

## Safety Data Sheet

according to UK REACH Regulation

### VITACOLL

Revision date: 10.07.2023

Product code: 040

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

### 1.1. Product identifier

VITACOLL

### 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

Flam. Liq. 2; H225  
Skin Irrit. 2; H315  
Eye Irrit. 2; H319  
Skin Sens. 1; H317  
STOT SE 3; H335  
STOT SE 3; H336

Full text of hazard statements: see SECTION 16.

### 2.2. Label elements

#### GB CLP Regulation

#### Hazard components for labelling

methyl methacrylate  
butanone; ethyl methyl ketone

**Signal word:** Danger**Pictograms:**

#### Hazard statements

H225	Highly flammable liquid and vapour.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.

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H335 May cause respiratory irritation.  
 H336 May cause drowsiness or dizziness.

#### Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
 P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
 P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.  
 P403+P235 Store in a well-ventilated place. Keep cool.  
 P405 Store locked up.

#### 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)			
78-93-3	butanone; ethyl methyl ketone			45 - < 50 %
	201-159-0	606-002-00-3	01-2119457290-43	
	Flam. Liq. 2, Eye Irrit. 2, STOT SE 3; H225 H319 H336 EUH066			
80-62-6	methyl methacrylate			45 - < 50 %
	201-297-1	607-035-00-6	01-2119452498-28	
	Flam. Liq. 2, Skin Irrit. 2, Skin Sens. 1, STOT SE 3; H225 H315 H317 H335			

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		
78-93-3	201-159-0	butanone; ethyl methyl ketone	45 - < 50 %
	dermal: LD50 = 5000 mg/kg		
80-62-6	201-297-1	methyl methacrylate	45 - < 50 %
	dermal: LD50 = > 5000 mg/kg		

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

##### After inhalation

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

##### 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. Medical treatment necessary. After contact with skin, wash immediately with plenty of water and soap.

##### 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.

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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**

Carbon dioxide (CO<sub>2</sub>), Foam, Extinguishing powder.

##### **Unsuitable extinguishing media**

Water.

#### **5.2. Special hazards arising from the substance or mixture**

Highly flammable. Vapours can form explosive mixtures with air.

#### **5.3. Advice for firefighters**

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

#### **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. Provide adequate ventilation. 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. Explosion risk.

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

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smoke, sniff.

#### 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: Oxidizing agent. Pyrophoric or self-heating substances.

#### 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 <sup>3</sup>	fibres/ml	Category	Origin
78-93-3	Butan-2-one (methyl ethyl ketone)	200	600		TWA (8 h)	WEL
		300	899		STEL (15 min)	WEL
80-62-6	Methyl methacrylate	50	208		TWA (8 h)	WEL
		100	416		STEL (15 min)	WEL

##### Biological Monitoring Guidance Values (EH40)

CAS No	Substance	Parameter	Value	Test material	Sampling time
78-93-3	Butan-2-one	butan-2-one	70 µmol/L	urine	Post shift

#### 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

. 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

Wear suitable protective clothing.

##### Respiratory protection

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

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## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state:	Liquid	
Colour:	colourless	
Odour:	characteristic	
Melting point/freezing point:		not determined
Boiling point or initial boiling point and boiling range:		79 °C
Flammability:		not applicable
		not applicable
Lower explosion limits:		1,8 vol. %
Upper explosion limits:		12,5 vol. %
Flash point:		< 12 °C
Auto-ignition temperature:		430 °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:		0,87200 g/cm <sup>3</sup>
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:

0,0 %

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Highly 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.

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#### 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
78-93-3	butanone; ethyl methyl ketone				
	dermal	LD50 mg/kg	5000		
80-62-6	methyl methacrylate				
	dermal	LD50 mg/kg	> 5000		

##### Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

##### Sensitising effects

May cause an allergic skin reaction. (methyl methacrylate)

##### Carcinogenic/mutagenic/toxic effects for reproduction

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

##### STOT-single exposure

May cause respiratory irritation. (methyl methacrylate)

May cause drowsiness or dizziness. (butanone; ethyl methyl ketone)

##### 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 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.

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#### 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

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 1993

##### 14.2. UN proper shipping name:

FLAMMABLE LIQUID, N.O.S. (methyl methacrylatebutanone; ethyl methyl ketone)

##### 14.3. Transport hazard class(es):

3

##### 14.4. Packing group:

II

Hazard label:

3



Classification code:

F1

Special Provisions:

274 601 640D

Limited quantity:

1 L

Excepted quantity:

E2

Transport category:

2

Hazard No:

33

Tunnel restriction code:

D/E

#### Inland waterways transport (ADN)

##### 14.1. UN number or ID number:

UN 1993

##### 14.2. UN proper shipping name:

FLAMMABLE LIQUID, N.O.S. (methyl methacrylate; butanone; ethyl methyl ketone)

##### 14.3. Transport hazard class(es):

3

##### 14.4. Packing group:

II

Hazard label:

3



Classification code:

F1

Special Provisions:

274 601 640D

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Limited quantity: 1 L  
 Excepted quantity: E2

#### Marine transport (IMDG)

**14.1. UN number or ID number:** UN 1993  
**14.2. UN proper shipping name:** FLAMMABLE LIQUID, N.O.S. (methyl methacrylate; butanone; ethyl methyl ketone)  
**14.3. Transport hazard class(es):** 3  
**14.4. Packing group:** II  
 Hazard label: 3



Special Provisions: 274  
 Limited quantity: 1 L  
 Excepted quantity: E2  
 EmS: F-E, S-E

#### Air transport (ICAO-TI/IATA-DGR)

**14.1. UN number or ID number:** UN 1993  
**14.2. UN proper shipping name:** FLAMMABLE LIQUID, N.O.S. (methyl methacrylate; butanone; ethyl methyl ketone)  
**14.3. Transport hazard class(es):** 3  
**14.4. Packing group:** II  
 Hazard label: 3



Special Provisions: A3  
 Limited quantity Passenger: 1 L  
 Passenger LQ: Y341  
 Excepted quantity: E2  
 IATA-packing instructions - Passenger: 353  
 IATA-max. quantity - Passenger: 5 L  
 IATA-packing instructions - Cargo: 364  
 IATA-max. quantity - Cargo: 60 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, Entry 75

Information according to 2012/18/EU (SEVESO III): P5c FLAMMABLE LIQUIDS



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#### 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):

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.

### 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>

Flam. Liq: Flammable liquids

Skin Irrit: Skin irritation

Eye Irrit: Eye irritation

Skin Sens: Skin sensitisation

STOT SE: Specific target organ toxicity - single exposure

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

Classification	Classification procedure
Flam. Liq. 2; H225	On basis of test data
Skin Irrit. 2; H315	Calculation method
Eye Irrit. 2; H319	Calculation method
Skin Sens. 1; H317	Calculation method
STOT SE 3; H335	Calculation method
STOT SE 3; H336	Calculation method

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#### Relevant H and EUH statements (number and full text)

H225	Highly flammable liquid and vapour.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
EUH066	Repeated exposure may cause skin dryness or cracking.

#### 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.

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