

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 Powder*
- **Article number:**
16000100, 16000100, 16000100, 16010100, 16011100, 16012100, 16013100, 16025100, 16014100, 16018100, 16019100, 16020100, 16021100, 16026100, 16026110, 16027100, 16017100, 16016100, 16022100, 16023100, 16024100, 16015100, 16011500, 16012500, 16013500, 16025500, 16010500, 16012010, 16013010, 16022010
- **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**
The product is not classified, according to the CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** *Void*
- **Hazard pictograms** *Void*
- **Signal word** *Void*
- **Hazard statements** *Void*
- **Labelling of packages where the contents do not exceed 125 ml**
- **Hazard pictograms** *Void*
- **Signal word** *Void*
- **Hazard statements** *Void*
- **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:** *Acryl-resin on base of polymethylmethacrylate*
- **Dangerous components:** *Void*
- **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** *No special measures required.*
- **After inhalation**
Rinse nose and throat thoroughly with water.
Supply fresh air; consult doctor in case of complaints.

(Contd. on page 2)

Safety data sheet

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

Printing date 23.12.2024

Version: 1

Revision: 23.12.2024

Trade name: *New Outline Powder*

(Contd. of page 1)

- **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. If symptoms persist, consult a doctor.
- **After swallowing**
Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.
- **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**
Water haze
Foam
Carbon dioxide
Fire-extinguishing powder
Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **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.
- **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** Prevent formation of dust.
- **Information about fire - and explosion protection:** No special measures required.
- **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:** 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

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.

(Contd. on page 3)

Safety data sheet

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

Printing date 23.12.2024

Version: 1

Revision: 23.12.2024

Trade name: *New Outline Powder*

(Contd. of page 2)

- **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**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:**
Not necessary if room is well-ventilated.
Use suitable respiratory protective device when high concentrations are present.
Dust protective mask
- **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** *Safety glasses*

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Physical state** *Solid.*
- **Colour:** *Different according to colouring*
- **Odour:** *Characteristic*
- **Odour threshold:** *Not determined.*
- **Melting point/freezing point:** *110 °C*
- **Boiling point or initial boiling point and boiling range** *undetermined*
- **Flammability** *Not determined.*
- **Lower and upper explosion limit**
- **Lower:** *Not determined.*
- **Upper:** *Not determined.*
- **Flash point:** *251 °C*
- **Auto-ignition temperature:** *>400 °C*
- **Decomposition temperature:** *Not determined.*
- **pH** *Mixture is non-soluble (in water).*
Not applicable.
Not applicable
- **Viscosity:**
- **Kinematic viscosity** *Not applicable.*
Not applicable
- **dynamic:** *Not applicable.*
Not applicable
- **Solubility**
- **Water:** *Insoluble*
Not miscible or difficult to mix
- **Partition coefficient n-octanol/water (log value)** *Not determined.*
- **Vapour pressure:** *Not applicable.*
- **Density and/or relative density**
- **Density at 20 °C:** *1.16 g/cm³*
- **Relative density** *Not determined.*
- **Bulk density:** *700-750 kg/m³*
- **Vapour density** *Not applicable.*

(Contd. on page 4)

Safety data sheet

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

Printing date 23.12.2024

Version: 1

Revision: 23.12.2024

Trade name: *New Outline Powder*

(Contd. of page 3)

· Particle characteristics	See section 3.
· 9.2 Other information	---
· Appearance:	
· Form:	Powder
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Solvent content:	
· Organic solvents:	0.0 %
· Solids content:	100.0 %
· Change in condition	
· Evaporation rate	Not applicable.
· Information with regard to physical hazard classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· 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:**
Can decompose slowly with localised heating above 150°C
- **10.3 Possibility of hazardous reactions** No dangerous reactions known
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:**
During thermic decomposition, flammable fumes which may irritate the eyes and which consist of methylmethacrylate are developed.

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** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.

(Contd. on page 5)

Safety data sheet

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

Printing date 23.12.2024

Version: 1

Revision: 23.12.2024

Trade name: **New Outline Powder**

(Contd. of page 4)

- **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** Based on available data, the classification criteria are not met.
- **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.
- **Additional toxicological information:**
Caused by our manufacturing procedures, there is a content of dibenzoylperoxide of max. 0,5 %.
- **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** Not determined
- **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.
- **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 02 13	waste plastic
----------	---------------

- **Uncleaned packaging:**
- **Recommendation:**
Dispose of packaging according to regulations on the disposal of packagings.
Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|---------------------------------------|------|
| · 14.1 UN number or ID number | |
| · ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name | |
| · ADR, ADN, IMDG, IATA | Void |

(Contd. on page 6)

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

Printing date 23.12.2024

Version: 1

Revision: 23.12.2024

Trade name: *New Outline Powder*

(Contd. of page 5)

· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA	
· Class	Void
· 14.4 Packing group	
· ADR, IMDG, IATA	Void
· 14.5 Environmental hazards:	
· Marine pollutant:	No
· 14.6 Special precautions for user	Not applicable.
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	
· IATA	
· Remarks:	Keep the packaging always closed.
· UN "Model Regulation":	Void

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.

· **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.

- **Department issuing SDS:** R&D, MANI MEDICAL GERMANY GmbH
- **Contact:** Fr. R.Naveenakumar
- **Date of previous version:** 14.05.2024

(Contd. on page 7)

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

Printing date 23.12.2024

Version: 1

Revision: 23.12.2024

Trade name: New Outline Powder

(Contd. of page 6)

· 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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

· * Data compared to the previous version altered.

IE