

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:** VITA VM LC PRE OPAQUE
- **Article number:** C445913
- **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)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**
The product is not classified according to the CLP regulation.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
- **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** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Additional information:**
Contains 2-dimethylaminoethyl methacrylate. May produce an allergic reaction.
- **Information concerning to particular hazards to man and environment**
- **Safety phrases:**
29 Do not empty into drains.
60 This material and its container must be disposed of as hazardous waste.
61 Avoid release to the environment. Refer to special instructions/safety data sheets.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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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	25-50%
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** Supply fresh air; consult doctor in case of complaints.

· **After skin contact** Generally the product does not irritate the skin.

· **After eye contact** Rinse opened eye for several minutes under running water.

· **After swallowing** If symptoms persist consult doctor.

· **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

· **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:**

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

· **6.4 Reference to other sections**

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:** No special requirements.

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- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Storage class** 10
- **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** Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not required.
- **Protection of hands:**
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**
e.g. Dermatril P, KCL Nr. 743
Nitrile rubber, NBR
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. KCL Dermatril P 30 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:** Goggles recommended during refilling.

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:** Ester-like
- **Odour threshold:** Not determined.
- **pH-value:** Not determined.
- **Change in condition**

Melting point/Melting range:	undetermined
Boiling point/Boiling range:	undetermined
- **Flash point:** 151 °C
- **Flammability (solid, gaseous)** Not applicable.

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· 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 determined.
· Density:	Not determined
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with Water:	Not miscible or difficult to mix
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
dynamic:	Not determined.
kinematic:	Not determined.
· Solvent content:	
Organic solvents:	0.0 %
· 9.2 Other information	No further relevant information available.

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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

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SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity**
- **LD/LC50 values relevant for classification:** Not determined
- **Specific symptoms in biological assay:** Not determined
- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenity, 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.

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· **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.
- **12.4 Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** Harmful to fish
- **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.
Harmful to aquatic organisms
- **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.
- **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. |

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· **UN "Model Regulation":**

Void

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-dioxa-5,12-diaza-hexadecan-1,16-diol-dimethacrylat (mixture of isomers)
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	Bisphenol-A-bis(hydroxypropylmethacrylat)
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2867-47-2	2-dimethylaminoethyl methacrylate
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10373-78-1	Camphorquinone
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· **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.

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

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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

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

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

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