

Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 23.12.2024

Version: 1

Revision: 23.12.2024

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

- **1.1 Product identifier**
- **Trade name:** New Outline Liquid
- **Article number:** 16100100, 16100250, 16100500, 16101000, 16100025
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Manufacture of dental prosthesis
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
anax dent GmbH, Dreifelderstr.5, D-70599 Stuttgart
Tel.: 0711/620092-0 Fax: 0711/620092-29
anaxdent.com
- **Further information obtainable from:** R&D, MANI MEDICAL GERMANY GmbH, Tel: +049 6003/8286-0
- **1.4 Emergency telephone number:**
+49 (0) 6003 82 86-0, MANI MEDICAL GERMANY GmbH (8:00 - 17:00) or
+49 (0) 6131 19240 Poison Information Center, University Mainz (24 h)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or 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.
- Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

- **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
di-urethane dimethacrylate
tetramethylene dimethacrylate
- **Hazard statements**
H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.
H412 Harmful to aquatic life with long lasting effects.
- **Precautionary statements**
- P210 *Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.*
- P241 *Use explosion-proof [electrical/ventilating/lighting] equipment.*
- P261 *Avoid breathing dust/fume/gas/mist/vapours/spray.*
- P303+P361+P353 *IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].*
- P405 *Store locked up.*

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P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- Labelling of packages where the contents do not exceed 125 ml
- Hazard pictograms



GHS02 GHS07

- Signal word *Danger*
- Hazard-determining components of labelling:
 - methyl methacrylate
 - di-urethane dimethacrylate
 - tetramethylene dimethacrylate
- Hazard statements
 - H317 May cause an allergic skin reaction.
 - H412 Harmful to aquatic life with long lasting effects.
- Precautionary statements
 - P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 - 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 Mixtures
- Description:
 - Liquid based on methacryl acid ester, containing an activator, used for the production of temporary crowns and bridges in dental medicine.

· **Dangerous components:**

CAS: 80-62-6 EINECS: 201-297-1	methyl methacrylate Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	50-75%
CAS: 41137-60-4	di-urethane dimethacrylate Aquatic Chronic 2, H411; Skin Sens. 1B, H317	10-25%
CAS: 2082-81-7 EINECS: 218-218-1	tetramethylene dimethacrylate Skin Sens. 1B, H317	2.5-10%

- Additional information For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- 4.1 Description of first aid measures
 - After inhalation Supply fresh air; consult doctor in case of complaints.
 - 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. Then consult a doctor.
 - After swallowing
 - Rinse out mouth and then drink plenty of water.
 - Call a doctor immediately.
- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.

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- **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**
Carbon dioxide
Fire-extinguishing powder
Foam
Water spray
- **For safety reasons unsuitable extinguishing agents** 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:** Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Ensure adequate ventilation
Wear protective equipment. Keep unprotected persons away.
Keep away from ignition sources
- **6.2 Environmental precautions:** 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).
Dispose contaminated material as waste according to section 13.
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**
Keep receptacles tightly sealed.
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **Information about fire - and explosion protection:**
Fumes can combine with air to form an explosive mixture.
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:** Storage between 10 °C and 25 °C.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:**
Keep receptacle tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
- **Storage class** Not determined
- **7.3 Specific end use(s)** No further relevant information available.

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SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

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

80-62-6 methyl methacrylate

OEL (Ireland)	Short-term value: 100 ppm Long-term value: 50 ppm IOELV, Sens
WEL (Great Britain)	Short-term value: 416 mg/m ³ , 100 ppm Long-term value: 208 mg/m ³ , 50 ppm
PEL (USA)	Long-term value: 410 mg/m ³ , 100 ppm
REL (USA)	Long-term value: 410 mg/m ³ , 100 ppm
TLV (USA)	Short-term value: 100 ppm Long-term value: 50 ppm DSEN, A4
IOELV (European Union)	Short-term value: 100 ppm Long-term value: 50 ppm

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

· 8.2 Exposure controls

· **Appropriate engineering controls** No further data; see section 7.

· **Individual protection measures, such as 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:**

Not necessary if room is well-ventilated.

Use suitable respiratory protective device when high concentrations are present.

Filter A

· **Hand protection** Protective gloves.

· **Material of gloves**

Butyl rubber, BR

Nitrile rubber, NBR

· **Penetration time of glove material**

0,3 mm

Penetration time 60 min.

0,11 mm

Penetration time 10 min.

· **Eye/face protection** Tightly sealed goggles.

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· **General Information**

· **Physical state**

Fluid

· **Colour:**

Clear

· **Odour:**

Characteristic

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

-48 °C

· **Boiling point or initial boiling point and boiling range**

101 °C

· **Flammability**

Not applicable.

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· Lower and upper explosion limit	
· Lower:	2.1 Vol % (Literatur)
· Upper:	12.5 Vol % (Literatur)
· Flash point:	10 °C (DIN 51755)
· Auto-ignition temperature:	430 °C (DIN 51794)
· Decomposition temperature:	Not determined.
· pH	Mixture is non-soluble (in water). Not determined. Not determined
· Viscosity:	
· Kinematic viscosity	Not determined.
· dynamic:	Not determined.
· Solubility	
· Water:	Not miscible or difficult to mix
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure at 20 °C:	47 hPa
· Density and/or relative density	
· Density:	Not determined
· Relative density	Not determined.
· Vapour density	Not determined.

· 9.2 Other information	---
· Appearance:	
· Form:	Fluid
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· Change in condition	
· Evaporation rate	Not determined.

· Information with regard to physical hazard classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Highly flammable liquid and vapour.
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

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 Exothermic polymerization

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· **12.7 Other adverse effects**· **Remark:** Harmful to 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.

Harmful to aquatic organisms

SECTION 13: Disposal considerations· **13.1 Waste treatment methods**· **Recommendation**

After prior treatment product has to be disposed of in an incinerator for hazardous waste adhering to the regulations pertaining to the disposal of particularly hazardous waste.

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· **European waste catalogue**

07 01 04* | other organic solvents, washing liquids and mother liquors

· **Uncleaned packaging:**· **Recommendation:** Disposal must be made according to official regulations.**SECTION 14: Transport information**· **14.1 UN number or ID number**· **ADR, IMDG, IATA**

UN1247

· **14.2 UN proper shipping name**· **ADR**1247 METHYL METHACRYLATE MONOMER,
STABILIZED mixture· **IMDG, IATA**METHYL METHACRYLATE MONOMER, STABILIZED
mixture· **14.3 Transport hazard class(es)**· **ADR**· **Class**

3 (F1) Flammable liquids.

· **Label**

3

· **IMDG, IATA**· **Class**

3 Flammable liquids.

· **Label**

3

· **14.4 Packing group**· **ADR, IMDG, IATA**

II

· **14.5 Environmental hazards:**· **Marine pollutant:**

No

· **14.6 Special precautions for user**

Warning: Flammable liquids.

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· Hazard identification number (Kemler code):	33
· EMS Number:	F-E,S-D
· Stowage Category	C
· Stowage Code	SW1 Protected from sources of heat. SW2 Clear of living quarters.
· 14.7 Maritime transport in bulk according to IMO instruments	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 1247 METHYL METHACRYLATE MONOMER, STABILIZED MIXTURE, 3, II

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 P5c** FLAMMABLE LIQUIDS
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5,000 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50,000 t
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

· **REGULATION (EU) 2019/1148**

· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

· **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

· **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients is listed.

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· **National regulations**· **Technical instructions (air):**

Class	Share in %
III	2.5-10

· **Waterhazard class:** Water hazard class 2 (Self-assessment): hazardous for water.· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This Safety Data Sheet is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

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.

H335 May cause respiratory irritation.

H411 Toxic to aquatic life with long lasting effects.

· **Department issuing SDS:** R&D, MANI MEDICAL GERMANY GmbH· **Contact:** Fr. R.Naveenakumar· **Date of previous version:** 18.12.2024· **Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

ADR: Accord relatif au transport international 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 – Category 2

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1B: Skin sensitisation – Category 1B

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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