MEGADENTA Dentalprodukte

Safety Data Sheet

according to Regulation (EC) No 1907/2006

MEGATRAY

Revision date: 25.07.2018

Product code: 100

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

1.1. Product identifier

MEGATRAY

Product group:

tray material

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

Light-cure impression tray material for the fabrication of custom trays, bite plates and base plates for needle-point tracing.

1.3. Details of the supplier of the safety data sheet

| Company name: | MEGADENTA Dentalprodukte GmbH | |
|--------------------------|--|-------------------------|
| Street: | Carl-Eschebach-Str. 1A | |
| Place: | 01454 Radeberg, Germany | |
| Telephone: | +49-3528 4530 | Telefax: +49-3528 45321 |
| e-mail: | info@megadenta.de | |
| Internet: | www.megadenta.de | |
| 1.4. Emergency telephone | +49-3528 453-0 (just during usual office | time: GMT+1) |

number:

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories: Acute toxicity: Acute Tox. 4 Respiratory or skin sensitisation: Skin Sens. 1 Hazard Statements: Harmful in contact with skin. May cause an allergic skin reaction.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling

Diurethane Dimethacrylate Aliphatic Urethane Acrylate 4-methoxyphenol, hydroquinone monomethyl ether, mequinol

Signal word:

Pictograms:



Warning

Hazard statements

| H312 | Harmful in contact with skin. |
|------|--------------------------------------|
| H317 | May cause an allergic skin reaction. |

Precautionary statements

| P261 | Avoid breathing dust/fume/gas/mist/vapours/spray. |
|-----------|--|
| P272 | Contaminated work clothing should not be allowed out of the workplace. |
| P280 | Wear protective gloves/protective clothing/eye protection/face protection. |
| P302+P352 | IF ON SKIN: Wash with plenty of water. |
| P312 | Call a POISON CENTER/doctor if you feel unwell. |
| P333+P313 | If skin irritation or rash occurs: Get medical advice/attention. |
| | |

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Take off contaminated clothing and wash it before reuse.

Special labelling of certain mixtures

EUH204 Contains isocyanates. May produce an allergic reaction.

2.3. Other hazards

No information available.

Water hazard class 2 - Hazardous to the aquatic environment.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Matrix of polyfunctional methacrylates, glass, photochemical initiators and petroleum jelly.

Hazardous components

| CAS No | Chemical name | | | Quantity |
|------------|---|----------|------------------|-------------|
| | EC No | Index No | REACH No | |
| | Classification according to Regulation (EC) No. 1272/2008 [CLP] | | | |
| 72869-86-4 | Diurethane Dimethacrylate | | | 10 - < 15 % |
| | 276-957-5 | | | |
| | Skin Sens. 1; H317 | | | |
| 21245-02-3 | 2-Ethylhexyl-p-dimethylaminobenzo | pate | | < 0.1 % |
| | 244-289-3 | | 01-2120766649-35 | |
| | Repr. 1B, Aquatic Acute 1 (M-Factor = 10); H360 H400 | | | |

Full text of H and EUH statements: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

Polymerized material is non-hazardous.

After inhalation

Provide fresh air. If breathing is irregular or stopped, administer artificial respiration. Medical treatment necessary. Not applicable as all components have got a boiling point above 250°C.

After contact with skin

After contact with skin, wash immediately with polyethylene glycol, followed by plenty of water. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary. After contact with skin: wash with water and soap.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water. In case of eye irritation consult an ophthalmologist.

After ingestion

Rinse mouth immediately and drink plenty of water.

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

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Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

Non-flammable.

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

Additional information

Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

If handled uncovered, arrangements with local exhaust ventilation have to be used. Avoid dust formation. Do not breathe dust. The unprotected substance must not be exposed to the light before processing, because it polymerizes. Only adequately trained personnel should handle this product. For use in dentistry only.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed. Light-sensitive substance. Protect from exposure to the light. Store not above 25°C.

Advice on storage compatibility

No special measures are necessary.

7.3. Specific end use(s)

Megatray is a light curing tray material for the fabrication of individual custom trays with extremely high dimensional stability.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters



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DNEL/DMEL values

| CAS No | Substance | | | | | |
|---|---|----------------|----------|------------------|--|--|
| DNEL type | | Exposure route | Effect | Value | | |
| 21245-02-3 2-Ethylhexyl-p-dimethylaminobenzoate | | | | - | | |
| Worker DNEL, | Worker DNEL, long-terminhalationsystemic0,5 mg/m³ | | | | | |
| Worker DNEL, long-term | | dermal | systemic | 6,7 mg/kg bw/day | | |
| 3 | | | | | | |

PNEC values

| CAS No | Substance | | | |
|--|--------------------------------------|-------------|--|--|
| Environmenta | Environmental compartment | | | |
| 21245-02-3 | 2-Ethylhexyl-p-dimethylaminobenzoate | | | |
| Freshwater 0 mg/l | | | | |
| Freshwater (intermittent releases) 0 mg/l | | | | |
| Marine water | | 0 mg/l | | |
| Freshwater sediment | | 0,042 mg/kg | | |
| Marine sediment | | 0,004 mg/kg | | |
| Micro-organisms in sewage treatment plants (STP) | | 100 mg/l | | |
| Soil | 0,008 mg/kg | | | |

Additional advice on limit values

To date, no national critical limit values exist.

8.2. Exposure controls

Appropriate engineering controls

Use a suitable dust extraction when grinding the polymerized plate.

Protective and hygiene measures

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat or drink.

Eye/face protection

Wear eye protection/face protection.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Skin protection

Wear suitable protective clothing.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| Physical state: | paste | |
|-----------------|------------------------------------|----------------|
| Colour: | white-gray transparent, pink, blue | |
| Odour: | characteristic | |
| pH-Value: | | not applicable |

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| Changes in the physical state | | |
| Melting point: | -20 °C | |
| Initial boiling point and boiling range: | 200 °C | |
| Flash point: | > 100 °C | |
| Flammability | | |
| Solid: | not applicable | |
| Gas: | not applicable | |
| Lower explosion limits: | not determined | |
| Upper explosion limits: | not determined | |
| Ignition temperature: | 445 °C | |
| Auto-ignition temperature | | |
| Solid: | not determined | |
| Gas: | not applicable | |
| Decomposition temperature: | not determined | |
| Oxidizing properties Not oxidising. | | |
| Vapour pressure: (at 20 °C) | 1 hPa | |
| Density: | 1,89 g/cm³ | |
| Water solubility: | insoluble | |
| Solubility in other solvents not determined | | |
| Partition coefficient: | not determined | |
| Flow time: | Data not available | |
| Vapour density: | not determined | |
| Evaporation rate: | not determined | |
| 2. Other information | | |
| Solid content: | 76,15 % | |

SECTION 10: Stability and reactivity

10.1. Reactivity

Material will polymerize when exposed to daylight.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

Direct light.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

With incomplete combustion toxic gases such as carbon monoxide may be generated.

SECTION 11: Toxicological information

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11.1. Information on toxicological effects

Acute toxicity

Harmful in contact with skin.

ATEmix tested

| | Dose | Species | Source |
|--------------|------------|---------|--------|
| LD50, oral | 5000 mg/kg | Rat | |
| LD50, dermal | 2000 mg/kg | Rat | |

| CAS No | Chemical name | | | | | | |
|------------|--------------------------------------|---------------------|---------|--------|--------|--|--|
| | Exposure route | Dose | Species | Source | Method | | |
| 21245-02-3 | 2-Ethylhexyl-p-dimethylaminobenzoate | | | | | | |
| | oral | LD50 14900 mg/kg | Rat | | | | |
| | dermal | LD50 >2000 mg/kg | Rat | | | | |

Irritation and corrosivity

Based on available data, the classification criteria are not met.

Sensitising effects

May cause an allergic skin reaction. (Diurethane Dimethacrylate)

Carcinogenic/mutagenic/toxic effects for reproduction

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 information on tests

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 12: Ecological information

12.1. Toxicity

The product is not: Ecotoxic.

| CAS No | Chemical name | | | | | | |
|------------|--------------------------------------|-----------------|-------|-----------|------------------------------------|--------------|--------|
| | Aquatic toxicity | Dose | | [h] [d] | Species | Source | Method |
| 21245-02-3 | 2-Ethylhexyl-p-dimethylaminobenzoate | | | | | | |
| | Acute fish toxicity | LC50 0 mg/l | ,235 | 96 h | | Manufacturer | |
| | Acute algae toxicity | ErC50 > mg/l | 0,015 | | Pseudokirchneriella subcapitata | | |
| | Acute crustacea toxicity | EC50 > mg/l | 0,031 | 48 h | Daphnia magna | | |
| | Acute bacteria toxicity | (>1000 mg/l) | | 3 h | | | |

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.



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Partition coefficient n-octanol/water

| CAS No | Chemical name | Log Pow |
|------------|--------------------------------------|---------|
| 72869-86-4 | Diurethane Dimethacrylate | 3 |
| 21245-02-3 | 2-Ethylhexyl-p-dimethylaminobenzoate | >6,2 |

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The product has not been tested.

12.6. Other adverse effects

No information available.

Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Water hazard class 2 - Hazardous to the aquatic environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

200139

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation.

Waste disposal number of waste from residues/unused products

MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; separately collected fractions (except 15 01); Plastics

Waste disposal number of used product

200139 MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; separately collected fractions (except 15 01); Plastics

Contaminated packaging

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

14.6. Special precautions for user

No information available.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

| Enclosure and an efficiency | |
|---|--|
| National regulatory information | |
| 2004/42/EC (VOC): Information according to 2012/18/EU (SEVESO III): | 12,104 % (228,766 g/l) Not subject to 2012/18/EU (SEVESO III) |
| 2010/75/EU (VOC): | 11,38 % (215,082 g/l) |
| | |

Employment restrictions:

Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC).

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| Water contaminating class (D): Skin resorption/Sensitization: | 3 - highly water contaminating Permeates easily through outer skin and causes poisoning. Causes allergic hypersensitivity reactions. | | | |
| 15.2. Chemical safety assessment | | | | |

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Changes

This data sheet contains changes from the previous version in section(s): 2,6,15.

Abbreviations and acronyms

ADR: Accord européen sur le transport 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 Harmonized 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 LC50: Lethal concentration, 50% LD50: Lethal dose, 50%

Classification for mixtures and used evaluation method according to Regulation (EC) No. 1272/2008 [CLP]

| Classification | Classification procedure |
|--------------------|--------------------------|
| Acute Tox. 4; H312 | On basis of test data |
| Skin Sens. 1; H317 | Calculation method |

Relevant H and EUH statements (number and full text)

| H312 | Harmful in contact with skin. |
|--------|---|
| H317 | May cause an allergic skin reaction. |
| H360 | May damage fertility or the unborn child. |
| H400 | Very toxic to aquatic life. |
| EUH204 | Contains isocyanates. May produce an allergic reaction. |
| | |

Further Information

The information is based on present level of our knowledge. It does not, however, give assurances of product properties and establishes no contract legal rights. The receiver of our product is singulary responsible for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)