

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 Primer

· **Article number:** 16200010

· **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** Adhering additive

· **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.

· **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

· **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**

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.

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

(Contd. on page 2)

Safety data sheet

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

Printing date 23.12.2024

Version: 2

Revision: 23.12.2024

Trade name: *New Outline Skin Primer*

(Contd. of page 1)

- 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
- Hazard statements
H317 May cause an allergic skin reaction.
- 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: Mixture of substances listed below with nonhazardous additions.

· Dangerous components:

CAS: 80-62-6	methyl methacrylate	75-100%
EINECS: 201-297-1		

- 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 Take affected persons into fresh air and keep quiet.
- After skin contact
Immediately wash with water and soap and rinse thoroughly.
If skin irritation continues, consult a doctor.
- 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 spray

(Contd. on page 3)

Safety data sheet

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

Printing date 23.12.2024

Version: 2

Revision: 23.12.2024

Trade name: *New Outline Skin Primer*

(Contd. of page 2)

- **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.
Wear fully protective suit.

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.
- **6.2 Environmental precautions:** *Do not allow to enter sewers/ surface or ground water.*
- **6.3 Methods and material for containment and cleaning up:**
Pick up mechanically.
When pumping out, please ensure grounding.
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose of the material collected according to regulations.
- **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.
- **Information about fire - and explosion protection:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
Use explosion-proof apparatus / fittings and spark-proof tools.
Fumes can combine with air to form an explosive mixture.
- **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:** -
- **Further information about storage conditions:** *Protect from exposure to the light.*
- **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

<i>OEL (Ireland)</i>	<i>Short-term value: 100 ppm</i> <i>Long-term value: 50 ppm</i> <i>IOELV, Sens</i>
<i>WEL (Great Britain)</i>	<i>Short-term value: 416 mg/m³, 100 ppm</i> <i>Long-term value: 208 mg/m³, 50 ppm</i>
<i>PEL (USA)</i>	<i>Long-term value: 410 mg/m³, 100 ppm</i>

(Contd. on page 4)

Safety data sheet

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

Printing date 23.12.2024

Version: 2

Revision: 23.12.2024

Trade name: *New Outline Skin Primer*

(Contd. of page 3)

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**

Do not inhale gases / fumes / aerosols.

Immediately remove all soiled and contaminated clothing

Store protective clothing separately.

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.

(Only when handling large quantities)

SECTION 9: Physical and chemical properties

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

· **General Information**

· **Colour:** Colourless

· **Odour:** Ester-like

· **Odour threshold:** Not determined.

· **Melting point/freezing point:** -48 °C

· **Boiling point or initial boiling point and boiling range** 101 °C (1013 hPa)

· **Flammability** Not applicable.

· **Lower and upper explosion limit**

· **Lower:** 2.1 Vol %

· **Upper:** 12.5 Vol %

· **Flash point:** 10 °C (DIN 51755)

· **Auto-ignition temperature:** 430 °C (DIN 51794)

· **Decomposition temperature:** Not determined.

· **pH** Not determined.

· **Viscosity:**

· **Kinematic viscosity** Not determined.

· **dynamic:** Not determined.

· **Solubility**

· **Water at 20 °C:** 1.6 g/l

· **Partition coefficient n-octanol/water (log value)** Not determined.

(Contd. on page 5)

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

Printing date 23.12.2024

Version: 2

Revision: 23.12.2024

Trade name: *New Outline Skin Primer*

(Contd. of page 4)

· Vapour pressure at 20 °C:	47 hPa
· Density and/or relative density	
· Density at 20 °C:	0.94 g/cm ³
· 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
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:**
In presence of radical formers (e. g. peroxides), deoxidizing substances, and/or heavy metal ions, polymerization with heat release is possible.
- **10.6 Hazardous decomposition products:** -

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.

(Contd. on page 6)

Safety data sheet

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

Printing date 23.12.2024

Version: 2

Revision: 23.12.2024

Trade name: *New Outline Skin Primer*

(Contd. of page 5)

- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **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.
- **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.
- **11.2 Information on other hazards**

· Endocrine disrupting properties
None of the ingredients is listed.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Type of test**

Effective concentration	Method	Assessment
--------------------------------	---------------	-------------------

 - Toxicity to fish: LC-50: >79 mg/l OECD 203
 - (MMA) NOEC: 40 mg/l ISO 7346
 - Time: 96 h EEC84
 - Species:
Oncorhynchus mykiss

 - Toxicity to Micro- ECO: 100 mg/l starting inhibition
 - Organisms Species: of cell growth
 - (MMA) Pseudomonas putida
- **12.2 Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Components:**
methyl methacrylate Biodegradability: 30,7 %
Time: 28 d
Method: OECD 301 C
Valuation: difficult to decompose
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **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.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation** Must be specially treated adhering to official regulations.

· European waste catalogue
07 01 04* other organic solvents, washing liquids and mother liquors

(Contd. on page 7)

Safety data sheet

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

Printing date 23.12.2024

Version: 2

Revision: 23.12.2024

Trade name: *New Outline Skin Primer*

(Contd. of page 6)

- **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 solution

· **IMDG, IATA** METHYL METHACRYLATE MONOMER, STABILIZED
solution

· **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.· **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

(Contd. on page 8)

Safety data sheet

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

Printing date 23.12.2024

Version: 2

Revision: 23.12.2024

Trade name: *New Outline Skin Primer*

(Contd. of page 7)

· 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 SOLUTION, 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**

- **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 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.

· **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

(Contd. on page 9)

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

Printing date 23.12.2024

Version: 2

Revision: 23.12.2024

Trade name: New Outline Skin Primer

(Contd. of page 8)

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

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

IE