA

Revision date: 05.08.2019

Product code: 161

Page 8 of 8

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