

Safety Data Sheet

according to UK REACH Regulation

VITA NP BOND PASTE

Revision date: 15.08.2023

Product code: 291

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

1.1. Product identifier

VITA NP BOND 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	

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

GB CLP Regulation

Special labelling of certain mixtures

EUH208	Contains reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction.
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

Mixtures Product/Substance is inorganic. Substance, organic

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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			20 - < 25 %
	236-675-5		01-2119489379-17	
	Carc. 2; H351			
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)			< 0.1 %
	-	613-167-00-5		
	Acute Tox. 2, Acute Tox. 2, Acute Tox. 3, Skin Corr. 1C, Eye Dam. 1, Skin Sens. 1A, Aquatic Acute 1, Aquatic Chronic 1; H330 H310 H301 H314 H318 H317 H400 H410 EUH071			

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	20 - < 25 %
	oral: LD50 = > 2000 mg/kg		
55965-84-9	-	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	< 0.1 %
	inhalation: ATE = 0.5 mg/l (vapours); inhalation: ATE = 0.05 mg/l (dusts or mists); dermal: ATE = 50 mg/kg; oral: ATE = 100 mg/kg Skin Corr. 1C; H314: >= 0.6 - 100 Skin Irrit. 2; H315: >= 0.06 - < 0.6 Eye Dam. 1; H318: >= 0.6 - 100 Eye Irrit. 2; H319: >= 0.06 - < 0.6 Skin Sens. 1A; H317: >= 0.0015 - 100 Aquatic Acute 1; H400: M=100 Aquatic Chronic 1; H410: M=100		

SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

Provide fresh air. If breathing is irregular or stopped, administer artificial respiration. Medical treatment necessary.

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. If skin irritation occurs: Get medical advice/attention.

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.

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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

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

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
56-81-5	Glycerol, mist	-	10		TWA (8 h)	WEL
13463-67-7	Titanium dioxide, total inhalable	-	10		TWA (8 h)	WEL

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DNEL/DMEL values

CAS No	Substance		
DNEL type	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	
Environmental compartment	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	

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 Dermatril P NBR (Nitrile rubber)

Skin protection

Use of protective clothing.

Respiratory protection

In case of inadequate ventilation wear respiratory protection. Open windows to ensure natural ventilation.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:

Colour: yellow

Odour: odourless

Melting point/freezing point: not determined

Boiling point or initial boiling point and boiling range: ?

Flammability:

not applicable

not applicable

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Lower explosion limits:	not determined
Upper explosion limits:	not determined
Flash point:	?
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

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

Solid content:

66,6 %

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

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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
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)				
	oral	ATE 100 mg/kg			
	dermal	ATE 50 mg/kg			
	inhalation vapour	ATE 0.5 mg/l			
	inhalation dust/mist	ATE 0.05 mg/l			

Irritation and corrosivity

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

Sensitising effects

Contains reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction.

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

Restrictions on use (REACH, annex XVII):

Entry 75

2004/42/EC (VOC):	0,015 %
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
Skin resorption/Sensitization:	Causes allergic hypersensitivity reactions.

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not 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%
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
VOC: Volatile Organic Compounds
SVHC: Substance of Very High Concern
For abbreviations and acronyms, see table at <http://abbrev.esdscom.eu>
Acute Tox: Acute toxicity
Skin Corr: Skin corrosion
Eye Dam: Eye damage
Skin Sens: Skin sensitisation
Carc: Carcinogenicity
Aquatic Acute: Acute aquatic hazard
Aquatic Chronic: Chronic aquatic hazard

Relevant H and EUH statements (number and full text)

H301 Toxic if swallowed.

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H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
H351	Suspected of causing cancer.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
EUH071	Corrosive to the respiratory tract.
EUH208	Contains reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction.
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.)