

Safety data sheet

according to 1907/2006/EG, Article 31

Printing date 03.05.2017





Version number 3

Revision: 03.05.2017

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

- **1.1 Product identifier**
- **Trade name:** Tru-Fit Gold
- **Article number:** according to Catalog
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Sector of Use** SU20 Health services
- **Environmental release category** ERC2 Formulation into mixture
- **Application of the substance / the mixture** Dental material
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Kentzler-Kaschner Dental GmbH
Mühlgraben 36
D-73479 Ellwangen
Tel: +49/7961/90730
Fax: +49/7961/52031
E-Mail: info@kkd-topdent.de
- **Further information obtainable from:**
During normal business hours
Monday-Thursday 08:30 - 12:30 and 13:00 - 16:30 CET
Friday 08:30 - 12:30 and 13:00 - 15:00 CET
- **1.4 Emergency telephone number:** Vergiftungs-Informations-Zentrale Freiburg, Tel. +49 761 19240

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
-  **GHS02 flame**
Flam. Liq. 2 H225 Highly flammable liquid and vapour.
-  **GHS08 health hazard**
Repr. 2 H361 Suspected of damaging fertility or the unborn child.
-  **GHS09 environment**
Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.
-  **GHS07**
Eye Irrit. 2 H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
STOT SE 3 H336 May cause drowsiness or dizziness.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.

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· **Hazard pictograms**



GHS02 GHS07 GHS08 GHS09

· **Signal word** *Danger*

· **Hazard-determining components of labelling:**

butanone
methyl methacrylate

· **Hazard statements**

H225 Highly flammable liquid and vapour.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
H361 Suspected of damaging fertility or the unborn child.
H336 May cause drowsiness or dizziness.
H411 Toxic to aquatic life with long lasting effects.

· **Precautionary statements**

P101 If medical advice is needed, have product container or label at hand.
P102 Keep out of reach of children.
P103 Read label before use.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P241 Use explosion-proof electrical/ventilating/lighting equipment.
P303+P361+P353 IF ON SKIN (or hair): 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.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **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:** Dental material

· **Dangerous components:**

CAS: 78-93-3 EINECS: 201-159-0	butanone Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336	50-75%
CAS: 7440-50-8 EINECS: 231-159-6	copper substance with a Community workplace exposure limit	10-25%
CAS: 7440-66-6 EINECS: 231-175-3	zinc powder -zinc dust (stabilized) Aquatic Acute 1, H400; Aquatic Chronic 1, H410	1-10%
CAS: 108-88-3 EINECS: 203-625-9	toluene Flam. Liq. 2, H225; Repr. 2, H361d; STOT RE 2, H373; Asp. Tox. 1, H304; Skin Irrit. 2, H315; STOT SE 3, H336	0.1-1%

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
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CAS: 80-62-6	methyl methacrylate	0.1-1%
EINECS: 201-297-1	 Flam. Liq. 2, H225;  Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3 H335	

· **Additional information:**

REACH-Registrierungsnummern in ECHA-Datenbank:
 REACH-Registrierungsnr (Butanon) : 01-2119485493-29
 REACH-Registrierungsnummer (Zink Pulver Stabilisiert): 1-2119467174-37
 REACH-Registrierungsnummer (Kupfer): keine Info
 REACH-Registrierungsnummer (TOLUEN): 01-2119471310-51-XXXX
 REACH-Registrierungsnummer (Methylmethacrylat): 01-2119452498--28

SECTION 4: First aid measures

· **4.1 Description of first aid measures**

· **General information:**

Take affected persons out of danger area and lay down.
 Do not leave affected persons unattended.
 Take affected persons out into the fresh air.

· **After inhalation:**

Take affected persons into fresh air and keep quiet.
 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:**

If skin irritation continues, consult a doctor.
 Immediately wash with water and soap and rinse thoroughly.

· **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· **After swallowing:** Inform doctor. Do not give milk or fatty oils.

· **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 with full jet

· **5.2 Special hazards arising from the substance or mixture** Carbon dioxide (CO₂)

· **5.3 Advice for firefighters**

· **Protective equipment:** No special measures required.

· **Additional information**

Collect contaminated fire fighting water separately. It must not enter the sewage system.

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:**

Do not allow product to reach sewage system or any water course.
 Inform respective authorities in case of seepage into water course or sewage system.
 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).

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- 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.

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:**
- Do not spray onto a naked flame or any incandescent material.
- 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:**
- Stockages VDS 3103
- Store only in the original receptacle.
- Store in a cool location.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:**
- Keep container tightly sealed.
- Store in cool, dry conditions in well sealed receptacles.
- **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:**

78-93-3 butanone	
WEL	Short-term value: 899 mg/m ³ , 300 ppm Long-term value: 600 mg/m ³ , 200 ppm Sk, BMGV
7440-50-8 copper	
WEL	Short-term value: 2** mg/m ³ Long-term value: 0.2* 1** mg/m ³ *fume **dusts and mists (as Cu)
108-88-3 toluene	
WEL	Short-term value: 384 mg/m ³ , 100 ppm Long-term value: 191 mg/m ³ , 50 ppm Sk
80-62-6 methyl methacrylate	
WEL	Short-term value: 416 mg/m ³ , 100 ppm Long-term value: 208 mg/m ³ , 50 ppm

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· Ingredients with biological limit values:**78-93-3 butanone**

BMGV	70 µmol/L
	Medium: urine
	Sampling time: post shift
	Parameter: butan-2-one

· **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.

Avoid contact with the eyes and skin.

· Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

DGUV 112-190 Breathing apparatus

Filter type A2

· Protection of hands:

Protective gloves

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

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

· Material of gloves

Fluorocarbon rubber (Viton)

Butyl rubber, BR

Recommended material thickness:

Butylkautschuk: 0,50 mm +/- 0,10 mm

Fluorkautschuk: 0,75 mm +/- 0,10 mm

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 application.

· Penetration time of glove material

Basis: DGUV 212-007

Permeation (Fluorkautschuk): + Level 6 (> 240 min)

Permeation (Butylkautschuk): + Level 6 (> 480 min)

The determined penetration times according to EN 374 part III are not performed under practical conditions. Therefore a maximum wearing time, which corresponds to 50% of the penetration time, is recommended.

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

· For the permanent contact gloves made of the following materials are suitable:

Fluorocarbon rubber (Viton)

Butyl rubber, BR

· Not suitable are gloves made of the following materials: Chloroprene rubber, CR

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· **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:	Gold coloured
Odour:	Recognisable
Odour threshold:	Not determined.

· **pH-value:** Not determined.· **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	80 °C

· **Flash point:** -4 °C (c.c.)· **Flammability (solid, gas):** Not applicable.· **Ignition temperature:** 514 °C· **Decomposition temperature:** Not determined.· **Auto-ignition temperature:** Product is not selfigniting.· **Explosive properties:** Product is not explosive. However, formation of explosive air/vapour mixtures are possible.· **Explosion limits:**

Lower:	1.8 Vol %
Upper:	11.5 Vol %

· **Vapour pressure at 20 °C:** 105 hPa· **Density:** Not determined.· **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.· **Solvent content:**

Organic solvents:	51.0 %
VOC (EC)	51.00 %

Solids content: 48.0 %

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- **9.2 Other information** No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **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** Open fire, hot surfaces, high temperatures
- **10.5 Incompatible materials:** oxidants, acids, bases
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

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

78-93-3 butanone

Oral	LD50	3300 mg/kg (Ratte)
Dermal	LD50	5000 mg/kg (Kaninchen)

108-88-3 toluene

Oral	LD50	5000 mg/kg (Ratte)
Dermal	LD50	12124 mg/kg (Kaninchen)
Inhalative	LC50/4 h	5320 mg/l (Maus)

80-62-6 methyl methacrylate

Oral	LD50	7872 mg/kg (Ratte)
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- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **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**
Suspected of damaging fertility or the unborn child.
- **STOT-single exposure**
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:**

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- Butanon: 96 h LC50 Fish (400 mg/L *Cyprinodon variegatus*)
 Cupper: 96 h LC 50 Fish (0,0103 mg/l *Pimephales promelas*)
 Zink Pulver, stabilisiert: LC50 Fisch (0,182 mg/l *Oncorhynchus tshawytscha*)
 Toluol: 96 h LC 50 Fish (5,80 mg/l *Oncorhynchus mykiss*)
 Methylmethacrylat: 96 h(79 mg/L *Oncorhynchus mykiss*)
- **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.
 - **Ecotoxicological effects:**
 - **Remark:** Toxic for fish
 - **Additional ecological information:**
 - **General notes:**
 Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
 Do not allow product to reach ground water, water course or sewage system.
 Danger to drinking water if even small quantities leak into the ground.
 Also poisonous for fish and plankton in water bodies.
 Toxic for aquatic organisms
 - **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.
 - **European waste catalogue**
- | | |
|-----------|--|
| 18 01 06* | chemicals consisting of or containing hazardous substances |
|-----------|--|
- **Uncleaned packaging:**
 - **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- **14.1 UN-Number**
 - **ADR, IMDG, IATA** UN1993
 - **14.2 UN proper shipping name**
 - **ADR** 1993 FLAMMABLE LIQUID, N.O.S. (ETHYL METHYL KETONE (METHYL ETHYL KETONE)), ENVIRONMENTALLY HAZARDOUS
 - **IMDG** FLAMMABLE LIQUID, N.O.S. (Butanone, Zinc powder, stabilised-Mixture), MARINE POLLUTANT
 - **IATA** Flammable liquid, n.o.s. (Butanone, Zinc powder, stabilized-Mixture)
 - **14.3 Transport hazard class(es)**
 - **ADR, IMDG**
- 

- **Class** 3 Flammable liquids.

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· Label	3
· IATA	
	
· Class	3 Flammable liquids.
· Label	3
· 14.4 Packing group · ADR, IMDG, IATA	II
· 14.5 Environmental hazards:	Product contains environmentally hazardous substances: zinc powder -zinc dust (stabilized)
· Marine pollutant:	Symbol (fish and tree)
· Special marking (ADR):	Symbol (fish and tree)
· 14.6 Special precautions for user · Danger code (Kemler): · EMS Number: · Stowage Category	Warning: Flammable liquids. 339 F-E,S-E B
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR	
· 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. (ETHYL METHYL KETONE (METHYL ETHYL KETONE)), 3, II, ENVIRONMENTALLY HAZARDOUS

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **Seveso category**
O2 Substances and mixtures which in contact with water emit flammable gases
E2 Hazardous to the Aquatic Environment
P5c FLAMMABLE LIQUIDS
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 100 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 t
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3, 48

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· **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.
- H304 May be fatal if swallowed and enters airways.
- 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.
- H361d Suspected of damaging the unborn child.
- H373 May cause damage to organs through prolonged or repeated exposure.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.

· **Department issuing SDS:**

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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 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)
VOC: Volatile Organic Compounds (USA, EU)
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 – Category 2
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
Repr. 2: Reproductive toxicity – Category 2
Repr. 2: Reproductive toxicity – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2
Asp. Tox. 1: Aspiration hazard – Category 1
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

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