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 number:

+49-(0)761-19240

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
3.2. Mixtures

Hazardous components

<table>
<thead>
<tr>
<th>CAS No</th>
<th>Chemical name</th>
<th>CAS No</th>
<th>Index No</th>
<th>REACH No</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>72869-86-4</td>
<td>7,7,9-Trimethyl-4,13-dioxo-3,14-dioxo-5,12-diaza-hexadecan-1,16-diol-dimethacrylat (mixture of isomers)</td>
<td>72869-86-4</td>
<td>7,7,9-Trimethyl-4,13-dioxo-3,14-dioxo-5,12-diaza-hexadecan-1,16-diol-dimethacrylat (mixture of isomers)</td>
<td>15 - &lt; 20 %</td>
<td></td>
</tr>
<tr>
<td>276-957-5</td>
<td>2,2'-ethylenedioxydiethyl dimethacrylate</td>
<td>276-957-5</td>
<td>01-2120751202-68</td>
<td>Skin Sens. 1B, Aquatic Chronic 3; H317 H412</td>
<td></td>
</tr>
<tr>
<td>109-16-0</td>
<td>2,2'-ethylenedioxydiethyl dimethacrylate</td>
<td>109-16-0</td>
<td>01-2199969287-21</td>
<td>Skin Sens. 1B; H317</td>
<td></td>
</tr>
</tbody>
</table>

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
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 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: characteristic
Odour: not determined
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.

Auto-ignition temperature
Solid: not determined
Gas: 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
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.
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.
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]

<table>
<thead>
<tr>
<th>Classification</th>
<th>Classification procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Sens. 1B; H317</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

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