

Safety Data Sheet

according to UK REACH Regulation

VITA ZETA HLC BOND

Revision date: 17.01.2023

Product code: 048

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

1.1. Product identifier

VITA ZETA HLC BOND

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

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

Hazard Statements:

Very toxic to aquatic life with long lasting effects.

2.2. Label elements

GB CLP Regulation

Signal word:

Warning

Pictograms:



Hazard statements

H410

Very toxic to aquatic life with long lasting effects.

Precautionary statements

P273

Avoid release to the environment.

P391

Collect spillage.

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

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Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
13463-67-7	Titanium dioxide			55 - < 60 %
	236-675-5		01-2119489379-17	
	Carc. 2; H351			

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		
13463-67-7	236-675-5	Titanium dioxide	55 - < 60 %
	oral: LD50 = > 2000 mg/kg		

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.

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.

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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.

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	
	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

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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 NBR (Nitrile rubber) KCL Dermatrill P

Skin protection

Wear suitable protective clothing.

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: solid
 Colour:
 Odour: characteristic

Changes in the physical state

Melting point/freezing point: not determined
 Boiling point or initial boiling point and boiling range: ?
 Flash point: not applicable

Flammability

Solid/liquid: not determined
 Gas: not applicable
 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: not determined
 Density: not determined

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Relative vapour density: not determined

9.2. Other information

Information with regard to physical hazard classes

Oxidizing properties
Not oxidising.

Other safety characteristics

Solid content: 100,0 %
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

Acute toxicity

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

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.

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Aspiration hazard

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

SECTION 12: Ecological information

12.1. Toxicity

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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	Artemina 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.

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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

Non-contaminated packages may be recycled. 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 3077

14.2. UN proper shipping name:

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide)

14.3. Transport hazard class(es):

9

14.4. Packing group:

III

Hazard label:



Classification code:

M7

Special Provisions:

274 335 375 601

Limited quantity:

5 kg

Excepted quantity:

E1

Transport category:

3

Hazard No:

90

Tunnel restriction code:

E

Inland waterways transport (ADN)

14.1. UN number or ID number:

UN 3077

14.2. UN proper shipping name:

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide)

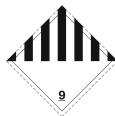
14.3. Transport hazard class(es):

9

14.4. Packing group:

III

Hazard label:



Classification code:

M7

Special Provisions:

274 335 375 601

Limited quantity:

5 kg

Excepted quantity:

E1

Marine transport (IMDG)

14.1. UN number or ID number:

UN 3077

14.2. UN proper shipping name:

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide)

14.3. Transport hazard class(es):

9

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14.4. Packing group:

Hazard label:

III

9



Special Provisions:

274, 335, 966, 967, 969

Limited quantity:

5 kg

Excepted quantity:

E1

EmS:

F-A, S-F

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number:

UN 3077

14.2. UN proper shipping name:

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide)

14.3. Transport hazard class(es):

9

14.4. Packing group:

III

Hazard label:

9



Special Provisions:

A97 A158 A179 A197

Limited quantity Passenger:

30 kg G

Passenger LQ:

Y956

Excepted quantity:

E1

IATA-packing instructions - Passenger:

956

IATA-max. quantity - Passenger:

400 kg

IATA-packing instructions - Cargo:

956

IATA-max. quantity - Cargo:

400 kg

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS:

Yes



Danger releasing substance:

zinc oxide

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

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

15.2. Chemical safety assessment

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

SECTION 16: Other information

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Changes

This data sheet contains changes from the previous version in section(s): 14.

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%

Relevant H and EUH statements (number and full text)

H351 Suspected of causing cancer.

H410 Very toxic to aquatic life with long lasting effects.

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.)