according to Regulation (EC) No 1907/2006

## **Combitray LC**

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

### 1.1. Product identifier

Combitray LC

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

#### Use of the substance/mixture

The product is intended for professional use.

#### Uses advised against

Do not use for private purposes (household).

#### 1.3. Details of the supplier of the safety data sheet

Company name: Merz Dental GmbH

Street: Kieferweg 1

Place: D-24321 Lütjenburg (GERMANY)

Telephone: +49-(0)4381-403-0 Telefax: +49-(0)4381-403-100

e-mail: info@merz-dental.de

Contact person: Dipl. Chem Dr. Thomas Panther Telephone: +49-(0)4381-403-448

e-mail: Thomas.Panther@merz-dental.de

Internet: www.merz-dental.de

Responsible Department: Qualitätssicherung (Quality Assurance)

**1.4. Emergency telephone** +49-(0)551-19240 (Giftinformationszentrum-Nord)

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

Hexanedioic acid, polymer with 1,2-ethanediol and 5-isocyanato-1-

(isocyanatomethyl)-1,3,3-trimethylcyclohexane, 2-hydroxyethyl acrylate-blocked

7,7,9-(resp.7,9,9-) Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadekan-1,16-dioldimethacrylat

Signal word: Warning

Pictograms:



### **Hazard statements**

H317 May cause an allergic skin reaction.

## **Precautionary statements**

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

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 IF ON SKIN: Wash with plenty of water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

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## Special labelling of certain mixtures

15 - < 20 % of the mixture consists of ingredient(s) of unknown acute toxicity (dermal).

#### 2.3. Other hazards

No information available.

## **SECTION 3: Composition/information on ingredients**

#### 3.2. Mixtures

#### **Chemical characterization**

Hexanedioic acid, polymer with 1,2-ethanediol and 5-isocyanato-1- (isocyanatomethyl)-1,3,3-trimethylcyclohexane, 2-hydroxyethyl acrylate-blocked

#### **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	7,7,9-(resp.7,9,9-) Trimethyl-4,13-di	7,9-(resp.7,9,9-) Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadekan-1,16-dioldimethacrylat				
	Skin Sens. 1, Aquatic Chronic 3; H317 H412					
71549-84-3	Hexanedioic acid, polymer with 1,2-ethanediol and 5-isocyanato-1- (isocyanatomethyl)-1,3,3-trimethylcyclohexane, 2-hydroxyethyl acrylate-blocked					
	Skin Sens. 1; H317					

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

# **SECTION 4: First aid measures**

#### 4.1. Description of first aid measures

#### **General information**

When in doubt or if symptoms are observed, get medical advice.

### After inhalation

If major quantitiy of dust is swallowed or inhaled, immediately drink:

#### After contact with skin

After contact with skin, wash immediately with polyethylene glycol, followed by plenty of water. If skin irritation occurs: Get medical advice/attention.

#### 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

Inhalation of dust may cause irritation of the respiratory system.

# 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. Foam, Carbon dioxide (CO2), Dry extinguishing powder, Extinguishing powder.

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## Unsuitable extinguishing media

High power water jet

### 5.2. Special hazards arising from the substance or mixture

No information available.

#### Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water. Do not inhale explosion and combustion gases.

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

#### 6.1. Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Do not breathe dust. Avoid contact with eyes and skin. Wear suitable protective clothing. (Protective clothing.: Dust protection eye glasses. Wear protective gloves.) After contact with skin, wash immediately with plenty of water and soap.

#### 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 product is intended for professional use. Keep out of the reach of children.

### Advice on protection against fire and explosion

No special fire protection measures are necessary.

### Further information on handling

Can polymerise exothermically if heated, exposed to air, sunlight or by addition or free radical initiators.

### 7.2. Conditions for safe storage, including any incompatibilities

### Requirements for storage rooms and vessels

Keep container tightly closed. Avoid: UV-radiation/sunlight

#### Advice on storage compatibility

No special measures are necessary.

# 7.3. Specific end use(s)

for professional use only Observe instructions for use.

## **SECTION 8: Exposure controls/personal protection**

## 8.1. Control parameters

### Additional advice on limit values

Personal air monitoring.

# 8.2. Exposure controls

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#### Appropriate engineering controls

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray. Preferably use hand tools or low-speed tools equipped, if necessary, with an appropriate dust-extraction facility. If high-speed tools are used, they should always be equipped with such a facility.

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

#### Eye/face protection

Dust protection eye glasses

#### 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: solid: / Paste
Colour: pink, blue
Odour: characteristic

Test method

pH-Value: not applicable

Changes in the physical state

Melting point: not determined

Initial boiling point and boiling range: > 250 °C OECD 103

Pour point: < -20 °C
Flash point: > 150 °C

Flammability

Solid: not determined
Gas: not applicable

**Explosive properties** 

none

Lower explosion limits:

Upper explosion limits:

Inot applicable
Inot applicable
Inot determined

**Auto-ignition temperature** 

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Solid: not determined Gas: not applicable

Decomposition temperature: not determined

**Oxidizing properties** 

Not oxidizing.

Vapour pressure: <1 hPa

(at 20 °C)

Density (at 20 °C): 2,1 g/cm³
Water solubility: practically insoluble

Solubility in other solvents

not determined

Partition coefficient: not determined

Vapour density: not determined

Evaporation rate: not determined

9.2. Other information

Solid content: not determined

# **SECTION 10: Stability and reactivity**

#### 10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

### 10.2. Chemical stability

Can polymerise exothermically if heated, exposed to air, sunlight or by addition or free radical initiators.

## 10.3. Possibility of hazardous reactions

No known hazardous reactions.

## 10.4. Conditions to avoid

UV-radiation/sunlight

#### 10.5. Incompatible materials

Polymerization with heat evolution may occur in the presence of radical forming substances (e.g. peroxides), reducing substances, and/or heavy metal ions.

#### 10.6. Hazardous decomposition products

No known hazardous decomposition products.

## **SECTION 11: Toxicological information**

#### 11.1. Information on toxicological effects

## Toxicocinetics, metabolism and distribution

No information available.

## **Acute toxicity**

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

## ATEmix tested

Dose Species Source
D50, oral 5000 mg/kg Rat

 LD50, oral
 5000 mg/kg
 Rat

 LD50, dermal
 2000 mg/kg
 Rat

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CAS No	Chemical name							
	Exposure route	Dose	Species	Source	Method			
72869-86-4	7,7,9-(resp.7,9,9-) Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadekan-1,16-dioldimethacrylat							
	oral	LD50 2000 mg/kg	Rat	OECD 401, limit test				
	dermal	Data lacking						
	inhalative	Data lacking						
71549-84-3	Hexanedioic acid, polymer with 1,2-ethanediol and 5-isocyanato-1- (isocyanatomethyl)-1,3,3-trimethylcyclohexane, 2-hydroxyethyl acrylate-blocked							
	oral	LD50 2000 mg/kg	Rat	OECD 401, limit test				
	dermal	LD50 > 2000 mg/kg	Rat	Supplier				
	inhalative	Data lacking						

#### Irritation and corrosivity

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

## Sensitising effects

May cause an allergic skin reaction. (7,7,9-(resp.7,9,9-)

Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadekan-1,16-dioldimethacrylat; Hexanedioic acid, polymer with 1,2-ethanediol and 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane, 2-hydroxyethyl acrylate-blocked)

#### Carcinogenic/mutagenic/toxic effects for reproduction

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

No information available.

#### STOT-single exposure

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

No information available.

# STOT-repeated exposure

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

No information available.

## **Aspiration hazard**

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

No information available.

### Specific effects in experiment on an animal

No information available.

### **Practical experience**

### Observations relevant to classification

No information available.

### Other observations

No information available.

## **SECTION 12: Ecological information**

## 12.1. Toxicity

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CAS No	Chemical name							
	Aquatic toxicity	Dose	[h]   [d]	Species	Source	Method		
72869-86-4	7,7,9-(resp.7,9,9-) Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadekan-1,16-dioldimethacrylat							
	Acute fish toxicity	LC50 10,1 mg/l	96 h	Brachydanio rerio	OECD 203			
71549-84-3	Hexanedioic acid, polymer with 1,2-ethanediol and 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane, 2-hydroxyethyl acrylate-blocked							
	Acute fish toxicity	LC50 10,1 mg/l	96 h	Brachydanio rerio	OECD 203			

### 12.2. Persistence and degradability

The product has not been tested.

#### 12.3. Bioaccumulative potential

The product has not been tested.

### 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**

Avoid release to the environment. Do not allow to enter into surface water or drains.

### **SECTION 13: Disposal considerations**

## 13.1. Waste treatment methods

### Advice on disposal

Dispose of waste according to applicable legislation.

## Waste disposal number of waste from 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

## 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

## Waste disposal number of contaminated packaging

150101 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND

PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately

collected municipal packaging waste); paper and cardboard packaging

## Contaminated packaging

Wash with plenty of water. Completely emptied packages can be recycled.

## **SECTION 14: Transport information**

## Land transport (ADR/RID)

14.1. UN number:No dangerous good in sense of this transport regulation.14.2. UN proper shipping name:No dangerous good in sense of this transport regulation.14.3. Transport hazard class(es):No dangerous good in sense of this transport regulation.14.4. Packing group:No dangerous good in sense of this transport regulation.

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Inland waterways transport (ADN)

14.1. UN number:No dangerous good in sense of this transport regulation.14.2. UN proper shipping name:No dangerous good in sense of this transport regulation.

Other applicable information (inland waterways transport)

No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

14.1. UN number:No dangerous good in sense of this transport regulation.14.2. UN proper shipping name:No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number: No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: no

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

2010/75/EU (VOC): not applicable 2004/42/EC (VOC): not applicable

**Additional information** 

To follow: 850/2004/EC, 79/117/EEC, 689/2008/EC

**National regulatory information** 

Employment restrictions: Observe restrictions to employment for juvenils according to the 'juvenile

work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers. Observe employment restrictions for women of

child-bearing age.

Water contaminating class (D): 1 - slightly water contaminating

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): 1,4,5,6,7,8,9,10,11,12,14.

#### 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%

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LD50: Lethal dose, 50%

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

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

#### **Further Information**

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

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