

Safety Data Sheet

according to UK REACH Regulation

VITAFOL H Hardener

Revision date: 10.07.2023

Product code: 059

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

1.1. Product identifier

VITAFOL H Hardener

UFI: 1F00-Q072-G00Q-4PKC

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 | |

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GB CLP Regulation

Flam. Liq. 3; H226
 Acute Tox. 4; H332
 Eye Irrit. 2; H319
 Repr. 2; H361d
 STOT SE 3; H335
 STOT RE 1; H372

Full text of hazard statements: see SECTION 16.

2.2. Label elements

GB CLP Regulation

Hazard components for labelling

ethyl silicate, tetraethyl silicate
 tetraethyl silicate; ethyl silicate
 Silicic acid (H₄SiO₄), tetraethyl ester, reaction products with bis(acetyloxy)dioctylstannane

Signal word: Danger

Pictograms:



Hazard statements

| | |
|------|-----------------------------------|
| H226 | Flammable liquid and vapour. |
| H319 | Causes serious eye irritation. |
| H332 | Harmful if inhaled. |
| H335 | May cause respiratory irritation. |

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H361d Suspected of damaging the unborn child.
 H372 Causes damage to organs through prolonged or repeated exposure.

Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
 P260 Do not breathe dust/fume/gas/mist/vapours/spray.
 P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
 P337+P313 If eye irritation persists: Get medical advice/attention.

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) | | | |
| 78-10-4 | ethyl silicate, tetraethyl silicate | | | 80 - < 85 % |
| | 201-083-8 | 014-005-00-0 | 01-2119496195-28 | |
| | Flam. Liq. 3, Acute Tox. 4, Eye Irrit. 2, STOT SE 3; H226 H332 H319 H335 | | | |
| 93925-43-0 | Silicic acid (H ₄ SiO ₄), tetraethyl ester, reaction products with bis(acetyloxy)dioctylstannane | | | 10 - < 15 % |
| | 300-346-5 | | | |
| | Flam. Liq. 3, Repr. 2, Acute Tox. 4, Eye Irrit. 2, STOT RE 1, Aquatic Chronic 4; H226 H361d H302 H319 H372 H413 | | | |
| 68299-15-0 | Bis(neodecanoyloxy)dioctylstannane | | | 1 - < 5 % |
| | 269-595-4 | | | |
| | STOT RE 2, Aquatic Chronic 4; H373 H413 | | | |

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

Specific Conc. Limits, M-factors and ATE

| CAS No | EC No | Chemical name | Quantity |
|------------|-----------|---|-------------|
| | | Specific Conc. Limits, M-factors and ATE | |
| 78-10-4 | 201-083-8 | ethyl silicate, tetraethyl silicate | 80 - < 85 % |
| | | inhalation: ATE = 11 mg/l (vapours); inhalation: ATE = 1.5 mg/l (dusts or mists); dermal: LD50 = 5860 mg/kg | |
| 93925-43-0 | 300-346-5 | Silicic acid (H ₄ SiO ₄), tetraethyl ester, reaction products with bis(acetyloxy)dioctylstannane | 10 - < 15 % |
| | | oral: ATE = 500 mg/kg | |

SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

Provide fresh air. Medical treatment necessary.

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 ophthalmologist immediately.

After ingestion

Rinse mouth immediately and drink plenty of water. Induce vomiting when the affected person is not

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unconscious. Medical treatment necessary.

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

Carbon dioxide (CO₂), Foam, Extinguishing powder.

Unsuitable extinguishing media

Water.

5.2. Special hazards arising from the substance or mixture

Flammable. Vapours can form explosive mixtures with air.

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. 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

Remove all sources of ignition. 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 uncontrolled discharge of product into the environment. Danger of explosion

6.3. Methods and material for containment and cleaning up

Other information

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). 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

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Advice on protection against fire and explosion

Keep away from sources of ignition - No smoking. Take precautionary measures against static discharges. Vapours can form explosive mixtures with air.

Advice on general occupational hygiene

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme. Wash

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hands and face before breaks and after work and take a shower if necessary. When using do not eat or drink.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaust at critical locations. Keep in a cool, well-ventilated place. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Hints on joint storage

Do not store together with: Oxidising agent. Pyrophoric or self-heating substances.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

| CAS No | Substance | ppm | mg/m ³ | fibres/ml | Category | Origin |
|---------|--------------------------|-----|-------------------|-----------|-----------|--------|
| 78-10-4 | Tetraethyl orthosilicate | 5 | 44 | | TWA (8 h) | WEL |

8.2. Exposure controls



Appropriate engineering controls

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

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 KCK Dermatrill P NBR (Nitrile rubber) Breakthrough time: 30 min

Skin protection

Wear suitable protective clothing.

Respiratory protection

Technical ventilation of workplace Provide adequate ventilation as well as local exhaust at critical locations.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|---|----------------|
| Physical state: | Liquid |
| Colour: | light red |
| Odour: | characteristic |
| Melting point/freezing point: | not determined |
| Boiling point or initial boiling point and boiling range: | 166 °C |

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| | |
|--|----------------|
| Flammability: | not applicable |
| Lower explosion limits: | not applicable |
| Upper explosion limits: | not determined |
| Flash point: | 37 °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: | <=1100 hPa |
| (at 50 °C) | |
| Density: | not determined |
| Relative vapour density: | not determined |

9.2. Other information

Information with regard to physical hazard classes

Self-ignition temperature

Solid:

not applicable

Gas:

not applicable

Oxidizing properties

Not oxidising.

Other safety characteristics

Evaporation rate:

not determined

Solid content:

0,0 %

SECTION 10: Stability and reactivity

10.1. Reactivity

Flammable.

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

Keep away from sources of heat (e.g. hot surfaces), sparks and open flames. Vapours can form explosive mixtures with air.

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

Harmful if inhaled.

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) 0.0000 mg/l; ATE (inhalation dust/mist) 1786.00000 mg/l

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| CAS No | Chemical name | | | | |
|------------|---|---------------|----------|--------|--------|
| | Exposure route | Dose | Species | Source | Method |
| 78-10-4 | ethyl silicate, tetraethyl silicate | | | | |
| | dermal | LD50 mg/kg | 5860 | | |
| | inhalation vapour | ATE | 11 mg/l | | |
| | inhalation dust/mist | ATE | 1.5 mg/l | | |
| 93925-43-0 | Silicic acid (H4SiO4), tetraethyl ester, reaction products with bis(acetyloxy)dioctylstannane | | | | |
| | oral | ATE mg/kg | 500 | | |

Irritation and corrosivity

Causes serious eye irritation.

Skin corrosion/irritation: 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

Suspected of damaging the unborn child. (Silicic acid (H4SiO4), tetraethyl ester, reaction products with bis(acetyloxy)dioctylstannane)

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

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

STOT-single exposure

May cause respiratory irritation. (ethyl silicate, tetraethyl silicate)

STOT-repeated exposure

Causes damage to organs through prolonged or repeated exposure. (Silicic acid (H4SiO4), tetraethyl ester, reaction products with bis(acetyloxy)dioctylstannane)

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

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.

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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

This material and its container must be disposed of as hazardous waste. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

| | |
|--|---------------------|
| 14.1. UN number or ID number: | UN 1292 |
| 14.2. UN proper shipping name: | TETRAETHYL SILICATE |
| 14.3. Transport hazard class(es): | 3 |
| 14.4. Packing group: | III |
| Hazard label: | 3 |



| | |
|--------------------------|-----|
| Classification code: | F1 |
| Limited quantity: | 5 L |
| Excepted quantity: | E1 |
| Transport category: | 3 |
| Hazard No: | 30 |
| Tunnel restriction code: | D/E |

Inland waterways transport (ADN)

| | |
|--|---------------------|
| 14.1. UN number or ID number: | UN 1292 |
| 14.2. UN proper shipping name: | TETRAETHYL SILICATE |
| 14.3. Transport hazard class(es): | 3 |
| 14.4. Packing group: | III |
| Hazard label: | 3 |



| | |
|----------------------|-----|
| Classification code: | F1 |
| Limited quantity: | 5 L |
| Excepted quantity: | E1 |

Marine transport (IMDG)

| | |
|--|---------------------|
| 14.1. UN number or ID number: | UN 1292 |
| 14.2. UN proper shipping name: | TETRAETHYL SILICATE |
| 14.3. Transport hazard class(es): | 3 |
| 14.4. Packing group: | III |
| Hazard label: | 3 |

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Special Provisions: -
 Limited quantity: 5 L
 Excepted quantity: E1
 EmS: F-E, S-D

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number: UN 1292
14.2. UN proper shipping name: TETRAETHYL SILICATE
14.3. Transport hazard class(es): 3
14.4. Packing group: III
 Hazard label: 3



Limited quantity Passenger: 10 L
 Passenger LQ: Y344
 Excepted quantity: E1
 IATA-packing instructions - Passenger: 355
 IATA-max. quantity - Passenger: 60 L
 IATA-packing instructions - Cargo: 366
 IATA-max. quantity - Cargo: 220 L

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

Warning: Combustible liquid.

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

Restrictions on use (REACH, annex XVII):
 Entry 3, Entry 40

National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

Water hazard class (D): 2 - obviously 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%
Flam. Liq: Flammable liquids
Acute Tox: Acute toxicity
Eye Irrit: Eye irritation
Repr: Reproductive toxicity
STOT SE: Specific target organ toxicity - single exposure
STOT RE: Specific target organ toxicity - repeated exposure
Aquatic Chronic: Chronic aquatic hazard

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

| Classification | Classification procedure |
|--------------------|--------------------------|
| Flam. Liq. 3; H226 | On basis of test data |
| Acute Tox. 4; H332 | Calculation method |
| Eye Irrit. 2; H319 | Calculation method |
| Repr. 2; H361d | Calculation method |
| STOT SE 3; H335 | Calculation method |
| STOT RE 1; H372 | Calculation method |

Relevant H and EUH statements (number and full text)

H226 Flammable liquid and vapour.
H302 Harmful if swallowed.
H319 Causes serious eye irritation.
H332 Harmful if inhaled.
H335 May cause respiratory irritation.
H361d Suspected of damaging the unborn child.
H372 Causes damage to organs through prolonged or repeated exposure.
H373 May cause damage to organs through prolonged or repeated exposure.
H413 May cause long lasting harmful effects to aquatic life.

Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)

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

1.1. Product identifier

VITAFOL H Paste

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 | |

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

GB CLP Regulation

Special labelling of certain mixtures

EUH210 Safety data sheet available on request.

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Paste, Substance, organic, Film former

Mixture of polymers/elastomers without hazards for human health or environment

Hazardous components

| CAS No | Chemical name | | | Quantity |
|------------|------------------------------------|----------|----------|----------|
| | EC No | Index No | REACH No | |
| | Classification (GB CLP Regulation) | | | |
| 14464-46-1 | Cristobalite | | | < 0.1 % |
| | 238-455-4 | | | |
| | STOT RE 1; H372 | | | |

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

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SECTION 4: First aid measures

4.1. Description of first aid measures

General information

When in doubt or if symptoms are observed, get medical advice.

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

Observe risk of aspiration if vomiting occurs. 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

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

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). 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

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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

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. Recommended glove articles KCL Butoject Butyl caoutchouc (butyl rubber)
Breakthrough time: 60 min

Skin protection

Use of protective clothing. Wear suitable protective clothing.

Respiratory protection

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

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|-----------------|----------------|
| Physical state: | Liquid |
| Colour: | light grey |
| Odour: | characteristic |

| | Test method |
|---|----------------|
| Melting point/freezing point: | not determined |
| Boiling point or initial boiling point and boiling range: | not determined |
| Flammability: | not applicable |
| | not applicable |
| Flash point: | 250 °C |

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| | |
|--|------------------------|
| Auto-ignition temperature: | >450 °C |
| Decomposition temperature: | > 200 °C |
| pH-Value: | not determined |
| Water solubility: | No OECD 116 |
| Solubility in other solvents not determined | |
| Partition coefficient n-octanol/water: | not determined |
| Vapour pressure: (at 50 °C) | not determined |
| Vapour pressure: | not determined |
| Density (at 23 °C): | 1,25 g/cm ³ |
| Bulk 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 applicable

Gas:

not applicable

Oxidizing properties

Not oxidising.

Other safety characteristics

Evaporation rate:

not determined

Sublimation point:

not determined

Softening point:

not determined

Pour point:

not determined

Viscosity / dynamic:

25000 mPa·s

(at 23 °C)

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

The product is stable under storage at normal ambient temperatures. Decomposition takes place from temperatures above: 150 °C May form hazardous decomposition products when exposed to high temperatures.

Formaldehyde

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.

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].

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.

Contaminated packaging

Packing which cannot be properly cleaned must be disposed of. Handle contaminated packages in the same way as the substance itself.

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SECTION 14: Transport information

Land transport (ADR/RID)

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

Inland waterways transport (ADN)

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

Marine transport (IMDG)

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

Air transport (ICAO-TI/IATA-DGR)

| | |
|---|--|
| <u>14.1. UN number or ID number:</u> | No dangerous good in sense of this transport regulation. |
| <u>14.2. UN proper shipping name:</u> | No dangerous good in sense of this transport regulation. |
| <u>14.3. Transport hazard class(es):</u> | No dangerous good in sense of this transport regulation. |
| <u>14.4. Packing group:</u> | 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>
STOT RE: Specific target organ toxicity - repeated exposure

Relevant H and EUH statements (number and full text)

H372 Causes damage to organs through prolonged or repeated exposure.
EUH210 Safety data sheet available on request.

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.)

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

1.1. Product identifier

VITAFOL H Retention crystals

Further trade names

VITAFOL H Haftkristalle, Retention Crystals, Cristaux rétentifs, Cristales adhesivos, Cristalli ritentivi

CAS No: 7631-86-9

EC No: 231-545-4

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

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GB CLP Regulation

This substance 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

3.1. Substances

Chemical characterization

Product/Substance is inorganic.

Hazardous components

none (according to UK REACH Regulation)

SECTION 4: First aid measures

4.1. Description of first aid measures

After contact with eyes

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

After ingestion

Rinse mouth immediately and drink plenty of water.

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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.

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

No special environmental measures are necessary. Clean contaminated articles and floor according to the environmental legislation.

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 or drink.

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.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls

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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.

Skin protection

Wear suitable 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: | translucent | |
| Odour: | odourless | |
| Melting point/freezing point: | | not determined |
| Boiling point or initial boiling point and boiling range: | | > 999 °C |
| Flammability: | | not determined not applicable |
| Lower explosion limits: | | not determined |
| Upper explosion limits: | | not determined |
| Flash point: | | X |
| 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: | | 2,20000 g/cm ³ |
| Relative vapour density: | | not determined |

9.2. Other information

Information with regard to physical hazard classes

Self-ignition temperature

Solid: not determined

Gas: not applicable

Oxidizing properties

Not oxidising.

Other safety characteristics

Evaporation rate: not determined

Solid content: 100,0 %

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.

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 substance 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.

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

This substance does not meet the PBT/vPvB criteria of UK REACH.

The product has not been tested.

12.6. Endocrine disrupting properties

This substance does not have endocrine disrupting properties with respect to non-target organisms.

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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

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

National regulatory information

Water hazard class (D): - - non-hazardous to water

15.2. Chemical safety assessment

For this substance a chemical safety assessment has not been carried out.

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SECTION 16: Other information

Changes

This data sheet contains changes from the previous version in section(s): 1.

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%

Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.