

Safety data sheet

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

Printing date 23.12.2024

Version: 2

Revision: 23.12.2024

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

- **1.1 Product identifier**
- **Trade name:** New Outline Skin Glaze
- **Article number:** 16201010
- **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** Dental sealing material
- **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.
Eye Irrit. 2	H319 Causes serious eye 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
2-Propenoic acid, reaction product with dipentaerythritole
diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide
- **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 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.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

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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.

- 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

2-Propenoic acid, reaction product with dipentaerythritole

diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide

- Hazard statements

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

- Precautionary statements

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.

- 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: 56744-60-6 EINECS: 260-363-8	Bisphenol-A-ethoxylat(4)dimethacrylat Aquatic Chronic 4, H413	10-25%
CAS: 1384855-91-7	2-Propenoic acid, reaction product with dipentaerythritole ⚠ Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412	10-25%
CAS: 75980-60-8 EINECS: 278-355-8	diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide ⚠ Repr. 2, H361f; ⚠ Aquatic Chronic 2, H411; ⚠ Skin Sens. 1B, H317	<2.5%

- SVHC

75980-60-8 | diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide

- 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

- General information Immediately remove any clothing soiled by the product.

- After inhalation Supply fresh air; consult doctor in case of complaints.

- After skin contact

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

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- **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.
Do not induce vomiting; call for medical help immediately.
- **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**
Carbon dioxide
Fire-extinguishing powder
Foam
Water haze
- **For safety reasons unsuitable extinguishing agents** Water with full jet.
- **5.2 Special hazards arising from the substance or mixture** Danger of polymerization.
- **5.3 Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.
- **Additional information**
Cool endangered receptacles with water spray.
Collect contaminated fire fighting water separately. It must not enter the sewage system.
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Ensure adequate ventilation
Keep away from ignition sources
Wear protective clothing.
Avoid eye and skin contact with the substance.
- **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).
Send for recovery or disposal in suitable receptacles.
When pumping out, please ensure grounding.
- **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.
- **Information about fire - and explosion protection:** Keep ignition sources away - Do not smoke.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:**
Close container immediately after use and protect product from light incidence.
Storage between 10 °C and 25 °C.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:** Store in cool, dry conditions in well sealed receptacles.

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· **7.3 Specific end use(s)** No further relevant information available.

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.

Short term filter device:

Filter A

· **Hand protection** Protective gloves.· **Material of gloves** Butyl rubber, BR· **Penetration time of glove material**

0,1 - 0,2 mm

Penetration time: 5 min.

· **Eye/face protection** Safety glasses· **Body protection:** Protective work clothing.

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**· **General Information**· **Colour:**

Colourless

· **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 %
· Upper:	12.5 Vol %
· Flash point:	10 °C
· Auto-ignition temperature:	430 °C
· Decomposition temperature:	Not determined.
· pH	Not determined.
· Viscosity:	
· Kinematic viscosity	Not determined
	Not determined.
· dynamic:	Not determined
	Not determined.
· Solubility	
· Water:	Slightly soluble
· 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 -

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- **12.7 Other adverse effects**
- **Remark:** Harmful to fish
- **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.

Harmful to aquatic organisms

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**

- **Recommendation**

Must be specially treated adhering to official regulations.

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

- **European waste catalogue**

08 01 11*	waste paint and varnish containing organic solvents or other hazardous substances
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- **Uncleaned packaging:**

- **Recommendation:**

Packagings that may not be cleansed are to be disposed of in the same manner as the product.

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):	339
· EMS Number:	F-E,S-D
· Stowage Category	B
· Stowage Code	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.

· **National regulations**

· **Information about limitation of use:**

Employment restrictions concerning pregnant and lactating women must be observed.

· **Waterhazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.

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- **Other regulations, limitations and prohibitive regulations**

- **Substances of very high concern (SVHC) according to REACH, Article 57**

75980-60-8	diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide
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- **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.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H361f Suspected of damaging fertility.

H411 Toxic to aquatic life with long lasting effects.

H412 Harmful to aquatic life with long lasting effects.

H413 May cause long lasting harmful effects to aquatic life.

- **Department issuing SDS:** R&D, MANI MEDICAL GERMANY GmbH

- **Contact:** Fr. R.Naveenakumar

- **Date of previous version:** 23.12.2024

- **Abbreviations and acronyms:**

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

SVHC: Substances of Very High Concern

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

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

Repr. 2: Reproductive toxicity – Category 2

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

Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4

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