MEGADENTA Dentalprodukte

Safety Data Sheet

according to Regulation (EC) No 1907/2006

FINO impression tray / FINO base plate

Revision date: 24.10.2024

Product code: 14975/14977/14978

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

1.1. Product identifier

Megatray/ Megatray Basisplatte

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)	

<u>number:</u>

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GB CLP Regulation

Skin Sens. 1; H317 Aquatic Chronic 2; H411

Full text of hazard statements: see SECTION 16.

2.2. Label elements

GB CLP Regulation

Hazard components for labelling Diurethane Dimethacrylate

Aliphatic Urethane Acrylate

Signal word:

Pictograms:



Warning

Hazard statements

May cause an allergic skin reaction. Toxic to aquatic life with long lasting effects.

Precautionary statements

Avoid breathing dust/fume/gas/mist/vapours/spray. Contaminated work clothing should not be allowed out of the workplace. Avoid release to the environment. Wear protective gloves/protective clothing. IF ON SKIN: Wash with plenty of water. Call a POISON CENTER/doctor if you feel unwell. Specific treatment (see ... on this label). If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse. Dispose of contents/container to

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Special labelling of certain mixtures

Restricted to professional users.

2.3. Other hazards

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.

Relevant ingredients

CAS No	Chemical name		Quantity	
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
72869-86-4	Diurethane Dimethacrylate		10 - < 15 %	
	276-957-5		01-2120751202-68	
	Skin Sens. 1, Aquatic Chronic 2; H317 H411			

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 plenty of water and soap. 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 1 glass of 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

Suitable extinguishing media

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

5.2. Special hazards arising from the substance or mixture

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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

General advice

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

For cleaning up

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

Other information

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.

Advice on general occupational hygiene

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, drink, smoke, sniff. 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.

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.

Hints on joint storage

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

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8.1. Control parameters

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.

Individual protection measures, such as personal protective equipment

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

Use of 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:	transparent, white-gray, pink, blue, green	
Odour:	characteristic	
		Test method
Melting point/freezing point:	< -20 °C	
Boiling point or initial boiling point and	200 °C	
boiling range:		
Flammability:	not applicable	
	not applicable	
Lower explosion limits:	not determined	VDI 2263
Upper explosion limits:	not determined	VDI 2263
Flash point:	> 100 °C	
Auto-ignition temperature:	445 °C	
Decomposition temperature:	not determined	
pH-Value:	not applicable	
Viscosity / kinematic:	not applicable	
Water solubility:	insoluble	
Solubility in other solvents		
not determined		
Partition coefficient n-octanol/water:	not determined	
Vapour pressure: (at 20 °C)	1 hPa	
Density:	1,89 g/cm³	
Relative vapour density:	not determined	
Particle characteristics:	not determined	
2. Other information		

9.2. Other information

Information with regard to physical hazard classes

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Explosive properties The product is not: Explosive. Oxidizing properties The product is not: oxidising.

Other safety characteristics

Evaporation rate: Solid content: Flow time: not determined 76,15 % Data not available

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

11.1. Information on hazard classes as defined in GB CLP Regulation

Acute toxicity

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

ATEmix tested

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

ATEmix calculated

ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

Irritation and corrosivity

Skin corrosion/irritation: Based on available data, the classification criteria are not met. Serious eye damage/eye irritation: 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

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

Other information

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

SECTION 12: Ecological information

12.1. Toxicity

Toxic to aquatic life with long lasting effects.

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
72869-86-4	Diurethane Dimethacrylate	3

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH.

The product has not been tested.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. 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

Disposal recommendations

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.

List of Wastes Code - residues/unused products

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

List of Wastes Code - 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.



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14.7. Maritime transport in bulk according to IMO instruments

not applicable

SECTION 15: Regulatory information

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

EU regulatory information

Lo regulatory miormation	
Restrictions on use (REACH, annex XVII Entry 75):
Directive 2010/75/EU on industrial emissions:	11,38 % (215,082 g/l)
Directive 2004/42/EC on VOC in paints and varnishes:	12,104 % (228,766 g/l)
Information according to Directive 2012/18/EU (SEVESO III):	Not subject to 2012/18/EU (SEVESO III)
National regulatory information	
Employment restrictions:	Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).
Water hazard class (D):	3 - highly hazardous to water
Skin resorption/Sensitization:	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.

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Abbreviations and acronyms Skin Sens: Skin sensitisation Aquatic Chronic: Chronic aquatic hazard 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% CLP: Classification, labelling and Packaging REACH: Registration, Evaluation and Authorization of Chemicals GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals **UN: United Nations** EC/EEC: European Community/European Economic Community EU: European Union DNEL: Derived No Effect Level DMEL: Derived Minimal Effect Level PNEC: Predicted No Effect Concentration ATE: Acute toxicity estimate LL50: Lethal loading, 50% EL50: Effect loading, 50% EC50: Effective Concentration 50% ErC50: Effective Concentration 50%, growth rate NOEC: No Observed Effect Concentration BCF: Bio-concentration factor PBT: persistent, bioaccumulative, toxic vPvB: very persistent, very bioaccumulative M-factor: Multiplying factor MARPOL: International Convention for the Prevention of Marine Pollution from Ships IBC: Intermediate Bulk Container VOC: volatile organic compound SVHC: Substance of Very High Concern For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

Relevant H and EUH statements (number and full text)

May cause an allergic skin reaction.

Toxic to aquatic life with long lasting effects.

Further Information

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

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