

Safety Data Sheet

according to UK REACH Regulation

VITA VM LC OPAQUE

Revision date: 15.08.2023

Product code: 148

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

1.1. Product identifier

VITA VM LC OPAQUE

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

| | | |
|-------------------------|---------------------------------------|-----------------------------|
| 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 | |

Further Information

medical device

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GB CLP Regulation

This mixture is not classified as hazardous in accordance with GB CLP Regulation.

2.2. Label elements

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Substance, organic Product/Substance is inorganic. Mixtures

Hazardous components

| CAS No | Chemical name | | | Quantity |
|------------|------------------------------------|----------|------------------|-------------|
| | EC No | Index No | REACH No | |
| | Classification (GB CLP Regulation) | | | |
| 13463-67-7 | Titanium dioxide | | | 20 - < 25 % |
| | 236-675-5 | | 01-2119489379-17 | |
| | Carc. 2; H351 | | | |

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

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Specific Conc. Limits, M-factors and ATE

| CAS No | EC No | Chemical name | Quantity |
|------------|-----------|--|-------------|
| | | Specific Conc. Limits, M-factors and ATE | |
| 13463-67-7 | 236-675-5 | Titanium dioxide | 20 - < 25 % |
| | | oral: LD50 = > 2000 mg/kg | |

SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

Provide fresh air.

After contact with skin

Wash with plenty of water. Take off contaminated clothing and wash it before reuse.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.

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

In case of fire: Wear self-contained breathing apparatus.

Additional information

Use water spray jet to protect personnel and to cool endangered containers. 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

Avoid dust formation. Do not breathe dust.

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

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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

Take off contaminated clothing. Wash hands before breaks and after work. When using do not eat, drink, smoke, sniff.

7.2. Conditions for safe storage, including any incompatibilities

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/m ³ | fibres/ml | Category | Origin |
|------------|-----------------------------------|-----|-------------------|-----------|-----------|--------|
| 13463-67-7 | Titanium dioxide, total inhalable | - | 10 | | TWA (8 h) | WEL |

DNEL/DMEL values

| CAS No | Substance | Exposure route | Effect | Value |
|--------------------------|------------------|----------------|----------|------------------------|
| 13463-67-7 | Titanium dioxide | | | |
| Worker DNEL, long-term | | inhalation | local | 1.25 mg/m ³ |
| Consumer DNEL, long-term | | oral | systemic | 700 mg/kg bw/day |

PNEC values

| CAS No | Substance | Value |
|--|------------------|------------|
| 13463-67-7 | Titanium dioxide | |
| Environmental compartment | | |
| Freshwater | | 0.184 mg/l |
| Freshwater (intermittent releases) | | 0.193 mg/l |
| Marine water | | 0.018 mg/l |
| Freshwater sediment | | 1000 mg/kg |
| Marine sediment | | 100 mg/kg |
| Micro-organisms in sewage treatment plants (STP) | | 100 mg/l |
| Soil | | 100 mg/kg |

8.2. Exposure controls

Individual protection measures, such as personal protective equipment

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Eye/face protection

Wear eye/face protection.

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 KCL Dermatril P NBR (Nitrile rubber)

Skin protection

Use of protective clothing.

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: | solid | |
| Colour: | | |
| Odour: | characteristic | |
| Melting point/freezing point: | | not determined |
| Boiling point or initial boiling point and boiling range: | | 2501 °C |
| Flammability: | | not determined not applicable |
| Lower explosion limits: | | not determined |
| Upper explosion limits: | | not determined |
| Flash point: | | > 250 °C |
| 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: | | not determined |
| Density: | | not determined |
| Relative vapour density: | | not determined |

9.2. Other information

Information with regard to physical hazard classes

Explosive properties

The product is not: Explosive.

Self-ignition temperature

Solid:

not determined

Gas:

not applicable

Oxidizing properties

Not oxidising.

Other safety characteristics

Evaporation rate:

not determined

Solid content:

100

SECTION 10: Stability and reactivity

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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

Acute toxicity

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

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

| CAS No | Chemical name | | | | |
|------------|------------------|-------------------|---------|---------------------|----------|
| | Exposure route | Dose | Species | Source | Method |
| 13463-67-7 | Titanium dioxide | | | | |
| | oral | LD50 > 2000 mg/kg | Rat | Study report (1996) | OECD 401 |

Irritation and corrosivity

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

Sensitising effects

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

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 not hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 12: Ecological information

12.1. Toxicity

The product is not: Ecotoxic.

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| CAS No | Chemical name | | | | | |
|------------|--------------------------|-------------------|-----------|--|---|---|
| | Aquatic toxicity | Dose | [h] [d] | Species | Source | Method |
| 13463-67-7 | Titanium dioxide | | | | | |
| | Acute fish toxicity | LC50 >100 mg/l | 96 h | Carassius | REACH Registration Dossier | OECD Guideline 203 |
| | Acute algae toxicity | ErC50 >50 mg/l | 72 h | Raphidocelis subcapitata | REACH Registration Dossier | OECD Guideline 201 |
| | Acute crustacea toxicity | EC50 >100 mg/l | 48 h | Artemia salina | REACH Registration Dossier | OECD Guideline 202 |
| | Fish toxicity | NOEC >=80 mg/l | 6 d | Danio rerio | REACH Registration Dossier | OECD TG 210 |
| | Algae toxicity | NOEC >=1 mg/l | 32 d | Synedra ulna, Scenedesmus quadricauda, Stigeocloni | Environ. Tox. Chem. 31,2414-2422 (2012) | In this study, the authors report there |
| | Crustacea toxicity | NOEC >1 mg/l | 10 d | Chironomus riparius | REACH Registration Dossier | other: OECD Guideline 219 |
| | Acute bacteria toxicity | (EC50 >1000 mg/l) | 3 h | activated sludge, domestic | REACH Registration Dossier | OECD Guideline 209 |

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

BCF

| CAS No | Chemical name | BCF | Species | Source |
|------------|------------------|-------------|----------------|----------------------|
| 13463-67-7 | Titanium dioxide | >0.47-<3.19 | Artemia salina | REACH Registration D |

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.

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

Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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Disposal recommendations

Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation.

Contaminated packaging

Wash with plenty of water. Completely emptied packages can be recycled.

SECTION 14: Transport information

Land transport (ADR/RID)

| | |
|--|--|
| 14.1. UN number or ID number: | No dangerous good in sense of this transport regulation. |
| 14.2. UN proper shipping name: | No dangerous good in sense of this transport regulation. |
| 14.3. Transport hazard class(es): | No dangerous good in sense of this transport regulation. |
| 14.4. Packing group: | No dangerous good in sense of this transport regulation. |

Inland waterways transport (ADN)

| | |
|--|--|
| 14.1. UN number or ID number: | No dangerous good in sense of this transport regulation. |
| 14.2. UN proper shipping name: | No dangerous good in sense of this transport regulation. |
| 14.3. Transport hazard class(es): | No dangerous good in sense of this transport regulation. |
| 14.4. Packing group: | No dangerous good in sense of this transport regulation. |

Marine transport (IMDG)

| | |
|--|--|
| 14.1. UN number or ID number: | No dangerous good in sense of this transport regulation. |
| 14.2. UN proper shipping name: | No dangerous good in sense of this transport regulation. |
| 14.3. Transport hazard class(es): | No dangerous good in sense of this transport regulation. |
| 14.4. Packing group: | No dangerous good in sense of this transport regulation. |

Air transport (ICAO-TI/IATA-DGR)

| | |
|--|--|
| 14.1. UN number or ID number: | No dangerous good in sense of this transport regulation. |
| 14.2. UN proper shipping name: | No dangerous good in sense of this transport regulation. |
| 14.3. Transport hazard class(es): | No dangerous good in sense of this transport regulation. |
| 14.4. Packing group: | No dangerous good in sense of this transport regulation. |

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

EU regulatory information

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

National regulatory information

Water hazard class (D): 1 - slightly hazardous to water

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.

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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

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

SVHC: Substance of Very High Concern

For abbreviations and acronyms, see table at <http://abbrev.esdscom.eu>

Carc: Carcinogenicity

Relevant H and EUH statements (number and full text)

H351 Suspected of causing cancer.

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.)