

**1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND
COMPANY/UNDERTAKING
INFORMATION ON THE PRODUCT**

1.1 Product identifier

Trade name

K-30 S LIQUID

**1.2 Relevant identifier uses of the substance or mixture and uses advised against
Recommended use**

Material for the fabrication of full and partial dentures.

1.3 Details of the supplier of the Safety Data Sheet

Manufacturer/supplier

Polident d.o.o.,
Dental Products Industry
Volčja Draga 42, 5293 Volčja Draga,
Slovenija
Tel.: 00386 5 3304840, Fax: 00386 5 3304870
E-mail: polident@polident.si

Information provided by

00386 5 3304859

1.4 Emergency telephone number

00386 5 3304840

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Mixture

Classification according to Regulation (EC) No. 1272/2008

Flam. Liq. 2 H225 Highly flammable liquid and vapour.
Skin Irrit. 2 H315 Causes skin irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
STOT SE 3 H335 May cause respiratory irritation.

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 statements

H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.

Precautionary statements

P 210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P 261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P 280 Wear protective gloves/protective clothing/eye protection/face protection.
P 303+P 361+P 353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing.
Rinse skin with water/shower.
P 501 Dispose of contents/container in accordance with local/regional/national/international

2.3	regulations. Other hazards Results of PBT and vPvB assessment PBT: Not applicable. vPvB: Not applicable.
3.	COMPOSITION/INFORMATION ON INGREDIENTS
3.1	Chemical characterization: Mixtures Description Product contents methyl methacrylate and trimethacrylate. Hazardous ingredients according to Regulation (EC) No. 1272/2008
Hazardous Ingredients	
Regulation (EC) No.1272/2008	
Methyl methacrylate	
50-100	
607-035-00-6	
Flam. Liq. 2	
H225	
201-297-1	
Skin Irrit. 2	
H315	
80-62-6	
Skin Sens. 1	
H317	
STOT SE 3	
H335	
Trimethylol propane	
2,5-10	
Aquatic Chronic 2	
H411	
trimethacrylate	
221-950-4	
3290-92-4	
4.	FIRST AID MEASURES
4.1	Description of first aid measures
General information	
Remove soiled, soaked clothing immediately.	
Inhalation	
Remove the casualty into fresh air. In case of complaints obtain medical attention.	
Skin contact	
Wash off immediately with water. If skin irritation occurs obtain medical attention.	
Eye contact	
Rinse opened eye with plenty of water and if it is necessary obtain medical attention.	
Ingestion	
Do not induce vomiting. Rinse mouth. Obtain immediately medical attention.	
4.2	Most important symptoms and effects, both acute and delayed
None known.	
4.3	Indication of any immediate medical attention and special treatment needed
Treat symptomatically.	
5.	FIRE – FIGHTING MEASURES
5.1	Extinguishing media
Suitable extinguishing media	
Water spray, foam, dry powder, carbon dioxide.	
Unsuitable extinguishing media for safety reasons	
Water with full yet.	
5.2	Special hazards arising from the substance or mixture
Highly flammable liquid.	
May polymerise on heating, the reaction is exotherm.	
Dangerous gases may be released in case of fire.	
5.3	Advice for firefighters
Wear self-contained breathing apparatus and suitable protective clothing.	
6.	ACCIDENTAL RELEASE MEASURES
6.1	Personal precautions, protective equipment and emergency procedures
Eliminate sources of ignition.	
Ensure suitable personal protection (including respiratory protection) during removal of spillages.	



Skin protection

Wear suitable protective gloves.



Material of gloves: Butyl rubber; EN 374

Suitability of gloves should be confirmed with glove manufacturer. Change gloves, if contamination occurs or duration of activity exceed break through time. Breakthrough time of the glove material: refer to the information provided by the glove's producer.

Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.

Respiratory protection

In the case of short term exposure use suitable mask with filter type A. In the event of particularly high levels of vapours a self contained breathing apparatus is appropriate.

Thermal hazards

None.

Environmental exposure controls

Ensure effective control measures when working within the boundaries as specified in section 6.2.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance

Form: liquid

Colour: colourless

Odour: characteristic strong

pH – value: not applicable

Changes in condition: /

Melting point (°C): - 48

Boiling point (°C): 100,5

Flash point (°C): 10

Relative evaporation rate (Ether=1): Not available

Flammability (solid, gas): Not applicable

Auto Ignition temperature(°C): 421

Decomposition temperature (°C): Not applicable

Lower explosion limit (%vv/v): 2,1

Upper explosion limit (%vv/v): 12,5

Vapour pressure (Pa): 3600 at 20°C

Vapour density (Air=1): 3,5

Density (g/cm³): 0,949 at 15,5 °C

Viscosity (mPas): 0,6 at 20°C

Solubility in water: slightly soluble, 1,6% at 20°C

Solubility (quantitative): miscible with most organic solvents

Partition coefficient (n-Octanol/water): 1,38

Explosive properties: Not applicable

Oxidising properties: Not applicable

9.2 Other information

None.

10. STABILITY AND REACTIVITY

10.1 Reactivity

Will exothermically polymerise in the presence of initiators.

10.2 Chemical stability

The product is stable under normal handling and storage conditions.

10.3 Possibility of hazardous reactions

Susceptible to polymerisation initiated by prolonged heating or the presence of catalyst.

10.4 Conditions to avoid

Heat and direct sunlight.

10.5 Incompatible materials

Polymerisation catalysts, such as peroxy or azo compounds, strong acids, alkalis and oxidising agents. Oxides and salts of transition metals. Organic Nitrogen containing compounds.

Cyclohexanone/Cyclohexenol tautomer.

10.6 Hazardous decomposition products

None when used and stored as prescribed.

Does not decompose up to auto-ignition temperature.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

Ingestion

Low oral toxicity, but ingestion may cause irritation of the gastrointestinal tract.

LD/LC50 values relevant for classification:

80-62-6 methyl methacrylate: LD50 (oral)=7872 mg/kg (rat)

Inhalation: May cause respiratory irritation. May cause drowsiness or dizziness.

Inhalation toxicity data: LC50 (vapour) 7093 ppm (29,8 mg/l)(4hr)

Skin irritation

May cause an allergic skin reaction. Causes skin irritation. Repeated and/or prolonged contact may cause dermatitis.

Eye contact

High vapour concentration will cause irritation.

Sensitization

Sensitization possible through skin contact. Not a respiratory sensitizer.

CMR effects

Carcinogenicity

No evidence of carcinogenicity.

Mutagenicity

Germ cell mutagenicity data: negative.

Toxicity for reproduction

Teratogenic and fetotoxic effects only observed in presence of maternal toxicity.

Repeated dose toxicity

Chronic exposure

Repeated exposure to high levels produces adverse effects on the heart, lungs, liver and kidneys.

Repeated exposure of animals by inhalation to levels at or above the occupational exposure level produces adverse effects on the nasal epithelium (levels of 100 and 400 ppm).

There is no reason to believe that methyl methacrylate represents a carcinogenic or mutagenic hazard to man based upon evidence from well conducted animal studies, relevant mutagenicity studies and adequate epidemiology studies in relevant cohorts.

Recent studies in animals have shown that high exposures do not produce embryo or foetotoxic nor teratogenic effects in the presence of maternal toxicity.

Further information on toxicology

Avoid contact with skin and eyes and inhalation of the vapours.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Hazardous to the aquatic environment

Low toxicity to fish. .

LC₅₀ (fish) > 100 mg/l

LC₅₀ (96 hr) (static) : 130 mg/l

Harmful to aquatic invertebrates

EC₅₀ (Daphnia magna) (48 hr) 69 mg/l

Low toxicity to algae.

EC₅₀ (skeletonema costatum) (96 hr) 170 mg/l

12.2 Persistence and degradability

Readily biodegradable.

12.3	Chemical oxygen demand (COD) 88% (28 days). Bioaccumulative potential The product has low potential for bioaccumulation.
12.4	Mobility in soil The product is predicted to have high mobility in soil.
12.5	Results of PBT and vPvB assessment PBT: Not applicable. vPvB: Not applicable.
12.6	Other adverse effects: No further relevant information available.
13.	DISPOSAL CONSIDERATIONS
13.1	Waste treatment methods Product: Must not be disposed together with household garbage. Do not allow product to reach sewage system. Disposal should be made in accordance with local, state and national legislation. Uncleaned packaging: Disposal should be made in accordance with local, state and national legislation.
14.	TRANSPORT INFORMATION
14.1	UN number: 1247
14.2	UN proper shipping name METHYL METHACRYLATE MONOMER, STABILIZED
14.3	Transport hazard class(es) ADR, IMDG, IATA  Class: 3 Flammable liquids Label: 3
14.4	Packing group ADR, IMDG, IATA: II
14.5	Environmental hazards Marine pollutant: Not classified as a marine pollutant.
14.6	Special precautions for user Warning: Flammable liquids. Danger code (Kemler): 339 EMS Number: F-E,S-E
14.7	Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.
14.8	Transport additional information ADR Limited quantities (LQ): 1L Transport category: 2 Tunnel restriction code: D/E
15.	REGULATORY INFORMATION
15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture Product is a medical device class IIa according to Directive 93/42/EEC.
15.2	Chemical Safety Assessment A chemical safety assessment has not been carried out for this mixture.
16.	OTHER INFORMATION This information is based on our present knowledge and experience. They are intended as a description of the products safety requirements and are not to be seen as a guarantee of certain product's features. Relevant phrases H225 Highly flammable liquid and vapour. H315 Causes skin irritation. H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

New versions of Safety Data Sheet will be *laying printed* for the data compared to the previous version altered.