

Safety Data Sheet

according to WHMIS

VITAVM LC BASE DENTINE_ENAMEL_EFFECT-ENAMEL_NEUTRAL_GINGIVA

Revision date: 10.07.2023 Product code: 161 Page 1 of 7

1. Identification

Product identifier

VITAVM LC BASE DENTINE_ENAMEL_EFFECT-ENAMEL_NEUTRAL_GINGIVA

Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

Use as laboratory reagent

Details of the supplier of the safety data sheet

Company name: VITA Zahnfabrik H.Rauter GmbH & Co.KG

Street: Spitalgasse 3

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D-79704 Bad Säckingen

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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

2. Hazard identification

Classification of the substance or mixture

WHMIS 2015

Respiratory or skin sensitization: Skin Sens. 1

Label elements

WHMIS 2015

Signal word: Warning

Pictograms:



Hazard statements

May cause an allergic skin reaction.

Precautionary statements

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

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

Other hazards

No information available.

3. Composition/information on ingredients

Mixtures



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Hazardous components

CAS No	Chemical name	Quantity
72869-86-4	7,7,9-Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadecan-1,16-diol-dimethacrylat (mixture of isomers)	10 - < 30% (*)
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate	10 - < 30% (*)

^(*) The actual concentration is withheld as a trade secret.

4. First-aid measures

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.

Most important symptoms and effects, whether acute or delayed

No information available.

Indication of immediate medical attention and special treatment needed

Treat symptomatically.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media

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

Specific hazards arising from the hazardous product

Non-flammable.

Special protective equipment and precautions for fire-fighters

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.

6. Accidental release measures

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.

Environmental precautions

Do not allow to enter into surface water or drains.

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.

Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

7. Handling and storage

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.

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.

8. Exposure controls/Personal protection

Control parameters

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 Dermatril P Breakthrough 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



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9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state:

Colour:

Odour: characteristic

Melting point/freezing point:

Boiling point or initial boiling point and

139 °C

boiling range:

Flammability: not determined

not applicable

Lower explosive limits:

Upper explosive limits:

Flash point:

not determined
not determined
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: <=1100 hPa

(at 50 °C)

Density: not determined Relative vapour density: not determined

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

Oxidizing properties

Not oxidising.

Other safety characteristics

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

10. Stability and reactivity

Reactivity

No hazardous reaction when handled and stored according to provisions.

Chemical stability

The product is stable under storage at normal ambient temperatures.

Possibility of hazardous reactions

No known hazardous reactions.

Conditions to avoid

none

Incompatible materials

No information available.



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Hazardous decomposition products

No known hazardous decomposition products.

11. Toxicological information

Information on toxicological effects

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.

Sensitizing 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].

12. Ecological information

Ecotoxicity

The product is not: Ecotoxic.

Persistence and degradability

The product has not been tested.

Bioaccumulative potential

The product has not been tested.

Mobility in soil

The product has not been tested.

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.

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.

13. Disposal considerations

Waste treatment methods



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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.

14. Transport information

Marine transport (IMDG)

<u>UN number or ID number:</u> No dangerous good in sense of this transport regulation.

<u>United Nations proper shipping</u> No dangerous good in sense of this transport regulation.

name:

<u>Transport hazard class(es):</u>
No dangerous good in sense of this transport regulation.
Packing group:
No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

<u>UN number or ID number:</u> No dangerous good in sense of this transport regulation. United Nations proper shipping No dangerous good in sense of this transport regulation.

name:

Transport hazard class(es):

Packing group:

No dangerous good in sense of this transport regulation.

No dangerous good in sense of this transport regulation.

Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

15. Regulatory information

Canadian regulations

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

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.)