

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 07.08.2015

Version number 2

Revision: 07.08.2015

Hazardous according to criteria of Australian Safety and Compensation Council

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

- **1.1 Product identifier**
- **Trade name:** VITAVM LC BASE DENTINE ENAMEL EFFECT-ENAMEL NEUTRAL GINGIVA
- **Article number:** C 4403..
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available
- **Application of the substance / product** Auxiliary for manufacture of dental prothesis
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
VITA Zahnfabrik
H. Rauter GmbH & Co. KG

- Postfach 1338
D 79704 Bad Säckingen
e-mail: info@vita-zahnfabrik.com

- **1.4 Emergency telephone number:**
Tel.: ++49-(0)7761-562-0
Tel.: ++49-(0)761-19240

Tel.: 07761/562-0
Fax: 07761/562299

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**



Xi; Irritant

- R36/38: Irritating to eyes and skin.
- **Information concerning particular hazards for human and environment:**
The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS07

(Contd. on page 2)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 07.08.2015

Version number 2

Revision: 07.08.2015

Trade name: VITAVM LC BASE DENTINE ENAMEL EFFECT-ENAMEL NEUTRAL GINGIVA

(Contd. of page 1)

- **Signal word** Warning
- **Hazard-determining components of labelling:**
triethylene glycol dimethacrylate
2-dimethylaminoethyl methacrylate
- **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
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.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Information concerning to particular hazards to man and environment**
- **Safety phrases:**
29 Do not empty into drains.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 72869-86-4	7,7,9-Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadecan-1,16-diol-dimethacrylat (mixture of isomers) R52/53	10-<25%
CAS: 109-16-0 Reg.nr.: 01-2119969287-21-xxxx	triethylene glycol dimethacrylate ☒ Xi R36/37/38; ☒ Xi R43 ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	10-<20%
CAS: 2867-47-2 EINECS: 220-688-8	2-dimethylaminoethyl methacrylate ☒ Xn R21/22; ☒ Xi R36/38; ☒ Xi R43 ⚠ Acute Tox. 4, H302; Acute Tox. 4, H312; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	< 2.5%

- **Additional information** For the wording of the listed risk phrases refer to section 16.

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **After inhalation** In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact**
Rinse open eye for several minutes with running water. If symptoms persist, consult a doctor.
- **After swallowing** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

(Contd. on page 3)

AUS

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 07.08.2015

Version number 2

Revision: 07.08.2015

Trade name: VITAVM LC BASE DENTINE ENAMEL EFFECT-ENAMEL NEUTRAL GINGIVA

(Contd. of page 2)

- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

*

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents** Use fire extinguishing methods suitable to surrounding conditions.
- **For safety reasons unsuitable extinguishing agents** Water.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

*

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **6.4 Reference to other sections**
No dangerous substances are released.
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

*

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special precautions are necessary if used correctly.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** Store in cool, dry place in tightly closed receptacles.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep receptacle tightly sealed.
- **Storage class 11**
- **7.3 Specific end use(s)** No further relevant information available.

*

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment**
- **General protective and hygienic measures**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
- **Respiratory protection:** Not required.

(Contd. on page 4)

AUS

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 07.08.2015

Version number 2

Revision: 07.08.2015

Trade name: VITAVM LC BASE DENTINE ENAMEL EFFECT-ENAMEL NEUTRAL GINGIVA

(Contd. of page 3)

· **Protection of hands:**



Protective gloves.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

Nitrile rubber, NBR

e.g. Dermatril P, KCL Nr. 743

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

e.g. Dermatril P, KCL 10 min

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**



Tightly sealed goggles.

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form:	Pasty
Colour:	According to product specification
Odour:	Characteristic
Odour threshold:	Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

Melting point/Melting range:	undetermined
Boiling point/Boiling range:	139 °C

· **Flash point:** 151 °C

· **Flammability (solid, gaseous)** Not determined.

· **Ignition temperature:**

Decomposition temperature: Not determined.

· **Self-igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.

(Contd. on page 5)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 07.08.2015

Version number 2

Revision: 07.08.2015

Trade name: VITAVM LC BASE DENTINE ENAMEL EFFECT-ENAMEL NEUTRAL GINGIVA

(Contd. of page 4)

· Oxidising properties	None
· Vapour pressure:	Not applicable.
· Density:	Not determined
· Relative density	Not determined.
· Vapour density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with Water:	Insoluble
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
dynamic:	Not applicable.
kinematic:	Not applicable.
· Solvent content:	
Organic solvents:	0.0 %
· 9.2 Other information	No further relevant information available.

*

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No decomposition if used and stored according to specifications.
- **10.2 Chemical stability** No decomposition if used and stored according to specifications.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity**
- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** 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.

*

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.

(Contd. on page 6)

AUS

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 07.08.2015

Version number 2

Revision: 07.08.2015

Trade name: VITAVM LC BASE DENTINE ENAMEL EFFECT-ENAMEL NEUTRAL GINGIVA

(Contd. of page 5)

- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water danger class 3 (German Regulation) (Self-assessment): extremely hazardous for water.
Do not allow product to reach ground water, water course or sewage system, even in small quantities.
Danger to drinking water if even extremely small quantities leak into the ground.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation** Disposal must be made according to official regulations.

- **European waste catalogue**

18 00 00	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care)
18 01 00	wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 06*	chemicals consisting of or containing dangerous substances

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|--|--|
| · 14.1 UN-Number | |
| · ADG, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name | |
| · ADG, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es) | |
| · ADG, ADN, IMDG, IATA | |
| · Class | Void |
| · 14.4 Packing group | |
| · ADG, IMDG, IATA | Void |
| · 14.5 Environmental hazards: | |
| · Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · Transport/Additional information: | Not dangerous according to the above specifications. |
| · UN "Model Regulation": | Void |

AUS

(Contd. on page 7)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 07.08.2015

Version number 2

Revision: 07.08.2015

Trade name: VITAVM LC BASE DENTINE ENAMEL EFFECT-ENAMEL NEUTRAL GINGIVA

(Contd. of page 6)

SECTION 15: Regulatory information

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

· **Australian Inventory of Chemical Substances**

72869-86-4	7,7,9-Trimethyl-4,13-dioxo-3,14-dioxo-5,12-diaza-hexadecan-1,16-diol-dimethacrylat (mixture of isomers)
109-16-0	triethylene glycol dimethacrylate
	Bisphenol-A-bis(hydroxypropylmethacrylat)
10373-78-1	Camphorquinone
2867-47-2	2-dimethylaminoethyl methacrylate

· **Standard for the Uniform Scheduling of Medicines and Poisons**

None of the ingredients is listed.

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **National regulations**

· **Waterhazard class:** Water danger class 3 (Self-assessment): extremely hazardous for water.

· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Relevant phrases**

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

R21/22 Harmful in contact with skin and if swallowed.

R36/37/38 Irritating to eyes, respiratory system and skin.

R36/38 Irritating to eyes and skin.

R43 May cause sensitisation by skin contact.

R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

· **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 Harmonised 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 (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 4: Acute toxicity, Hazard Category 4

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

· *** Data compared to the previous version altered.**