

Trade name: FotoDent guide

Substance number: 9370 Version: 2 / GB Date revised: 20.02.2024

Replaces Version: 1 / GB Print date: 20.02.2024

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

#### 1.1. Product identifier

FotoDent guide

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

#### Use of the substance/preparation

Material on methacrylate resin basis for DLP systems with 385nm resp. 405nm LED for manufacturing of dental surgical drill guides for tooth-supported and/or teethridge-supported and surgical invasive application

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

#### Address/Manufacturer

Dreve Dentamid GmbH Max-Planck-Straße 31

59423 Unna

Telephone no. +49 2303 8807-0 Fax no. +49 2303 8807-29

Information provided Department Research & Development: Fax: +49 2303 8807-562

by / telephone

E-mail address of sicherheitsdatenblatt@dreve.com

person responsible

for this SDS

#### 1.4. Emergency telephone number

Henkel Fire Department / 24h-Emergency-Contact-No.: +49 211 797-3350

#### **SECTION 2: Hazards identification \*\*\***

#### 2.1. Classification of the substance or mixture

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

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

Eye Irrit. 2 H319 Skin Sens. 1 H317 Aquatic Chronic 3 H412

The product is classified and labelled in accordance with Regulation (EC) No 1272/2008 For explanation of abbreviations see section 16.

#### 2.2. Label elements

## Labelling according to regulation (EC) No 1272/2008

#### Hazard pictograms



Signal word



Trade name: FotoDent guide

Substance number: 9370 Version: 2 / GB Date revised: 20.02.2024

Replaces Version: 1 / GB Print date: 20.02.2024

Warning

#### **Hazard statements**

H319 Causes serious eye irritation. H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

#### **Precautionary statements**

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

P264.1 Wash hands thoroughly after handling. P273 Avoid release to the environment.

P280 Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact

lenses, if present and easy to do. Continue rinsing.

P501.1 Dispose of contents/container to industrial incineration plant.

#### Hazardous component(s) to be indicated on label (Regulation (EC) No. 1272/2008)

contains 2-hydroxyethyl methacrylate; Hydroxylpropyl methacrylate; 7,7,9(7,9,9)-trimethyl-

4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diylbismethacrylate

%

#### 2.3. Other hazards

No special hazards have to be mentioned.

\*\*\*

This product does not contain a substance that has endocrine disrupting properties with respect to human. The product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms. The product contains substances meeting the PBT criteria. See SECTION 3 in this safety data sheet. The product contains substances meeting the vPvB criteria. See SECTION 3 in this safety data sheet.

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

#### 3.2. Mixtures

#### **Hazardous ingredients**

#### Bisphenol A, ethoxylated, dimethacrylate

CAS No. 41637-38-1 EINECS no. 609-946-4

Registration no. 01-2119980659-17 Concentration >= 50

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

Aquatic Chronic 4 H413

#### 7,7,9(7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diylbismethacrylate

CAS No. 72869-86-4 EINECS no. 276-957-5

Registration no. 01-2120751202-68

Concentration >= 2,5 < 10 %

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

Skin Sens. 1B H317 Aquatic Chronic 2 H411

#### 2-hydroxyethyl methacrylate

CAS No. 868-77-9 EINECS no. 212-782-2

Registration no. 01-2119490169-29

Concentration  $\Rightarrow$  1 < 6,3 %



Trade name: FotoDent guide

Substance number: 9370 Version: 2 / GB Date revised: 20.02.2024

Replaces Version: 1 / GB Print date: 20.02.2024

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

Skin Irrit. 2 H315 Eye Irrit. 2 H319 Skin Sens. 1 H317

Additional remarks:

CLP Regulation (EC) No 1272/2008, Annex VI, Note D

Aliphatic urethane methacrylate

EINECS no. 933-881-3

Concentration >= 1 < 10 %

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

Eye Irrit. 2 H319

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

CAS No. 75980-60-8 EINECS no. 278-355-8

Registration no. 01-2119972295-29

Concentration >= 1 < 3 %

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

Repr. 2 H361f

Supplemental information

The substance is contained in the Candidate List for inclusion in Annex XIV of

Regulation (EC) No. 1907/2006 (REACH).

Hydroxylpropyl methacrylate

CAS No. 27813-02-1 EINECS no. 248-666-3

Registration no. 01-2119490226-37

Concentration >= 1 < 10 %

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

Eye Irrit. 2 H319 Skin Sens. 1 H317

ATE oral 2.000 mg/kg

Acrylic Resin

Concentration >= 1 < 3.6 %

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

Skin Irrit. 2 H315 Eye Irrit. 2 H319

**Further ingredients** 

**Bumetrizole** 

CAS No. 3896-11-5 EINECS no. 223-445-4

Registration no. 01-2119971796-18

Concentration < 1 %

Advice: [1], [2]

Supplemental information

The substance is contained in the Candidate List for inclusion in Annex XIV of

Regulation (EC) No. 1907/2006 (REACH).

Note

[1] PBT substance

[2] vPvB substance



Trade name: FotoDent guide

Substance number: 9370 Version: 2 / GB Date revised: 20.02.2024

Replaces Version: 1 / GB Print date: 20.02.2024

#### **SECTION 4: First aid measures**

#### 4.1. Description of first aid measures

#### **General information**

Remove contaminated clothing immediately and dispose of safely. Adhere to personal protective measures when giving first aid

#### After inhalation

Remove the casualty into fresh air and keep him calm. In the event of symptoms take medical treatment.

#### After skin contact

After contact with skin, wash immediately with plenty of water and soap. Consult a doctor if skin irritation persists.

#### After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). Take medical treatment.

#### After ingestion

Call in a physician immediately and show him the Safety Data Sheet. Rinse mouth thoroughly with water. Let plenty of water be drunk in small gulps. Do not induce vomiting.

#### Adhere to personal protective measures when giving first aid

First aider: Pay attention to self-protection!

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

Until now no symptoms known so far.

# 4.3. Indication of any immediate medical attention and special treatment needed Hints for the physician / hazards

In the case of swallowing with subsequent vomiting, aspiration of the lungs can occur which can lead to chemical pneumonia or asphyxiation.

## **SECTION 5: Firefighting measures**

#### 5.1. Extinguishing media

#### Suitable extinguishing media

Recommended: alcohol resistant foam, CO2, powders, water spray/mist, Extinguishing measures to suit surroundings

#### Non suitable extinguishing media

Full water iet

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

In case of combustion evolution of dangerous gases possible.

#### 5.3. Advice for firefighters

#### Special protective equipment for fire-fighting

Do not inhale explosion and/or combustion gases. In case of combustion use a suitable breathing apparatus. Wear full protective suit.

#### Other information

Collect contaminated fire-fighting water separately, must not be discharged into the drains. Fire residues and contaminated fire-fighting water must be disposed of in accordance with the local regulations.



Trade name: FotoDent guide

Substance number: 9370 Version: 2 / GB Date revised: 20.02.2024

Replaces Version: 1 / GB Print date: 20.02.2024

Observe manufacturer's / distributor`s instructions.

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

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

Keep away sources of ignition. Ensure adequate ventilation. Use breathing apparatus if exposed to vapours/dust/aerosol. Avoid contact with skin, eyes and clothing. Use personal protective clothing. Refer to protective measures listed in Sections 7 and 8.

### 6.2. Environmental precautions

Prevent spread over a wide area (e.g. by containment or oil barriers). Do not discharge into the drains/surface waters/groundwater. Do not discharge into the subsoil/soil. Retain and dispose of contaminated wash water. In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

#### 6.3. Methods and material for containment and cleaning up

Pick up rest with suitable absorbent materials. Do not pick up with the help of saw-dust or other combustible substances. Clean contaminated floors and objects thoroughly, observing environmental regulations. Containers in which spilt substance has been collected must be adequately labelled. Dispose of as prescribed.

#### 6.4. Reference to other sections

Refer to protective measures listed in Sections 7 and 8.

## **SECTION 7: Handling and storage**

#### 7.1. Precautions for safe handling

#### Advice on safe handling

Provide good ventilation of working area (local exhaust ventilation if necessary). Avoid formation of aerosols. Avoid impact, friction and electro-static loading; risk of ignition!. Keep container tightly closed.

#### Advice on protection against fire and explosion

Keep away from sources of heat and ignition. No smoking. Take action to prevent static discharges. Avoid impact and friction. Use only explosion-proof equipment. Keep away from combustible material. Wear shoes with conductive soles.

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

#### Requirements for storage rooms and vessels

Keep in original packaging, tightly closed. Storage rooms must be properly ventilated. Containers which are opened must be carefully resealed and kept upright to prevent leakage.

#### Hints on storage assembly

Do not store together with foodstuffs. Do not store with strong oxidizing agents.

#### Further information on storage conditions

Keep under lock and key or accessible only to specialists or people who are authorized. Keep container tightly closed and in a well-ventilated place. Keep in a cool place

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

#### 8.1. Control parameters



Trade name: FotoDent guide

Substance number: 9370 Version: 2 / GB Date revised: 20.02.2024

Replaces Version: 1 / GB Print date: 20.02.2024

mg/kg/d

#### Other information

Contains no substances with occupational exposure limit values.

#### Derived No/Minimal Effect Levels (DNEL/DMEL)

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Type of value Derived No Effect Level (DNEL)

Reference group Worker
Duration of exposure Long term
Route of exposure dermal

Mode of action Systemic effects
Concentration 0,233

Type of value Derived No Effect Level (DNEL)

Reference group Consumer

Duration of exposure Long term

Route of exposure inhalative

Mode of action Systemic effects

Concentration 0,145 mg/m<sup>3</sup>

Type of value Derived No Effect Level (DNEL)

Reference group Consumer
Duration of exposure Long term
Route of exposure dermal

Mode of action Systemic effects

Concentration 0,0833 mg/kg/d

Type of value Derived No Effect Level (DNEL)

Reference group Consumer
Duration of exposure Long term
Route of exposure oral

Mode of action Systemic effects

Concentration 0,0833 mg/kg/d

Bisphenol A, ethoxylated, dimethacrylate

Type of value Derived No Effect Level (DNEL)

Reference group

Duration of exposure

Route of exposure

Mode of action

Concentration

Worker

Long term

inhalative

Systemic effects

Concentration 3,52 mg/m<sup>3</sup>

Type of value Derived No Effect Level (DNEL)

Reference group Worker
Duration of exposure Long term
Route of exposure dermal

Mode of action Systemic effects

Concentration 2 mg/kg

Type of value Derived No Effect Level (DNEL)

Reference group

Duration of exposure

Route of exposure

Mode of action

Consumer

Long term

inhalative

Systemic effects

Concentration 0,87 mg/m³

Type of value Derived No Effect Level (DNEL)



Trade name: FotoDent guide

Substance number: 9370 Version: 2 / GB Date revised: 20.02.2024

> Replaces Version: 1 / GB Print date: 20.02.2024

Reference group Consumer Duration of exposure Long term Route of exposure dermal

Mode of action Systemic effects

mg/kg Concentration

Type of value Derived No Effect Level (DNEL)

Reference group Consumer Duration of exposure Long term Route of exposure oral

Mode of action Systemic effects

Concentration 0,5 mg/kg

2-hydroxyethyl methacrylate

Type of value Derived No Effect Level (DNEL)

Reference group Worker Duration of exposure Long term Route of exposure inhalative Mode of action Systemic effects

Concentration

mg/m<sup>3</sup> 4,9

Type of value Derived No Effect Level (DNEL)

Reference group Worker Duration of exposure Long term Route of exposure dermal

Mode of action Systemic effects

Concentration 1,39 mg/kg/d

Type of value Derived No Effect Level (DNEL)

Reference group Consumer Duration of exposure Long term Route of exposure inhalative Mode of action Systemic effects

mg/m<sup>3</sup> Concentration 1.45

Type of value Derived No Effect Level (DNEL)

Reference group Consumer Duration of exposure Long term Route of exposure dermal

Mode of action Systemic effects

Concentration 0,83 mg/kg/d

Hydroxylpropyl methacrylate

Reference substance Hydroxylpropyl methacrylate Derived No Effect Level (DNEL) Type of value

Reference group Worker Route of exposure inhalative Concentration

14.7 mg/m<sup>3</sup>

Hydroxylpropyl methacrylate

Type of value Derived No Effect Level (DNEL) Worker

Reference group dermal Route of exposure

Concentration 4,2 mg/kg/d

Derived No Effect Level (DNEL) Type of value



Trade name: FotoDent guide

Substance number: 9370 Version: 2 / GB Date revised: 20.02.2024

Replaces Version: 1 / GB Print date: 20.02.2024

Reference group Consumer Route of exposure dermal

Concentration 2,5 mg/kg

Type of value Derived No Effect Level (DNEL)

Reference group Consumer Route of exposure inhalative

Concentration 8,8 mg/m³

Type of value Derived No Effect Level (DNEL)

Reference group Consumer Route of exposure oral

Concentration 2,5 mg/kg

7,7,9(7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diylbismethacrylate

Type of value Derived No Effect Level (DNEL)

Reference group Worker

Duration of exposure Long term

Route of exposure inhalative

Mode of action Systemic effects

Concentration 3,3 mg/m³

Type of value Derived No Effect Level (DNEL)

Reference group Worker
Duration of exposure Long term
Route of exposure dermal

Mode of action Systemic effects

Concentration 1,3 mg/kg

Type of value Derived No Effect Level (DNEL)

Reference group

Duration of exposure

Route of exposure

Mode of action

Consumer

Long term

inhalative

Systemic effects

Concentration 0,6 mg/m<sup>3</sup>

Type of value Derived No Effect Level (DNEL)

Reference group Consumer
Duration of exposure Long term
Route of exposure oral

Mode of action Systemic effects

Concentration 0,3 mg/kg

Type of value Derived No Effect Level (DNEL)

Reference group Consumer
Duration of exposure Long term
Route of exposure dermal

Mode of action Systemic effects

Concentration 0,7 mg/kg

**Predicted No Effect Concentration (PNEC)** 

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Type of value PNEC
Type Saltwater

Concentration 0,00014 mg/l



Trade name: FotoDent guide

Substance number: 9370 Version: 2 / GB Date revised: 20.02.2024

Replaces Version: 1 / GB Print date: 20.02.2024

Type of value PNEC

Type Freshwater sediment

Concentration 0,115 mg/kg

Type of value PNEC

Type Marine sediment

Concentration 0,0115 mg/kg

Type of value PNEC Type Soil

Concentration 0,0222 mg/kg

2-hydroxyethyl methacrylate

Type of value PNEC
Type Freshwater

Concentration 0,482 mg/l

Type of value PNEC Type Soil

Concentration 0,476 mg/kg

Type of value PNEC

Type Sewage treatment plant (STP)

Concentration 10 mg/l

Type of value PNEC

Type Freshwater sediment

Concentration 3,79 mg/kg

Type of value PNEC Saltwater

Concentration 0,482 mg/l

Type of value PNEC

Type Marine sediment

Concentration 3,79 mg/kg

Type of value PNEC

Type Man via the environment

Concentration 0,83 mg/kg/d

Type of value PNEC

Type Water (intermittent release)

Concentration 1 mg/l

Hydroxylpropyl methacrylate

Reference substance Hydroxylpropyl methacrylate

Type of value PNEC Freshwater

Concentration 0,904 mg/l

Hydroxylpropyl methacrylate

Type of value PNEC

Type Freshwater sediment

Concentration 6,28 mg/kg



Trade name: FotoDent guide

Substance number: 9370 Version: 2 / GB Date revised: 20.02.2024

Replaces Version: 1 / GB Print date: 20.02.2024

Hydroxylpropyl methacrylate

Type of value PNEC Type Soil

Concentration 0,727 mg/kg

Hydroxylpropyl methacrylate

Type of value PNEC

Type Sewage treatment plant (STP)

Concentration 10 mg/l

Type of value PNEC Type Marine

Concentration 0,904 mg/l

Type of value PNEC

Type Marine sediment

Concentration 6,28 mg/kg

7,7,9(7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diylbismethacrylate

Type of value PNEC
Type Freshwater

Concentration 0,01 mg/l

Type of value PNEC

Type Freshwater sediment

Concentration 4,56 mg/kg

Type of value PNEC
Type Saltwater

Concentration 0,001 mg/l

Type of value PNEC

Type Marine sediment

Concentration 0,46 mg/kg

Type of value PNEC
Type Soil

Concentration 0,91 mg/kg

Type of value PNEC

Type Sewage treatment plant (STP)

Concentration 3,61 mg/l

Type of value PNEC

Type Water (intermittent release)

Concentration 0,1 mg/l

#### 8.2. Exposure controls

#### General protective and hygiene measures

Do not smoke during work time. Hold emergency shower available. Hold eye wash fountain available. Do not inhale gases/vapours/aerosols. Avoid contact with skin and eyes. Take off immediately all contaminated clothing. Do not eat or drink during work time. Storage of foodstuffs in work rooms is forbidden. Wash hands before breaks and after work. Clean skin thoroughly after work; apply skin cream.

#### Respiratory protection



Trade name: FotoDent guide

Substance number: 9370 Version: 2 / GB Date revised: 20.02.2024

Replaces Version: 1 / GB Print date: 20.02.2024

Do not inhale vapours; Use suitable respiratory protective device in case of insufficient ventilation

#### Hand protection

There is no one glove material or combination of materials that will give unlimited resistance to any individual or combination of chemicals.

The instructions and information provided by the glove manufacturer on use, storage, maintenance and replacement must be followed.

Gloves should be replaced regularly and if there is any sign of damage to the glove material.

Hand protection must comply with EN 374.

Appropriate Material nitrile

#### Eye protection

Safety glasses

#### **Body protection**

Clothing as usual in the chemical industry.

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

#### 9.1. Information on basic physical and chemical properties

Physical state liquid

**Colour** Various, depending on coloration

**Odour** characteristic

**Melting point** 

Remarks not determined

**Freezing point** 

Remarks not determined

Boiling point or initial boiling point and boiling range

Value > 100 °C

**Flammability** 

evaluation not determined

Upper and lower explosive limits

Remarks not determined

Flash point

Value 100 °C

Method closed cup

Ignition temperature

Remarks not determined

**Decomposition temperature** 

Remarks not determined

pH value

Remarks not determined

Viscosity

Remarks not determined

Solubility(ies)

Remarks not determined

Partition coefficient n-octanol/water (log value)

Remarks not determined

Vapour pressure



Trade name: FotoDent guide

Substance number: 9370 Version: 2 / GB Date revised: 20.02.2024

Replaces Version: 1 / GB Print date: 20.02.2024

Remarks not determined

Density and/or relative density

Value 1,1 g/cm<sup>3</sup>

Temperature 20 °C

Relative vapour density

Remarks not determined

9.2. Other information

**Odour threshold** 

Remarks not determined

**Evaporation rate (ether = 1):** 

Remarks not determined

Solubility in water

Remarks virtually insoluble

**Explosive properties** 

evaluation not determined

**Oxidising properties** 

Remarks not determined

Other information
None known

## **SECTION 10: Stability and reactivity**

#### 10.1. Reactivity

No hazardous reactions when stored and handled according to prescribed instructions.

#### 10.2. Chemical stability

No hazardous reactions known.

#### 10.3. Possibility of hazardous reactions

No hazardous reactions known.

#### 10.4. Conditions to avoid

Protect from heat and direct sunlight

#### 10.5. Incompatible materials

None known

#### 10.6. Hazardous decomposition products

Irritant gases/vapours

## **SECTION 11: Toxicological information**

#### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

**Acute oral toxicity** 

ATE > 10.000 mg/kg Method calculated value (Regulation (EC) No. 1272/2008)

**Acute oral toxicity (Components)** 



Trade name: FotoDent guide

Substance number: 9370 Version: 2 / GB Date revised: 20.02.2024

Replaces Version: 1 / GB Print date: 20.02.2024

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Species rat

LD50 > 5000 mg/kg

Method OECD 401

Bisphenol A, ethoxylated, dimethacrylate

Species rat

LD50 > 2000 mg/kg Remarks Test conducted with a similar formulation.

2-hydroxyethyl methacrylate

Species rat

LD50 > 5564 mg/kg

Hydroxylpropyl methacrylate

Species rat

LD50 >= 2000 mg/kg

Method OECD 401

7,7,9(7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diylbismethacrylate

Species rat

LD50 > 5000 mg/kg

Method OECD 401

**Acrylic Resin** 

LD50 > 2000 mg/kg

Aliphatic urethane methacrylate

Species rat

LD50 > 2000 mg/kg

**Bumetrizole** 

Species rat

LD50 > 2000 mg/kg

Acute dermal toxicity

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

**Acute dermal toxicity (Components)** 

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Species rat

LD50 > 2000 mg/kg

Method OECD 402 **Bisphenol A, ethoxylated, dimethacrylate** 

Species rat

opecies iai

LD50 > 2000 mg/kg

Method OECD 402

Remarks Test conducted with a similar formulation.

2-hydroxyethyl methacrylate

Species hamster

LD50 > 5000 mg/kg
Remarks Test conducted with a similar formulation.

Hydroxylpropyl methacrylate

Species rabbit

LD50 > 5000 mg/kg

7,7,9(7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diylbismethacrylate

Species rat

LD50 > 2000 mg/kg

Method OECD 402

**Acrylic Resin** 

LD50 > 2000 mg/kg



Trade name: FotoDent guide

Substance number: 9370 Version: 2 / GB Date revised: 20.02.2024

Replaces Version: 1 / GB Print date: 20.02.2024

Aliphatic urethane methacrylate

Species rabbit

LD50 > 2000 mg/kg

**Bumetrizole** 

Species rat

LD50 > 2000 mg/kg

Method OECD 402

Acute inhalational toxicity

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

**Acute inhalative toxicity (Components)** 

**Acrylic Resin** 

LC50 > 5 mg/l

Duration of exposure 4 h

Administration/Form Dust/Mist

Aliphatic urethane methacrylate

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

Skin corrosion/irritation

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

Skin corrosion/irritation (Components)

**Acrylic Resin** 

evaluation irritant

Aliphatic urethane methacrylate

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

Serious eye damage/irritation

evaluation irritant

Remarks The classification criteria are met.

Serious eye damage/irritation (Components)

2-hydroxyethyl methacrylate

Species rabbit

evaluation slightly irritant

Hydroxylpropyl methacrylate

Species rabbit

evaluation slightly irritant

**Acrylic Resin** 

evaluation irritant

Aliphatic urethane methacrylate

Species rabbit
evaluation irritant

**Sensitization** 

evaluation May cause sensitization by skin contact. Remarks The classification criteria are met.

Sensitization (Components)

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Route of exposure dermal Species mouse

evaluation May cause sensitization by skin contact.

2-hydroxyethyl methacrylate

Remarks Possible sensitization potential with human beings.

Hydroxylpropyl methacrylate



Trade name: FotoDent guide

Substance number: 9370 Version: 2 / GB Date revised: 20.02.2024

Replaces Version: 1 / GB Print date: 20.02.2024

Species mouse

evaluation non-sensitizing Method OECD 429

Remarks May cause sensitization by skin contact.

7,7,9(7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diylbismethacrylate

Route of exposure dermal species mouse evaluation sensitizing

Aliphatic urethane methacrylate

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

Subacute, subchronic, chronic toxicity

Remarks not determined

Mutagenicity

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

**Mutagenicity (Components)** 

Aliphatic urethane methacrylate

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

Reproductive toxicity

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

**Reproduction toxicity (Components)** 

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

evaluation Suspected of damaging fertility.

Aliphatic urethane methacrylate

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

Carcinogenicity

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

Carcinogenicity (Components)
Aliphatic urethane methacrylate

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

Specific Target Organ Toxicity (STOT)

Single exposure

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

Repeated exposure

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

**Specific Target Organ Toxicity (STOT) (Components)** 

Aliphatic urethane methacrylate

Remarks 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 with respect to humans** 

The product does not contain a substance that has endocrine disrupting properties with respect to humans.

**Experience in practice** 

Inhalation may lead to irritation of the respiratory tract.

Other information



Trade name: FotoDent guide

Substance number: 9370 Version: 2 / GB Date revised: 20.02.2024

Replaces Version: 1 / GB Print date: 20.02.2024

No toxicological data are available.

## **SECTION 12: Ecological information**

#### 12.1. Toxicity

#### **General information**

not determined

#### Fish toxicity (Components)

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Species carp (Cyprinus carpio)

LC50 1,4 mg/l

Duration of exposure 96 h

Method OECD 203

Bisphenol A, ethoxylated, dimethacrylate

Species rainbow trout (Oncorhynchus mykiss)

LL50 > 100 mg/l

Method OECD 203

Remarks Test conducted with a similar formulation.

2-hydroxyethyl methacrylate

Species Oryzias latipes

LC50 > 100 mg/l

Duration of exposure 96 h

Method OECD 203

Hydroxylpropyl methacrylate

Species golden orfe (Leuciscus idus)

LC50 493 mg/l

Duration of exposure 48 h Method DIN 38412 / Part 15

7,7,9(7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diylbismethacrylate

Species zebra fish (Brachydanio rerio)

LC50 10,1 mg/l

Duration of exposure 96 h

Method OECD 203

**Bumetrizole** 

Species zebra fish (Brachydanio rerio)

LC50 > 100 mg/l

Duration of exposure 96 h

Method OECD 203

#### **Daphnia toxicity (Components)**

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Species Daphnia magna

EC50 3,53 mg/l

Duration of exposure 48 h

Method OECD 202

Bisphenol A, ethoxylated, dimethacrylate

Species Daphnia magna

EL50 > 100 mg/l

Duration of exposure 48 h

Method OECD 202

2-hydroxyethyl methacrylate

Species Daphnia magna



Print date: 20.02.2024

Trade name: FotoDent guide

Substance number: 9370 Version: 2 / GB Date revised: 20.02.2024

Replaces Version: 1 / GB

EC50 380 mg/l

Duration of exposure 48 h

Method OECD 202

2-hydroxyethyl methacrylate

Species Daphnia magna

NOEC 24,1 mg/l

Duration of exposure 21 d

Method OECD 211

Hydroxylpropyl methacrylate

Species Daphnia magna

EC50 > 143 mg/l

Duration of exposure 48 h

Method OECD 202

Hydroxylpropyl methacrylate

Species Daphnia magna

NOEC 45,2 mg/l

Duration of exposure 21 d

Method OECD 211

7,7,9(7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diylbismethacrylate

Species Daphnia magna

EC50 1,2 mg/l

Duration of exposure 48 h

Method OECD 202

**Bumetrizole** 

Species Daphnia magna

EC50 >= 100 mg/l

Duration of exposure 48 h

Method OECD 202

**Bumetrizole** 

Species Daphnia magna

NOEC >= 10 mg/l

Duration of exposure 21 d

Method OECD 211

Algae toxicity (Components)

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Species Pseudokirchneriella subcapitata

EC50 > 2,01 mg/l

Duration of exposure 72 h

Method OECD 201

Bisphenol A, ethoxylated, dimethacrylate

Species Pseudokirchneriella subcapitata

EL50 > 100 mg/l

Duration of exposure 72 h

Method OECD 201

Remarks Test conducted with a similar formulation.

2-hydroxyethyl methacrylate

Species Pseudokirchneriella subcapitata

EC50 345 mg/l

Duration of exposure 72 h

Method OECD 201

Hydroxylpropyl methacrylate

Species Pseudokirchneriella subcapitata

EC50 > 97,2 mg/l

Duration of exposure 72 h



Trade name: FotoDent guide

Substance number: 9370 Version: 2 / GB Date revised: 20.02.2024

Replaces Version: 1 / GB Print date: 20.02.2024

Method OECD 201

7,7,9(7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diylbismethacrylate

Species Scenedesmus subspicatus

EC50 > 0,68 mg/l

Duration of exposure 72 h

Method OECD 201

**Bumetrizole** 

Species Scenedesmus subspicatus

EC50 > 100 mg/l

Duration of exposure 72 h

**Bacteria toxicity (Components)** 

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Species activated sludge

EC50 > 1000 mg/l

Duration of exposure 3 h

Method OECD 209

Bisphenol A, ethoxylated, dimethacrylate

Species activated sludge

NOEC 14,3 mg/l

Duration of exposure 28 d

Remarks Test conducted with a similar formulation.

2-hydroxyethyl methacrylate

Species Pseudomonas fluorescens

EC0 > 3000 mg/l

Duration of exposure 16 h

7,7,9(7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diylbismethacrylate

Species activated sludge

NOEC >= 36,1 mg/l

Duration of exposure 14 d

**Bumetrizole** 

Species activated sludge

EC50 > 100 mg/l

Duration of exposure 3 h

Method OECD 209

12.2. Persistence and degradability

**General information** 

not determined

**Biodegradability (Components)** 

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Value < 0 to 10 %

Duration of test 28 d evaluation not readily degradable

Bisphenol A, ethoxylated, dimethacrylate

Value 24 %

Duration of test 28 d

evaluation Readily biodegradable (according to OECD criteria)

2-hydroxyethyl methacrylate

Value 92 to 100 %

Duration of test 14 d

evaluation Readily biodegradable (according to OECD criteria)

7,7,9(7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diylbismethacrylate

Value 22 %



Trade name: FotoDent guide

Substance number: 9370 Version: 2 / GB Date revised: 20.02.2024

Replaces Version: 1 / GB Print date: 20.02.2024

Duration of test 28 d evaluation not readily degradable

**Bumetrizole** 

Value 10 to 20 %

Duration of test 28 d evaluation sparingly degradable

Ready degradability (Components)

Hydroxylpropyl methacrylate

Value 81 %

Duration of test 28 Days

12.3. Bioaccumulative potential

**General information** 

not determined

Partition coefficient n-octanol/water (log value)

Remarks not determined

Octanol/water partition coefficient (log Pow) (Components)

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

log Pow 3,1
Temperature 23 °C

Bisphenol A, ethoxylated, dimethacrylate

log Pow 4,39

2-hydroxyethyl methacrylate

log Pow 0,42

Temperature 25 °C

Method OECD 107

Hydroxylpropyl methacrylate

log Pow 0,97

Temperature 20 °C

7,7,9 (7,9,9) - trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazah exade can e-1,16-diylbis methacry lateral control of the control

log Pow 3,39

Temperature 20 °C

**Bumetrizole** 

log Pow > 6,5

Temperature 23 °C

**Bioconcentration factor (BCF) (Components)** 

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

BCF 47 to 55

Concentration 0,1 mg/l
Duration of exposure 8 Weeks
Medium Freshwater

Species carp (Cyprinus carpio)

12.4. Mobility in soil

**General information** 

not determined

12.5. Results of PBT and vPvB assessment

**General information** 

not determined

Results of PBT and vPvB assessment



Trade name: FotoDent guide

Substance number: 9370 Version: 2 / GB Date revised: 20.02.2024

Replaces Version: 1 / GB Print date: 20.02.2024

The product contains PBT-substances. The product contains vPvB-substances.

#### Results of PBT and vPvB assessment (Ingredients)

#### Bumetrizole

The Substance meets PBT-criteria

#### **Bumetrizole**

The substance meets vPvB-criteria.

#### 12.6 Endocrine disrupting properties

#### Endocrine disrupting properties with respect to the envrionment

The product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms.

#### 12.7. Other adverse effects

#### **General information**

not determined

#### General information / ecology

Do not allow to enter soil, waterways or waste water canal. Avoid release into the atmosphere.

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

#### 13.1. Waste treatment methods

#### Disposal recommendations for the product

Must not be disposed together with household garbage. Dispose of waste according to applicable legislation.

#### Disposal recommendations for packaging

Packaging that cannot be cleaned should be disposed off as product waste.

## **SECTION 14: Transport information \*\*\***

	Land transport ADR/RID  ***	Marine transport IMDG/GGVSee ***	Air transport ICAO/IATA
14.1. UN number or ID number	The product does not constitute a hazardous substance in land transport.	The product does not constitute a hazardous substance in sea transport.	The product does not constitute a hazardous substance in air transport.
14.2. UN proper shipping name	-	-	-
14.3. Transport hazard class(es)		-	-
Label			
14.4. Packing group		-	-



Trade name: FotoDent guide

Substance number: 9370 Version: 2 / GB Date revised: 20.02.2024

Replaces Version: 1 / GB Print date: 20.02.2024

### **SECTION 15: Regulatory information**

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

#### Other information

All components are contained in the TSCA inventory or exempted.

#### 15.2. Chemical safety assessment

For this preparation a chemical safety assessment has not been carried out.

#### **SECTION 16: Other information**

## Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

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

Eye Irrit. 2 H319 Calculation method Skin Sens. 1 H317 Calculation method Aquatic Chronic 3 H412 Calculation method

#### Hazard statements listed in Chapter 2/3

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H361f Suspected of damaging fertility.

H411 Toxic to aquatic life with long lasting effects.
 H412 Harmful to aquatic life with long lasting effects.
 H413 May cause long lasting harmful effects to aquatic life.

#### CLP categories listed in Chapter 2/3

Aquatic Chronic 2 Hazardous to the aquatic environment, chronic, Category 2
Aquatic Chronic 3 Hazardous to the aquatic environment, chronic, Category 3
Aquatic Chronic 4 Hazardous to the aquatic environment, chronic, Category 4

Eye Irrit. 2 Eye irritation, Category 2

Repr. 2 Reproductive toxicity, Category 2
Skin Irrit. 2 Skin irritation, Category 2
Skin Sens. 1 Skin sensitization, Category 1
Skin Sens. 1B Skin sensitization, Category 1B

#### **Supplemental information**

Relevant changes compared with the previous version of the safety data sheet are marked with: \*\*\* This information is based on our present state of knowledge. However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.