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

· 1.1 Product identifier

· Trade name: anaxBlend Opaquer

· Article number:

20300003, 20301003, 20302003, 20303003, 20303503, 20304003, 20322003, 20323003, 20332003 20343003

· 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 Masking 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

Acute Tox. 4 H332 Harmful if inhaled.

Skin Sens. 1 H317 May cause an allergic skin reaction.

Aquatic Chronic 2 H411 Toxic 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





GHS07

GHS09

- · Signal word Warning
- · Hazard-determining components of labelling:

di-urethane dimethacrylate

2-[[(butylamino)carbonyl]oxy]ethyl acrylate

tetramethylene dimethacrylate

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

· Hazard statements

H332 Harmful if inhaled.

H317 May cause an allergic skin reaction.

H411 Toxic to aquatic life with long lasting effects.

· Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P312 Call a POISON CENTER/doctor if you feel unwell.

P321 Specific treatment (see on this label).

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

Additional information:

Warning! Hazardous respirable droplets may be formed when sprayed. Do not breathe spray or mist.

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





- · Signal word Warning
- · Hazard-determining components of labelling:

di-urethane dimethacrylate

2-[[(butylamino)carbonyl]oxy]ethyl acrylate

tetramethylene dimethacrylate

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

· Hazard statements

H317 May cause an allergic skin reaction.

· Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves.

P321 Specific treatment (see on this label).

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.

| · Dangerous components: | | |
|-------------------------|--|---------|
| CAS: 41137-60-4 | di-urethane dimethacrylate | 25-50% |
| | 🕸 Aquatic Chronic 2, H411; 🕚 Skin Sens. 1B, H317 | |
| CAS: 63225-53-6 | 2-[[(butylamino)carbonyl]oxy]ethyl acrylate | 2.5-10% |
| | ♠ Acute Tox. 4, H332; Skin Sens. 1A, H317 | |
| CAS: 2082-81-7 | tetramethylene dimethacrylate | 2.5-10% |
| EINECS: 218-218-1 | ♦ Skin Sens. 1B, H317 | |
| CAS: 75980-60-8 | diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide | <2.5% |
| EINECS: 278-355-8 | 🗞 Repr. 2, H361f; 슣 Aquatic Chronic 2, H411; 아 Skin Sens. 1B, H317 | |
| CAS: 10373-78-1 | dl-bornane-2,3-dione | <2.5% |
| | ♦ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335 | |

·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.

· After eye contact Rinse opened eye for several minutes under running water. Then consult a doctor.

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· After swallowing

Rinse out mouth and then drink plenty of water.

Seek medical treatment.

- 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 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:

Do not inhale explosion gases or combustion gases.

Mount respiratory protective device.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation

Keep people at a distance and stay on the windward side.

- 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.

6.4 Reference to other sections

No dangerous substances are released.

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: Not required.
- · Further information about storage conditions: None.
- · 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.

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- · 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 Immediately remove all soiled and contaminated clothing
- · Respiratory protection: Not necessary if room is well-ventilated.
- · 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 Fluid

· Colour: According to product specification

Odour: Characteristic
 Odour threshold: Not determined.
 Melting point/freezing point: undetermined

· Boiling point or initial boiling point and boiling

range 251 °C

· Flammability Not applicable.

· Lower and upper explosion limit

Lower: Not determined.
 Upper: Not determined.
 Flash point: 151 °C
 Auto-ignition temperature: >370 °C
 Decomposition temperature: Not determined.

pH Mixture is non-soluble (in water).

Not determined.

· Viscosity:

Kinematic viscositydynamic:Not determined.Not determined.

Solubility

• Water: Not miscible or difficult to mix

• Partition coefficient n-octanol/water (log value) Not determined. • Vapour pressure: Not determined.

· Density and/or relative density

Density: Not determined
Relative density Not determined.
Vapour density Not determined.

· 9.2 Other information

· Appearance:

· Form: Pasty

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 %

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| | | (Contd. of page |
|--|-----------------|-----------------|
| · Change in condition | | |
| · Evaporation rate | Not determined. | |
| Information with regard to physical hazard o | elasses | |
| · 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 flamm | able | |
| 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: No dangerous decomposition products known

SECTION 11: Toxicological information

- · 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity Harmful if inhaled.
- LD/LC50 values relevant for classification:

tetramethylene dimethacrylate LD-50 oral > 5000 mg/kg (rat)

- · 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 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 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.

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· 11.2 Information on other hazards

(Contd. of page 5)

- · Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 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
- · Remark: Toxic for 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.

Also poisonous for fish and plankton in water bodies.

Toxic for 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

08 01 12 waste paint and varnish other than those mentioned in 08 01 11

- · Uncleaned packaging:
- · Recommendation:

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

Recommended cleansing agents: Alcohol

| · 14.1 UN number or ID number | |
|--------------------------------|---|
| · ADR, IMDG, IATA | UN3082 |
| · 14.2 UN proper shipping name | |
| $\cdot ADR$ | 3082 ENVIRONMENTALLY HAZARDOU |
| | SUBSTANCE, LIQUID, N.O.S. (di-urethan |
| | dimethacrylate, 2-[[(butylamino)carbonyl]oxy]ethy |
| | acrylate) |

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| | (Contd. of page |
|--|---|
| · IMDG | ENVIRONMENTALLY HAZARDOUS SUBSTANC LIQUID, N.O.S. (di-urethane dimethacrylate, [[(butylamino)carbonyl]oxy]ethyl acrylate), MARIN POLLUTANT |
| · IATA | ENVIRONMENTALLY HAZARDOUS SUBSTANC LIQUID, N.O.S. (di-urethane dimethacrylate, [[(butylamino)carbonyl]oxy]ethyl acrylate) |
| · 14.3 Transport hazard class(es) | |
| · ADR | |
| ************************************** | |
| · Class · Label | 9 (M6) Miscellaneous dangerous substances and article 9 |
| · IMDG, IATA | |
| · Class · Label | 9 Miscellaneous dangerous substances and articles. 9 |
| · 14.4 Packing group · ADR, IMDG, IATA | III |
| · 14.5 Environmental hazards: · Marine pollutant: | No Symbol (fish and tree) |
| · Special marking (ADR): · Special marking (IATA): | Symbol (fish and tree) Symbol (fish and tree) |
| · 14.6 Special precautions for user | Warning: Miscellaneous dangerous substances as articles. |
| · Hazard identification number (Kemler code): · EMS Number: | 90 F-A,S-F |
| · Stowage Category | A |
| · 14.7 Maritime transport in bulk according to IM instruments | 10 Not applicable. |
| Transport/Additional information: | |
| - | |
| · Limited quantities (LQ) · Excepted quantities (EQ) | 5L Code: E1 Maximum net quantity per inner packaging: 30 ml |
| · Transport category · Tunnel restriction code | Maximum net quantity per outer packaging: 1000 ml 3 (-) |
| · IMDG | |
| · Limited quantities (LQ) · Excepted quantities (EQ) | 5L Code: E1 Maximum net quantity per inner packaging: 30 ml |
| · UN "Model Regulation": | Maximum net quantity per outer packaging: 1000 ml UN 3082 ENVIRONMENTALLY HAZARDOU SUBSTANCE, LIQUID, N.O.S. (DI-URETHAN |

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OXY]ETHYL ACRYLATE), 9, III

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 E2 Hazardous to the Aquatic Environment
- Qualifying quantity (tonnes) for the application of lower-tier requirements 200 t
- · Qualifying quantity (tonnes) for the application of upper-tier requirements 500 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
- · Technical instructions (air):

| Class | Share in % |
|-------|------------|
| III | 2.5-10 |

- · Waterhazard class: Water hazard class 2 (Self-assessment): hazardous for water.
- · 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

• 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This Safety Data Sheets 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

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

H361f Suspected of damaging fertility.

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H411 Toxic to aquatic life with long lasting effects.

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

· Contact: Fr. R.Naveenakumar

Date of previous version: 20.03.2024

· 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)

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organisation

ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)

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

Acute Tox. 4: Acute toxicity - Category 4

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. 1A: Skin sensitisation - Category 1A

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

· * Data compared to the previous version altered.

ΙE