

according to UK REACH Regulation

VITA VM LC WINDOW

Revision date: 13.08.2019

Product code: 264

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

1.1. Product identifier

VITA VM LC WINDOW

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

Use of the substance/mixture

Use as laboratory reagent

1.3. Details of the supplier of the safety data sheet

| 1.3. Details of the supplier of the s | 1.3. Details of the supplier of the safety data sheet | | | | |
|---------------------------------------|---|-----------------------------|--|--|--|
| Company name: | VITA Zahnfabrik H.Rauter GmbH & Co.KG | | | | |
| Street: | Spitalgasse 3 | | | | |
| Place: | D-79713 Bad Säckingen | | | | |
| Post-office box: | 1338 | | | | |
| | D-79704 Bad Säckingen | | | | |
| Telephone: | +49(0)7761-562-0 | Telefax: +49(0)7761-562-299 | | | |
| 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 | | | | |
| 1.4. Emergency telephone | +49-(0)761-19240 | | | | |
| | | | | | |

number:

Further Information

medical device

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GB CLP Regulation

Eye Irrit. 2; H319 Skin Sens. 1B; H317 Aquatic Chronic 3; H412

Full text of hazard statements: see SECTION 16.

2.2. Label elements

GB CLP Regulation

Hazard components for labelling

2-hydroxyethyl methacrylate

7,7,9-Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadecan-1,16-diol-dimethacrylat (mixture of isomers) 2-dimethylaminoethyl methacrylate Warning

Signal word:

Pictograms:



Hazard statements

| H317 | May cause an allergic skin reaction. |
|------|--|
| H319 | Causes serious eye irritation. |
| H412 | Harmful to aquatic life with long lasting effects. |



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Precautionary statements

| P261 | Avoid breathing dust/fume/gas/mist/vapours/spray. |
|-----------|---|
| P280 | Wear protective gloves/protective clothing/eye protection/face protection/hearing protection. |
| P362+P364 | Take off contaminated clothing and wash it before reuse. |

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous components

| CAS No | Chemical name | | | Quantity |
|------------|---|-------------------------------------|-------------------------|-------------|
| | EC No | Index No | REACH No | |
| | Classification (GB CLP Regulation) |) | | |
| 72869-86-4 | 7,7,9-Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadecan-1,16-diol-dimethacrylat (mixture of isomers) | | | 30 - < 35 % |
| | 276-957-5 | | 01-2120751202-68 | |
| | Skin Sens. 1B, Aquatic Chronic 3; I | H317 H412 | | |
| 94108-97-1 | Ditrimethylolpropane Tetraacrylate | | 10 - < 15 % | |
| | 302-434-9 | | 01-2119977121-41 | |
| | Eye Irrit. 2, Aquatic Chronic 2; H31 | | | |
| 79-41-4 | Methacrylsäure | | | < 1 % |
| | 201-204-4 | | 01-2119463884-26 | |
| | Acute Tox. 3, Acute Tox. 4, Acute | Гох. 4, Skin Corr. 1A, STOT SE 3; Н | 311 H332 H302 H314 H335 | |
| 2867-47-2 | 2-dimethylaminoethyl methacrylate | | < 1 % | |
| | 220-688-8 | 607-132-00-3 | | |
| | Acute Tox. 4, Acute Tox. 4, Skin Irr | H302 H315 H319 H317 | | |

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

| CAS No | EC No | EC No Chemical name | |
|-----------|---|--|-------|
| | Specific Conc | Limits, M-factors and ATE | |
| 79-41-4 | 201-204-4 | Methacrylsäure | < 1 % |
| | | inhalation: ATE = 11 mg/l (vapours); inhalation: ATE = 1.5 mg/l (dusts or mists); dermal: ATE = 300 mg/kg; oral: ATE = 500 mg/kg | |
| 2867-47-2 | 220-688-8 | 2-dimethylaminoethyl methacrylate | < 1 % |
| | dermal: ATE = 1100 mg/kg; oral: ATE = 500 mg/kg | | |

SECTION 4: First aid measures

4.1. 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. After contact with skin, wash immediately with plenty of water and soap.

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



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ophthalmologist immediately.

After ingestion

Rinse mouth immediately and drink plenty of water.

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

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

5.2. Special hazards arising from the substance or mixture

Non-flammable.

5.3. Advice for firefighters

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.

SECTION 6: Accidental release measures

6.1. 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.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Other information

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

SECTION 7: Handling and storage

7.1. 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.

7.2. Conditions for safe storage, including any incompatibilities



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Requirements for storage rooms and vessels

Keep container tightly closed.

Hints on joint storage

No special measures are necessary.

7.3. Specific end use(s)

Use as laboratory reagent

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

| CAS No | Substance | ppm | mg/m³ | fibres/ml | Category | Origin |
|---------|------------------|-----|-------|-----------|---------------|--------|
| 79-41-4 | Methacrylic acid | 20 | 72 | | TWA (8 h) | WEL |
| | | 40 | 143 | | STEL (15 min) | WEL |

8.2. 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 Dermatril P Breakthrough time: 30 min NBR (Nitrile rubber)

Skin protection

Use of protective clothing.

Respiratory protection

In case of inadequate ventilation wear respiratory protection. Provide adequate ventilation as well as local exhaustion at critical locations. Technical ventilation of workplace

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| Physical state: Colour: Odour: | characteristic |
|--|----------------|
| Changes in the physical state Melting point/freezing point: | not determined |
| Boiling point or initial boiling point and boiling range: | 251 °C |
| Flash point: | > 250 °C |
| Flammability | |



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| Solid/liquid: | not determined | |
| Gas: | not applicable | |
| Explosive properties The product is not: Explosive. | | |
| Lower explosion limits: | not determined | |
| Upper explosion limits: | not determined | |
| Self-ignition temperature | | |
| Solid: | not determined | |
| Gas: | not applicable | |
| 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: (at 50 °C) | <=1100 hPa | |
| Density: | not determined | |
| Relative vapour density: | not determined | |
| 9.2. Other information | | |
| Information with regard to physical hazard classe | S | |
| Oxidizing properties Not oxidising. | | |
| Other safety characteristics | | |
| Solid content: | 98,5 % | |
| Evaporation rate: | not determined | |
| Further Information | | |

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

none

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in GB CLP Regulation



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Acute toxicity

Based on available data, the classification criteria are not met.

| CAS No | Chemical name | | | | | |
|-----------|-------------------------------------|--------------|----------|---------|--------|--------|
| | Exposure route | Dose | | Species | Source | Method |
| 79-41-4 | Methacrylsäure | | | | | |
| | oral | ATE mg/kg | 500 | | | |
| | dermal | ATE mg/kg | 300 | | | |
| | inhalation vapour | ATE | 11 mg/l | | | |
| | inhalation dust/mist | ATE | 1.5 mg/l | | | |
| 2867-47-2 | 2 2-dimethylaminoethyl methacrylate | | | | | |
| | oral | ATE mg/kg | 500 | | | |
| | dermal | ATE mg/kg | 1100 | | | |

Irritation and corrosivity

Causes serious eye irritation.

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Sensitising 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-dimethylaminoethyl methacrylate)

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].

SECTION 12: Ecological information

12.1. Toxicity

Harmful to aquatic life with long lasting effects.

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH. The product has not been tested.



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12.6. 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.

12.7. 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.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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. Waste codes/waste designations according to EWC/AVV

SECTION 14: Transport information

14.1. UN number or ID number: 14.2. UN proper shipping name:

14.3. Transport hazard class(es):

Inland waterways transport (ADN) 14.1. UN number or ID number:

14.2. UN proper shipping name: 14.3. Transport hazard class(es):

14.1. UN number or ID number:

14.2. UN proper shipping name: 14.3. Transport hazard class(es):

14.2. UN proper shipping name: 14.3. Transport hazard class(es):

Land transport (ADR/RID)

14.4. Packing group:

<u>14.4. Packing group:</u> Marine transport (IMDG)

14.4. Packing group: Air transport (ICAO-TI/IATA-DGR) 14.1. UN number or ID number: No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation.

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14.4. Packing group: 14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS:

No

14.6. Special precautions for user

No information available.

14.7. Maritime transport in bulk according to IMO instruments

not applicable

SECTION 15: Regulatory information

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



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EU regulatory information

| Restrictions on use (REACH, annex XVII): Entry 75 | |
|--|--|
| 2010/75/EU (VOC): | 0,173 % |
| 2004/42/EC (VOC): | 0,173 % |
| Information according to 2012/18/EU | Not subject to 2012/18/EU (SEVESO III) |

(SEVESO III): National regulatory information

| Employment restrictions: | Observe restrictions to employment for juveniles according to the 'juvenile |
|--------------------------------|---|
| | work protection guideline' (94/33/EC). |
| Water hazard class (D): | 3 - highly hazardous to water |
| Skin resorption/Sensitization: | Causes allergic hypersensitivity reactions. |

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Changes

This data sheet contains changes from the previous version in section(s): 1,2,4,5,6,7,8,9,11,12,13,14,15,16.

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



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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

Classification for mixtures and used evaluation method according to GB CLP Regulation

| Classification | Classification procedure |
|-------------------------|--------------------------|
| Eye Irrit. 2; H319 | Calculation method |
| Skin Sens. 1B; H317 | Calculation method |
| Aquatic Chronic 3; H412 | Calculation method |

Relevant H and EUH statements (number and full text)

| H302 | Harmful if swallowed. |
|------|--|
| H311 | Toxic in contact with skin. |
| H312 | Harmful in contact with skin. |
| H314 | Causes severe skin burns and eye damage. |
| H315 | Causes skin irritation. |
| H317 | May cause an allergic skin reaction. |
| H319 | Causes serious eye irritation. |
| H332 | Harmful if inhaled. |
| H335 | May cause respiratory irritation. |
| H411 | Toxic to aquatic life with long lasting effects. |
| H412 | Harmful to aquatic life with long lasting effects. |
| | |

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.)