

according to UK REACH Regulation

VITA TITANKERAMIK

Revision date: 15.08.2023

Product code: 101

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

1.1. Product identifier

VITA TITANKERAMIK

CAS No: EC No: 66402-68-4 266-340-9

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

| VITA Zahnfabrik H.Rauter GmbH & Co.KG | |
|---------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Spitalgasse 3 | |
| D-79713 Bad Säckingen | |
| 1338 | |
| D-79704 Bad Säckingen | |
| +49(0)7761-562-0 | Telefax: +49(0)7761-562-299 |
| info@vita-zahnfabrik.com | |
| regulatory affairs | |
| info@vita-zahnfabrik.com | |
| www.vita-zahnfabrik.com | |
| Regulatory Affairs | |
| | Spitalgasse 3 D-79713 Bad Säckingen 1338 D-79704 Bad Säckingen +49(0)7761-562-0 info@vita-zahnfabrik.com regulatory affairs info@vita-zahnfabrik.com www.vita-zahnfabrik.com |

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 Ceramic

Hazardous components

none (according to UK REACH Regulation)

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.



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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

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

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.



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Hints on joint storage

No special measures are necessary.

7.3. Specific end use(s)

medical device

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls

Individual protection measures, such as personal protective equipment

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. NBR (Nitrile rubber) Recommended glove articles KCL Dermatril P

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: | Powder | |
|--------------------------------------------|-----------|-----------------------|
| Colour: | | |
| Odour: | odourless | |
| Melting point/freezing point: | | not determined |
| Boiling point or initial boiling point and | | not determined |
| boiling range: | | |
| Flammability: | | not determined |
| | | not applicable |
| Lower explosion limits: | | not determined |
| Upper explosion limits: | | not determined |
| Flash point: | | 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: | | <=1100 hPa |
| (at 50 °C) | | |
| Density: | | 2,4 g/cm ³ |
| Relative vapour density: | | not determined |
| 2. Other information | | |

9.2. Other information

Information with regard to physical hazard classes

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| not determined not applicable | | | | |
| | | | | |
| not determined 100,0 % | | | | |
| | Product code: 101 not determined not applicable not determined | | | |

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

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

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].



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SECTION 12: Ecological information

12.1. Toxicity

The product is not: Ecotoxic.

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.

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

Disposal recommendations

Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation. Waste codes/waste designations according to EWC/AVV

Contaminated packaging

Wash with plenty of water. Completely emptied packages can be recycled. Waste codes/waste designations according to EWC/AVV

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number or ID number:14.2. UN proper shipping name:14.3. Transport hazard class(es):14.4. Packing group:Inland waterways transport (ADN)14.1. UN number or ID number:14.2. UN proper shipping name:

14.3. Transport hazard class(es): 14.4. Packing group:

Marine transport (IMDG)

14.1. UN number or ID number:

14.2. UN proper shipping name:

14.3. Transport hazard class(es):

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.

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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| 14.2. 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 not applicable | to IMO instruments | | | |
| SECTION 15: Regulatory information | | | | |
| 15.1. Safety, health and environmental reg | ulations/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 sub | ostances 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 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.)