

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 27.07.2015

Version number 2

Revision: 27.07.2015

Hazardous according to criteria of Australian Safety and Compensation Council

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

· **1.1 Product identifier**

· **Trade name:** VITACOLL

· **Article number:** A9C100

· **1.2 Relevant identified uses of the substance or mixture and uses advised against**

No further relevant information available.

· **Application of the substance / product** Auxiliary for manufacture of dental prothesis

· **1.3 Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

VITA Zahnfabrik

H. Rauter GmbH & Co. KG

Postfach 1338

D 79704 Bad Säckingen

e-mail: info@vita-zahnfabrik.com

Tel.: 07761/562-0

Fax: 07761/562299

· **1.4 Emergency telephone number:** Tel.: ++49-(0)761-19240

SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**

· **Classification according to Regulation (EC) No 1272/2008**



flame

Flam. Liq. 2 H225

Highly flammable liquid and vapour.



Skin Irrit. 2 H315

Causes skin irritation.

Eye Irrit. 2 H319

Causes serious eye irritation.

Skin Sens. 1 H317

May cause an allergic skin reaction.

STOT SE 3 H335-H336 May cause respiratory irritation. May cause drowsiness or dizziness.

· **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**



Xi; Irritant

R36/37/38: Irritating to eyes, respiratory system and skin.



Xi; Sensitising

R43: May cause sensitisation by skin contact.



F; Highly flammable

R11: Highly flammable.

R67: Vapours may cause drowsiness and dizziness.

· **Information concerning particular hazards for human and environment:**

The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

(Contd. on page 2)

AUS

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 27.07.2015

Version number 2

Revision: 27.07.2015

Trade name: VITACOLL

(Contd. of page 1)

*Has a narcotising effect.***· Classification system:***The classification is according to the latest editions of the EU-lists, and extended by company and literature data.***· 2.2 Label elements****· Labelling according to Regulation (EC) No 1272/2008***The product is classified and labelled according to the CLP regulation.***· Hazard pictograms**

GHS02 GHS07

· Signal word Danger**· Hazard-determining components of labelling:***methyl methacrylate**butanone***· Hazard statements***H225 Highly flammable liquid and vapour.**H315 Causes skin irritation.**H319 Causes serious eye irritation.**H317 May cause an allergic skin reaction.**H335-H336 May cause respiratory irritation. May cause drowsiness or dizziness.***· Precautionary statements***P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.**P261 Avoid breathing dust/fume/gas/mist/vapours/spray.**P280 Wear protective gloves/protective clothing/eye protection/face protection.**P303+P361+P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.**P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.**P501 Dispose of contents/container in accordance with local/regional/national/international regulations.***· Information concerning to particular hazards to man and environment****· Safety phrases:***9 Keep container in a well-ventilated place.**16 Keep away from sources of ignition - No smoking.**23 Do not breathe gas/fumes/vapour/spray.**24 Avoid contact with skin.**37 Wear suitable gloves.**60 This material and its container must be disposed of as hazardous waste.***· 2.3 Other hazards****· Results of PBT and vPvB assessment****· PBT:** *Not applicable.***· vPvB:** *Not applicable.***SECTION 3: Composition/information on ingredients****· 3.2 Chemical characterisation: Mixtures****· Description:** *Mixture of substances listed below with nonhazardous additions.***· Dangerous components:**

(Contd. on page 3)

AUS

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 27.07.2015

Version number 2

Revision: 27.07.2015

Trade name: VITACOLL

(Contd. of page 2)

CAS: 80-62-6 EINECS: 201-297-1 Reg.nr.: 01-2119452498-28	methyl methacrylate ☒ Xi R37/38; ☒ Xi R43; ☒ F R11 ☒ Flam. Liq. 2, H225; ☒ Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	25-50%
CAS: 78-93-3 EINECS: 201-159-0 Reg.nr.: 01-2119457290-43	butanone ☒ Xi R36; ☒ F R11 R66-67 ☒ Flam. Liq. 2, H225; ☒ Eye Irrit. 2, H319; STOT SE 3, H336	25-50%

· **Additional information** For the wording of the listed risk phrases refer to section 16.

SECTION 4: First aid measures

· 4.1 Description of first aid measures

· After inhalation

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

· After skin contact Immediately wash with water and soap and rinse thoroughly.

· After eye contact

Rinse open eye for several minutes with running water. If symptoms persist, consult a doctor.

· After swallowing Rinse out mouth and then drink plenty of water.

· 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.

· 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

· 5.1 Extinguishing media

· Suitable extinguishing agents CO₂, sand, extinguishing powder. Do not use water.

· For safety reasons unsuitable extinguishing agents

Water.

Water with full jet.

· 5.2 Special hazards arising from the substance or mixture No further relevant information available.

· 5.3 Advice for firefighters

· Protective equipment: No special measures required.

· Additional information None

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

· 6.2 Environmental precautions:

Prevent seepage into sewage system, workpits and cellars.

Do not allow to enter sewers/ surface or ground water.

· 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Ensure adequate ventilation.

Do not flush with water or aqueous cleansing agents

· 6.4 Reference to other sections

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

AUS

(Contd. on page 4)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 27.07.2015

Version number 2

Revision: 27.07.2015

Trade name: VITACOLL

(Contd. of page 3)

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **Information about fire - and explosion protection:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** Store in a cool place with good ventilation
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Keep receptacle tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
- **Storage class 3**
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.

- **8.1 Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

80-62-6 methyl methacrylate

NES	Short-term value: 416 mg/m ³ , 100 ppm
	Long-term value: 208 mg/m ³ , 50 ppm

78-93-3 butanone

NES	Short-term value: 890 mg/m ³ , 300 ppm
	Long-term value: 445 mg/m ³ , 150 ppm

- **Additional information:** The lists valid during the making were used as basis.

- **8.2 Exposure controls**

- **Personal protective equipment**

- **General protective and hygienic measures**

Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.

- **Respiratory protection:** Use ventilation hood

- **Protection of hands:**



Protective gloves.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

Butyl rubber, BR

e.g. Butoject, KCL Nr. 897

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the

(Contd. on page 5)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 27.07.2015

Version number 2

Revision: 27.07.2015

Trade name: VITACOLL

(Contd. of page 4)

application.

- **Penetration time of glove material**
e.g. KCL Butoject 60 min

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye protection:**



Tightly sealed goggles.

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

· Form:	Fluid
· Colour:	Colourless
· Odour:	Characteristic
· Odour threshold:	Not determined.

- **pH-value:** Not determined.

- **Change in condition**

· Melting point/Melting range:	undetermined
· Boiling point/Boiling range:	79 °C

- **Flash point:** < -5 °C

- **Flammability (solid, gaseous)** Not applicable.

- **Ignition temperature:** 430 °C

- **Decomposition temperature:** Not determined.

- **Self-igniting:** Product is not selfigniting.

- **Danger of explosion:** Product is not explosive. However, formation of explosive air/vapour mixtures are possible.

- **Explosion limits:**

· Lower:	1.8 Vol %
· Upper:	12.5 Vol %

- **Oxidising properties** None

- **Vapour pressure at 20 °C:** 105 hPa

- **Density at 20 °C:** 0.872 g/cm³
- **Relative density** Not determined.
- **Vapour density** Not determined.
- **Evaporation rate** Not determined.

- **Solubility in / Miscibility with**

· **Water:** Not miscible or difficult to mix

- **Partition coefficient (n-octanol/water):** Not determined.

- **Viscosity:**

· dynamic:	Not determined.
· kinematic:	Not determined.

(Contd. on page 6)

AUS

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 27.07.2015

Version number 2

Revision: 27.07.2015

Trade name: VITACOLL

(Contd. of page 5)

- **Solvent content:**
- Organic solvents:** 50.0 %
- **9.2 Other information** No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No decomposition if used and stored according to specifications.
- **10.2 Chemical stability** No decomposition if used and stored according to specifications.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity**

- **LD/LC50 values relevant for classification:**

80-62-6 methyl methacrylate

Oral	LD50	>5000 mg/kg (rat)
Dermal	LD50	>5000 mg/kg (rabbit)
Inhalative	LC50/4 h	29.8 mg/l (rat)

78-93-3 butanone

Oral	LD50	3300 mg/kg (rat)
Dermal	LD50	5000 mg/kg (rbt)

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure**
May cause respiratory irritation. May cause drowsiness or dizziness.
- **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.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.

(Contd. on page 7)

AUS

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 27.07.2015

Version number 2

Revision: 27.07.2015

Trade name: VITACOLL


(Contd. of page 6)

- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
Disposal must be made according to official regulations.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|--|--|
| <ul style="list-style-type: none"> · 14.1 UN-Number · ADG, IMDG, IATA | UN1993 |
| <ul style="list-style-type: none"> · 14.2 UN proper shipping name · ADG · IMDG, IATA | UN1993 FLAMMABLE LIQUID, N.O.S. (vapour pressure at 50 °C not more than 110 kPa) (ETHYL METHYL KETONE (METHYL ETHYL KETONE), METHYL METHACRYLATE MONOMER, STABILIZED)
FLAMMABLE LIQUID, N.O.S. (ETHYL METHYL KETONE (METHYL ETHYL KETONE), METHYL METHACRYLATE MONOMER, STABILIZED) |
| <ul style="list-style-type: none"> · 14.3 Transport hazard class(es) · ADG, IMDG, IATA | <div style="text-align: center;">  </div> |
| <ul style="list-style-type: none"> · Class · Label | 3 Flammable liquids.
3 |
| <ul style="list-style-type: none"> · 14.4 Packing group · ADG, IMDG, IATA | II |
| <ul style="list-style-type: none"> · 14.5 Environmental hazards: · Marine pollutant: | No |
| <ul style="list-style-type: none"> · 14.6 Special precautions for user · Danger code (Kemler): · EMS Number: | Warning: Flammable liquids.
33
F-E,S-E |
| <ul style="list-style-type: none"> · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |

(Contd. on page 8)

AUS

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 27.07.2015

Version number 2

Revision: 27.07.2015

Trade name: VITACOLL

(Contd. of page 7)

· Transport/Additional information:**· ADG****· Limited quantities (LQ)**

1L

· Excepted quantities (EQ)

Code: E2

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 500 ml

· Transport category

2

· Tunnel restriction code

D/E

· IMDG**· Limited quantities (LQ)**

1L

· Excepted quantities (EQ)

Code: E2

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 500 ml

· UN "Model Regulation":

UN 1993 FLAMMABLE LIQUID, N.O.S. (VAPOUR PRESSURE AT 50 °C NOT MORE THAN 110 KPA) (ETHYL METHYL KETONE (METHYL ETHYL KETONE), METHYL METHACRYLATE MONOMER, STABILIZED), 3, II

SECTION 15: Regulatory information**· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****· Australian Inventory of Chemical Substances**

All ingredients are listed.

· Standard for the Uniform Scheduling of Medicines and Poisons

80-62-6 methyl methacrylate

S6, S10

78-93-3 butanone

S5

· Directive 2012/18/EU**· Named dangerous substances - ANNEX I** None of the ingredients is listed.**· National regulations****· Technical instructions (air):**

Class	Share in %
NK	25-50

· Waterhazard class: Water hazard class 1 (Self-assessment): slightly hazardous for water.**· 15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.**SECTION 16: Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Relevant phrases

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.

R11 Highly flammable.

(Contd. on page 9)

AUS

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 27.07.2015

Version number 2

Revision: 27.07.2015

Trade name: VITACOLL

(Contd. of page 8)

R36 Irritating to eyes.

R37/38 Irritating to respiratory system and skin.

R43 May cause sensitisation by skin contact.

R66 Repeated exposure may cause skin dryness or cracking.

R67 Vapours may cause drowsiness and dizziness.

· **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 Harmonised 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 (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids, Hazard Category 2

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

· *** Data compared to the previous version altered.**

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