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

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

· 1.1 Product identifier

· Trade name: anaxGum Paint

- · Article number: 25203003, 25204003, 25202003, 25201003, 25205003
- 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* crown and bridge facing 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 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



· Signal word Warning

• Hazard-determining components of labelling: di-urethane dimethacrylate tetramethylene dimethacrylate

 $diphenyl (2,4,6-\ trimethyl benzoyl) phosphine\ oxide$ 

- · Hazard statements
- 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.

- *P273 Avoid release to the environment.*
- P280 Wear protective gloves.
- *P333+P313 If skin irritation or rash occurs: Get medical advice/attention.*
- *P321* Specific treatment (see on this label).
- *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



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#### Trade name: anaxGum Paint

| • | Signal | word | War | ning        |
|---|--------|------|-----|-------------|
|   | ~      |      |     | · · · · · o |

(Contd. of page 1)

| 0  |
|--|
| · Hazard-determining components of labelling:  |
| di-urethane dimethacrylate   |
| 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.   |
| P333+P313 If skin irritation or rash occurs: Get medical advice/attention.                         |
| P321 Specific treatment (see on this label).   |
| <i>P501</i> 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: Preparation of methacryl acid ester.

| <ul> <li>Dangerous compone</li> </ul> | ents: |    |  |
|---------------------------------------|-------|----|--|
| CIC (111)7 (0 (                       | 1.    | .1 |  |

| CAS: 41137-60-4   | CAS: 41137-60-4 di-urethane dimethacrylate                         |        |
|---|--|--------|
|   | 🚯 Aquatic Chronic 2, H411; 🚸 Skin Sens. 1B, H317                   |        |
| CAS: 2082-81-7  | tetramethylene dimethacrylate                                      | 10-25% |
| EINECS: 218-218-1   | 𝚯 Skin Sens. 1B, H317  |        |
| CAS: 75980-60-8   | diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide                   | <2.5%  |
| EINECS: 278-355-8   | 🗞 Repr. 2, H361f; 🕸 Aquatic Chronic 2, H411; 🚸 Skin Sens. 1B, H317 |        |
| ·SVHC   |  |        |
| 75080 60 8 diphamil(24.6 tuimathulbanzoul) phasenhina arida |  |        |

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 eve contact Rinse opened eve for several minutes under running water. Then consult a doctor.
- *After swallowing 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

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Water spray Foam

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: Wear self-contained respiratory protective device.

### **SECTION 6:** Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures 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. • 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: 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.

Close container immediately after use and protect product from light incidence.

· 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** 

· 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.

- 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 Wash hands before breaks and at the end of work.
- · 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.

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<sup>· 8.1</sup> Control parameters

<sup>· 8.2</sup> Exposure controls

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#### Trade name: anaxGum Paint

0,11 mm

Penetration time 10 min.

· Eye/face protection Goggles recommended during refilling.

## **SECTION 9: Physical and chemical properties**

| 9.1 Information on basic physical and chemical p     | roperties   |  |
|--|---|--|
| General Information                                  |   |  |
| · Physical state                                     | Fluid   |  |
| · Colour:  | According to product specification                |  |
| · Odour:   | Weak, characteristic                              |  |
| · Odour threshold:                                   | Not determined.                                   |  |
| · Melting point/freezing point:                      | undetermined                                      |  |
| · Boiling point or initial boiling point and boiling |   |  |
| range  | 251 °C (41137-60-4 di-urethane dimethacrylate)    |  |
| · Flammability                                       | Not applicable.                                   |  |
| · Lower and upper explosion limit                    |   |  |
| · Lower:   | Not determined.                                   |  |
| · Upper:   | Not determined.                                   |  |
| · Flash point:                                       | 113 °C (2082-81-7 tetramethylene dimethacrylate)  |  |
|  | Not determined.                                   |  |
| Decomposition temperature:                           |   |  |
| · pH   | Mixture is non-soluble (in water).                |  |
| 17   | Not determined.                                   |  |
| Viscosity:   |   |  |
| Kinematic viscosity                                  | Not determined.                                   |  |
| · dynamic:   | Not determined.                                   |  |
| · Solubility   |   |  |
| · Water:   | Fully miscible                                    |  |
| · Partition coefficient n-octanol/water (log value)  | Not determined.                                   |  |
| · Vapour pressure at 110 °C:                         | 1.3 hPa (2082-81-7 tetramethylene dimethacrylate) |  |
| · 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    | •   |  |
|  | u   |  |
| environment, and on safety.                          | Due due t is not selfiquiting                     |  |
| · Ignition temperature:                              | Product is not selfigniting.                      |  |
| Explosive properties:                                | Product does not present an explosion hazard.     |  |
| Change in condition                                  |   |  |
| · Evaporation rate                                   | Not determined.                                   |  |
| · Information with regard to physical hazard classe  | <i>'S</i>   |  |
| · 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  |  |
| Sey-neuting substances and mixtures                  | r 010   |  |
|  |   |  |

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Trade name: anaxGum Paint

|          | (Contd. of page 4)                   |
|----------|--------------------------------------|
| lammable |                                      |
| Void     |                                      |
|          | Void<br>Void<br>Void<br>Void<br>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
- Photoreactive
- Exothermic polymerization
- $\cdot$  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 Based on available data, the classification criteria are not met.
- · 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.
- · 11.2 Information on other hazards

#### · Endocrine disrupting properties

128-37-0 Butylated hydroxytoluene

List II

#### **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.

• 12.6 Endocrine disrupting properties For information on endocrine disrupting properties see section 11.

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<sup>·</sup> vPvB: Not applicable.

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#### Trade name: anaxGum Paint

· 12.7 Other adverse effects

• Remark: Toxic for 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.

Also poisonous for fish and plankton in water bodies.

Toxic for 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.

· Uncleaned packaging:

· Recommendation:

Disposal must be made according to official regulations.

Packagings that may not be cleansed are to be disposed of in the same manner as the product. • **Recommended cleansing agents:** Alcohol

## **SECTION 14: Transport information**

| · 14.1 UN number or ID number<br>· ADR, IMDG, IATA | UN3082   |
|--|--|
| · 14.2 UN proper shipping name<br>· ADR            | 3082 ENVIRONMENTALLY HAZARDOUS   |
| · IMDG   | SUBSTANCE, LIQUID, N.O.S. (di-urethan<br>dimethacrylate)<br>ENVIRONMENTALLY HAZARDOUS SUBSTANCE<br>LIQUID, N.O.S. (di-urethane dimethacrylate<br>diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide) |
| ·IATA  | MARINE POLLUTANT<br>ENVIRONMENTALLY HAZARDOUS SUBSTANCE<br>LIQUID, N.O.S. (di-urethane dimethacrylate)   |
| · 14.3 Transport hazard class(es)                  |  |
|  |  |
| · Class<br>· Label                                 | 9 (M6) Miscellaneous dangerous substances and article.<br>9  |
| · IMDG, IATA                                       |  |
| · Class<br>· Label                                 | 9 Miscellaneous dangerous substances and articles.<br>9  |
|  | (Contd. on page  |

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|   | (Contd. of page                                   |
|---|---|
| 14.4 Packing group<br>ADR, IMDG, IATA           | III   |
| ADK, IMDG, IATA                                 | 111   |
| 14.5 Environmental hazards:                     |   |
| Marine pollutant:                               | Symbol (fish and tree)                            |
| Special marking (ADR):                          | Symbol (fish and tree)                            |
| Special marking (IATA):                         | Symbol (fish and tree)                            |
| 14.6 Special precautions for user               | Warning: Miscellaneous dangerous substances an    |
|   | articles.   |
| Hazard identification number (Kemler code):     | 90  |
| EMS Number:                                     | F-A,S-F   |
| Stowage Category                                | A   |
| 14.7 Maritime transport in bulk according to IM | 10  |
| instruments                                     | Not applicable.                                   |
| Transport/Additional information:               |   |
| ADR   |   |
| Limited quantities (LQ)                         | 5L  |
| Excepted quantities (EQ)                        | Code: E1  |
|   | Maximum net quantity per inner packaging: 30 ml   |
|   | Maximum net quantity per outer packaging: 1000 ml |
| Transport category                              | 3   |
| Tunnel restriction code                         | (-)   |
| IMDG  |   |
| Limited quantities (LQ)                         | 5L  |
| Excepted quantities (EQ)                        | Code: E1  |
|   | Maximum net quantity per inner packaging: 30 ml   |
|   | Maximum net quantity per outer packaging: 1000 ml |
| UN "Model Regulation":                          | UN 3082 ENVIRONMENTALLY HAZARDOU                  |
|   | SUBSTANCE, LIQUID, N.O.S. (DI-URETHAN             |
|   | DIMETHACRYLATE), 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

 $\cdot$  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.

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· Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and

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Trade name: anaxGum Paint

None of the ingredients is listed.

third countries in drug precursors

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

| intra countries in arug precursors   |
|--|
| None of the ingredients is listed.   |
| · National regulations   |
| · Technical instructions (air):  |
| Class Share in %   |
| III 10-25  |
|  |
| • Waterhazard class: Water hazard class 1 (Self-assessment): slightly 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.<br>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   |
| H317 May cause an allergic skin reaction.  |
| H361f Suspected of damaging fertility.   |
| H411 Toxic to aquatic life with long lasting effects.  |
| • Department issuing SDS: R&D, MANI MEDICAL GERMANY GmbH   |
| • Contact: Fr. R.Naveenakumar<br>• Version number of previous version: 2   |
| · 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)<br>IMDG: International Maritime Code for Dangerous Goods                                    |
| IATA: International Air Transport Association<br>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<br>CAS: Chemical Abstracts Service (division of the American Chemical Society)           |
| LC50: Lethal concentration, 50 percent   |
| LD50: Lethal dose, 50 percent<br>PBT: Persistent, Bioaccumulative and Toxic  |
| SVHC: Substances of Very High Concern  |
| vPvB: very Persistent and very Bioaccumulative<br>Skin Sens. 1: Skin sensitisation – Category 1  |
| Skin Sens. 1B: Skin sensitisation – Category 1B  |
| Repr. 2: Reproductive toxicity – Category 2<br>Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2 |
| I I I I I I I I I I I I I I I I I I I  |
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|  |