

according to Regulation (EC) No 1907/2006

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

Regulation (EC) No 1272/2008

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

Regulation (EC) No 1272/2008

Hazard components for labelling

methyl methacrylate butanone; ethyl methyl ketone anal word: Danger

Signal word: Pictograms:

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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 statemer	nts	
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	on.
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 (Regulation (EC) No	1272/2008)		
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	s. 1, STOT SE 3; H225 H315 H317 H	335	

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 (CO2), 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 exhaustion 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

Occupational exposure limit values

CAS No	Name of agent	ppm	mg/m³	fib/cm³	Category	Origin
78-93-3	Butanone	200	600		TWA (8 h)	
		300	900		STEL (15 min)	
80-62-6	Methyl methacrylate	50	-		TWA (8 h)	
		100	-		STEL (15 min)	

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 exhaustion at critical locations.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:

Liquid



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Colour:	colourless	
Odour:	characteristic	
Melting point/freezing point:	not determ	nined
Boiling point or initial boiling point and	7	79 °C
boiling range:		
Flammability:	not applic	
	not applic	
Lower explosion limits:	1,8 v	
Upper explosion limits:	12,5 v	
Flash point:		12 °C
Auto-ignition temperature:		30 °C
Decomposition temperature:	not determ	
pH-Value:	not determ	
Water solubility:		No
Solubility in other solvents		
not determined	n at data w	-i
Partition coefficient n-octanol/water:	not determ	
Vapour pressure: (at 50 °C)	<=1100	nPa
Density:	0,87200 c	a/cm ³
Relative vapour density:	not determ	
<u>9.2. Other information</u>		inited in the second seco
Information with regard to physical haz	ard classes	
Explosive properties The product is not: Explosive.		
Self-ignition temperature		
Solid:	not applic	able
Gas:	not applic	
Oxidizing properties		
Not oxidising.		
Other safety characteristics		
Evaporation rate:	not determ	lined
Solid content:	C	0,0 %
SECTION 10: Stability and reactivity		

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.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

No known hazardous decomposition products.



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SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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 ke	etone			
	dermal	LD50 5000 mg/kg			
80-62-6	methyl methacrylate				
	dermal	LD50 > 5000 mg/kg			

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.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII. The product has not been tested.



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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:	I
Hazard label:	3
Classification code:	F1
Special Provisions:	274 601 640D
Limited quantity:	1L
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:	I
Hazard label:	3
Classification code:	F1
Special Provisions:	274 601 640D
Limited quantity:	1 L
Excepted quantity:	E2
Marine transport (IMDG)	



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<u>14.1. UN number or ID number:</u> 14.2. UN proper shipping name:	UN 1993 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	
<u>14.4. Packing group:</u> Hazard label:	II 3	
Special Provisions: Limited quantity Passenger:	A3 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	
4.5. Environmental hazards		
ENVIRONMENTALLY HAZARDOUS:	No	
4.6. Special precautions for user Warning: Combustible liquid.		
4.7. Maritime transport in bulk according not applicable	to IMO instruments	
ECTION 15: Regulatory information		
5.1. Safety, health and environmental reg	ulations/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	
National regulatory information		
Employment restrictions:	Observe restrictions to employment for juveniles according to the 'juver work protection guideline' (94/33/EC).	nile
Water hazard class (D):	1 - slightly hazardous to water	
vision No: 4 - Replaces version: 3	M - en Print da	te: 10.07.2023



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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.

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, Lig: Flammable liquid Skin Irrit: Skin irritation Eye Irrit: Eye irritation Skin Sens: Skin sensitisation STOT SE: Specific target organ toxicity - single exposure



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Classification for mixtures and used evaluation method according to Regulation (EC) No 1272/2008 [CLP]

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

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.

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