according to Regulation (EC) No 1907/2006

Revision date: 11.06.2021

Product code: 0000LC018

Page 1 of 8

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

# 1.1. Product identifier

LC base plate

Product group:

Dental tray material (medical device)

# 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 nam	ne: MEGADENTA Dentalprodukte GmbH	Exclusive distribution: Müller-Omicron GmbH & Co.KG
Street:	Carl-Eschebach-Str. 1A	Schlosserstr. 1
Place:	01454 Radeberg, Germany	D-51789 Lindlar, Germany
Telephone: e-mail: Internet:	+49-3528 4530 info@megadenta.de www.megadenta.de	Tel. +49 (0) 2266 4742-0 info@mueller-omicron.de www.mueller-omicron.com

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: Respiratory or skin sensitisation: Skin Sens. 1 Hazard Statements: May cause an allergic skin reaction.

# 2.2. Label elements

#### Regulation (EC) No. 1272/2008

#### Hazard components for labelling

Diurethane Dimethacrylate Aliphatic Urethane Acrylate Warning

Signal word:

**Pictograms:** 



#### Hazard statements

May cause an allergic skin reaction.

# **Precautionary statements**

Protect from sunlight.

If skin irritation or rash occurs: Get medical advice/attention. Contaminated work clothing should not be allowed out of the workplace. Avoid breathing dust/fume/gas/mist/vapours/spray. Wear protective gloves/protective clothing/eye protection/face protection/hearing protection. IF ON SKIN: Wash with plenty of water.

# Special labelling of certain mixtures

Restricted to professional users.

according to Regulation (EC) No 1907/2006

# LC-base plate

Revision date: 11.06.2021

Product code: 0000LC018

Page 2 of 8

# 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	
	GHS Classification			
72869-86-4	Diurethane Dimethacrylate			10 - < 15 %
	276-957-5		01-2120751202-68	
	Skin Sens. 1; H317			
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide			< 0.1 %
	278-355-8	015-203-00-X		
Repr. 2; H361f				

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

# Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
	Specific Conc. Limits, M-factors and ATE		
75980-60-8	278-355-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	< 0.1 %
	inhalation: Da	ta lacking (gases); oral: LD50 = >5000 mg/kg	

# **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**

according to Regulation (EC) No 1907/2006

# LC-base plate

Revision date: 11.06.2021

Product code: 0000LC018

Page 3 of 8

# 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

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

#### **General measures**

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

#### 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.

#### 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**

# 8.1. Control parameters

according to Regulation (EC) No 1907/2006

LC-base plate

Revision date: 11.06.2021

Product code: 0000LC018

Page 4 of 8

# **DNEL/DMEL** values

CAS No	Substance			
DNEL type		Exposure route	Effect	Value
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide			
Worker DNEI	_, long-term	dermal	systemic	0,233 mg/kg bw/day
Consumer DI	NEL, long-term	inhalation	systemic	0,145 mg/m <sup>3</sup>
Consumer Di	NEL, long-term	dermal	systemic	0,0833 mg/kg bw/day
Consumer Di	NEL, long-term	oral	systemic	0,0833 mg/kg bw/day

# 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/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: Colour:	paste white-gray transparent, pink, blue	
Odour:	characteristic	
		Test method
pH-Value:	not applicable	
Changes in the physical state		
Melting point:	-20 °C	
Boiling point or initial boiling point and boiling range:	200 °C	
Flash point:	> 100 °C	
Flammability Solid/liquid:	not applicable	

according to Regulation (EC) No 1907/2006

	LC-base plate	
Revision date: 11.06.2021	Product code: 0000LC018	Page 5 of 8
Gas:	not applicable	
Lower explosion limits:	not determined	VDI 2263
Upper explosion limits:	not determined	VDI 2263
Auto-ignition temperature:	445 °C	
<b>Self-ignition temperature</b> Solid: Gas:	not determined 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 n-octanol/water:	not determined	
Flow time:	Data not available	
Relative vapour density:	not determined	
Evaporation rate:	not determined	
9.2. 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**

# 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.

#### **ATEmix tested**

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

according to Regulation (EC) No 1907/2006

# LC-base plate

Revision date: 11.06.2021

Product code: 0000LC018

Page 6 of 8

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
75980-60-8	liphenyl(2,4,6-trimethylbenzoyl)phosphine oxide				
	oral	LD50 >5000 mg/kg	Rat		
	inhalation	Data lacking			

#### 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
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide						
	Acute fish toxicity	LC50	6,53 mg/l	96 h	Oryzias latipes		
	Acute algae toxicity	ErC50	2,01 mg/l		Pseudokirchneriella subcapitata	OECD 201	
	Acute crustacea toxicity	EC50	3,53 mg/l	48 h	Daphnia magna	OECD Guideline 202	

# 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
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	3,257

# 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.

according to Regulation (EC) No 1907/2006

# LC-base plate

Revision date: 11.06.2021

Product code: 0000LC018

Page 7 of 8

# 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.

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

2010/75/EU (VOC):	11,38 % (215,082 g/l)
2004/42/EC (VOC):	12,104 % (228,766 g/l)
Information according to 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**

#### Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route

# according to Regulation (EC) No 1907/2006

# LC-base plate

Revision date: 11.06.2021

Product code: 0000LC018

Page 8 of 8

(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%

# Relevant H and EUH statements (number and full text)

May cause an allergic skin reaction. Suspected of damaging fertility.

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