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

- · 1.1 Product identifier
- · Trade name: VITA VM LC OPAQUE PASTE and VM LC GINGIVA OPAQUE PASTE
- · Article number: C44..
- · 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



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; Sensitising

May cause sensitisation by skin contact.

· 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



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

2-dimethylaminoethyl methacrylate

· Hazard statements

H315 Causes skin irritation.

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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.

P321 Specific treatment (see on this label).

P362 Take off contaminated clothing and wash before reuse.

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

regulations.

- · 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 compone	ents:	
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 Aquatic Chronic 3, H412	10-<25%
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-<10%
CAS: 10373-78-1 EINECS: 233-814-1	Camphorquinone Xi R36/37/38 ◆ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	2.5-<10%
CAS: 75980-60-8	diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide Xn R62 Repr. Cat. 3 ❖ Repr. 2, H361f	2.5-<3%

· 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 and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

· After skin contact

Immediately wash with water and soap and rinse thoroughly.

Immediately rinse with water.

- · After eye contact Rinse opened eye for several minutes under running water. Then 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.
- · 4.3 Indication of any immediate medical attention and special treatment needed No further relevant information available.

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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.
- \cdot 6.3 Methods and material for containment and cleaning up:

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

· 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

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

- · 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.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: None.
- · Storage class 6.1 A
- · 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

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

· Respiratory protection: Use ventilation hood

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· 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

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

KCL Dermatril P 480 min

· Vapour pressure:

· Relative density

· Density:

The exact break trough 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

SECTION 9: Physical and chemical properties				
· 9.1 Information on basic physical a	nd 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.			
· Ignition temperature:	255 °C			
· 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			

Not determined.

Not determined

Not determined.

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Vapour density
Evaporation rate
Not determined.
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.

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.
- $\cdot \textbf{10.5 Incompatible materials:} \ \textit{No further relevant information available}.$
- · 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 (carcinogenity, mutagenicity and toxicity for reproduction)
- $\cdot \textit{Germ cell mutagenicity } \textit{Based on available data, the classification criteria are not met.} \\$
- · 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.
- · 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.

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Danger to drinking water if even extremely small quantities leak into the ground.

- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- \cdot **vPvB:** Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

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

14.1 UN-Number			
ADR, IMDG, IATA	UN3243		
14.2 UN proper shipping name			
ADR	UN3243 SOLIDS CONTAINING TOXIC LIQUID, N.C.		
	(2-DIMETHYLAMINOETHYL METHACRYLATE)		
IMDG, IATA	SOLIDS CONTAINING TOXIC LIQUID, N.O.S.		
	DIMETHYLAMINOETHYL METHACRYLATE)		
14.3 Transport hazard class(es)			
ADR			
6			
	(1m)		
Class Label	6.1 Toxic substances. 6.1		
	0.1		
IMDG	(1m) 1 .		
Class	6.1 Toxic substances.		
14.4 Packing group			
ADR, IMDG, IATA	II		
14.5 Environmental hazards:			
Marine pollutant:	No		
14.6 Special precautions for user	Warning: Toxic substances.		
Danger code (Kemler):	60		
14.7 Transport in bulk according to Anne	ex II of		
Marpol and the IBC Code	Not applicable.		
Transport/Additional information:			
ADR			
Limited quantities (LQ)	500 g		
Excepted quantities (\widetilde{EQ})	Code: E4		
	Maximum net quantity per inner packaging: 1 ml		
T	Maximum net quantity per outer packaging: 500 ml		
Transport category Tunnel restriction code	2 D/E		

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Trade name: VITA VM LC OPAQUE PASTE and VM LC GINGIVA OPAQUE PASTE

· IMDG
· Limited quantities (LQ)
· Excepted quantities (EQ)

- Excepted quantities (EQ)

- Maximum net quantity per inner packaging: 1 ml
- Maximum net quantity per outer packaging: 500 ml

- UN "Model Regulation":

- UN 3243 SOLIDS CONTAINING TOXIC LIQUID, N.O.S.
(2-DIMETHYLAMINOETHYL METHACRYLATE), 6.1, II

SECTION 15: Regulatory information

- · 15.1 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.
- · 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	Harmf	ul 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.

H361f Suspected of damaging fertility.

H412 Harmful to aquatic life with long lasting effects.

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.

R62 Possible risk of impaired fertility.

· 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

Repr. 2: Reproductive toxicity, Hazard Category 2

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

Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3

* Data compared to the previous version altered.