Tel.: 07761/562-0

Fax: 07761/562299

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

Version number 2 Revision: 08/07/2015 Printing date 08/07/2015

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

- · Product identifier
- · Trade name: VITAVM LC BASE DENTINE ENAMEL EFFECT-ENAMEL NEUTRAL GINGIVA
- · Article number: C 4403..
- · 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
- · 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

· Emergency telephone number:

Tel.: ++49-(0)7761-562-0Tel.: ++49-(0)761-19240

2 Hazards identification

· Classification of the substance or mixture



Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2A 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



X Irritant

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

- · Label elements
- · GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms



- · Signal word Warning
- · Hazard-determining components of labelling:

triethylene glycol dimethacrylate

2-dimethylaminoethyl methacrylate

(Contd. on page 2)

Printing date 08/07/2015 Version number 2 Revision: 08/07/2015

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

(Contd. of page 1)

· 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.

P280 Wear 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.

P321 Specific treatment (see on this label).

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

- · Other hazards
- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable. · **vPvB**: Not applicable.

3 Composition/information on ingredients

- · 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. 2A, H319; Skin Sens. 1, H317; STOT SE 3, H335	10-<20%
CAS: 2867-47-2	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; Flam. Liq. 4, H227	0.1-<1%

[·] Additional information For the wording of the listed risk phrases refer to section 16.

4 First aid measures

- · 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.
- · Information for doctor
- · Most important symptoms and effects, both acute and delayed No further relevant information available.
- · Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Firefighting measures

- · Extinguishing media
- · Suitable extinguishing agents Use fire extinguishing methods suitable to surrounding conditions.

(Contd. on page 3)

Printing date 08/07/2015 Version number 2 Revision: 08/07/2015

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

(Contd. of page 2)

- · For safety reasons unsuitable extinguishing agents Water.
- · Special hazards arising from the substance or mixture No further relevant information available.
- · Advice for firefighters
- · Protective equipment: No special measures required.

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- · Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · Methods and material for containment and cleaning up: Pick up mechanically.
- · 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.

7 Handling and storage

- · Handling
- · Precautions for safe handling No special precautions are necessary if used correctly.
- · Information about fire and explosion protection: No special measures required.
- · 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
- · Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · 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.
- · 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.
- · Protection of hands:



Protective gloves.

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

(Contd. on page 4)

Printing date 08/07/2015 Version number 2 Revision: 08/07/2015

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

(Contd. of page 3)

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 trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection:



Tightly sealed goggles.

9 Physical a	and chem	ical properties
--------------	----------	-----------------

· Information on basic physical and chemical properties

· General Information

· Appearance:

· pH-value:

Form: Pasty

Colour: According to product specification

Not applicable.

Odour: CharacteristicOdour threshold: Not determined.

· 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.

· Oxidising properties None

· Vapour pressure: Not applicable.

· Density: Not determined

Relative density
Vapour density
Not determined.
Not applicable.

• Vapour density Not applicable. • Evaporation rate Not applicable.

(Contd. on page 5)

Printing date 08/07/2015 *Version number* 2 *Revision:* 08/07/2015

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

(Contd. of page 4)

· 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 %

· Other information No further relevant information available.

10 Stability and reactivity

· Reactivity No decomposition if used and stored according to specifications.

- · Chemical stability No decomposition if used and stored according to specifications.
- · Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity
- · Primary irritant effect:
- · Skin corrosion/irritation Irritant to skin and mucous membranes.
- · Serious eye damage/irritation Irritating effect.
- · Respiratory or skin sensitisation No sensitising effects known.
- · Additional toxicological information:

The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

Irritant

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · 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.

- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.

(Contd. on page 6)

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

(Contd. of page 5)

· Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- $\cdot \textit{Recommendation Disposal must be made according to official regulations}.$

· European waste catalogue		
	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.

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

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · 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.
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

70.1

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

(Contd. of page 6)

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.

· Abbreviations and acronyms:

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

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

Flam. Liq. 4: Flammable liquids, Hazard Category 4

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

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

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.

CDN