

**Safety data sheet**  
according to Regulation (EC) No 1907/2006, Article 31

Printing date 07.08.2024

Version number 11 (replaces version 10)

Revision: 07.08.2024

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

- **1.1 Product identifier**
- **Trade name:** ***SR Ivolen Monomer***
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Custom tray material
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Ivoclar Vivadent AG  
Bendererstrasse 2  
9494 Schaan  
PRINCIPALITY OF LIECHTENSTEIN
- Tel: +423 235 35 35  
Fax: +423 235 33 60
- **Further information obtainable from:**  
Regulatory Affairs  
sds@ivoclar.com
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, 9494 Schaan, Liechtenstein)

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
Flam. Liq. 2 H225 Highly flammable liquid and vapour.  
Skin Irrit. 2 H315 Causes skin irritation.  
Skin Sens. 1 H317 May cause an allergic skin reaction.  
STOT SE 3 H335 May cause respiratory irritation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the GB CLP regulation.
- **Hazard pictograms**



GHS02 GHS07

- **Signal word** *Danger*
- **Hazard-determining components of labelling:**  
methyl methacrylate  
2,2'-[(4-methylphenyl)imino]bisethanol
- **Hazard statements**  
H225 Highly flammable liquid and vapour.  
H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H335 May cause respiratory irritation.
- **Precautionary statements**  
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

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- P262 Do not get in eyes, on skin, or on clothing.
- P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
- P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **2.3 Other hazards**
  - **Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.
  - **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 80-62-6 EINECS: 201-297-1 Reg.nr.: 01-2119452498-28-XXXX	methyl methacrylate Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	50-100%
CAS: 8002-74-2 EINECS: 232-315-6	Paraffin waxes and Hydrocarbon waxes substance with a Community workplace exposure limit	≤10%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** Immediately remove any clothing soiled by the product.
- **After inhalation:**  
Supply fresh air; consult doctor in case of complaints.  
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:**  
Immediately rinse with water.  
If skin irritation continues, consult a doctor.
- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:**  
Rinse out mouth and then drink plenty of water.  
Do not induce vomiting; call for medical help immediately.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:** CO<sub>2</sub>, sand, extinguishing powder. Do not use water.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

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· **Additional information** Cool endangered receptacles with water spray.

### SECTION 6: Accidental release measures

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

Wear protective equipment. Keep unprotected persons away.

#### · 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.

#### · 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Ensure adequate ventilation.

#### · 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

### SECTION 7: Handling and storage

#### · 7.1 Precautions for safe handling

Only adequately trained personnel should handle this product.

Ensure good ventilation/exhaustion at the workplace.

For use in dentistry only.

#### · Information about fire - and explosion protection:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

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

##### · Storage:

##### · Requirements to be met by storerooms and receptacles:

Store only in the original receptacle.

Store in a cool location.

##### · Information about storage in one common storage facility: Store away from oxidising agents.

##### · Further information about storage conditions:

Keep container tightly sealed.

Store receptacle in a well ventilated area.

Protect from heat and direct sunlight.

#### · 7.3 Specific end use(s) No further relevant information available.

### SECTION 8: Exposure controls/personal protection

#### · 8.1 Control parameters

##### · Ingredients with limit values that require monitoring at the workplace:

##### CAS: 80-62-6 methyl methacrylate

WEL Short-term value: 416 mg/m<sup>3</sup>, 100 ppmLong-term value: 208 mg/m<sup>3</sup>, 50 ppm

##### CAS: 8002-74-2 Paraffin waxes and Hydrocarbon waxes

WEL Short-term value: 6 mg/m<sup>3</sup>Long-term value: 2 mg/m<sup>3</sup>· **Additional information:** The lists valid during the making were used as basis.

#### · 8.2 Exposure controls

· **Appropriate engineering controls** No further data; see section 7.

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- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**  
 Usual hygienic measures for dental practice and dental laboratories.  
 Keep away from foodstuffs, beverages and feed.  
 Immediately remove all soiled and contaminated clothing  
 Wash hands before breaks and at the end of work.  
 Avoid contact with the eyes and skin.  
 Do not inhale gases / fumes / aerosols.
- **Respiratory protection:**  
 In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Recommended filter device for short term use:**  
 Filter A1  
 Filter A2  
 Filter A3
- **Hand protection**



Protective gloves (EN 374)

After use of gloves apply skin-cleaning agents and skin cosmetics.

- **Material of gloves**  
 Butyl rubber, BR  
 Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Penetration time of glove material**  
 The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Not suitable are gloves made of the following materials:**  
 Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.
- **Eye/face protection**



Tightly sealed goggles (EN 166)

## SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Colour:** Colourless
- **Odour:** Pungent
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** -48 °C
- **Boiling point or initial boiling point and boiling range** 101 °C
- **Lower and upper explosion limit**
- **Lower:** 2.1 Vol %
- **Upper:** 12.5 Vol %
- **Flash point:** 10 °C
- **Auto-ignition temperature:** 430 °C
- **pH** Not determined.

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· <b>Viscosity:</b>	
· <b>Kinematic viscosity</b>	Not determined.
· <b>Dynamic:</b>	Not determined.
· <b>Solubility</b>	
· <b>water at 20 °C:</b>	1.6 g/l
· <b>Partition coefficient n-octanol/water (log value)</b>	Not determined.
· <b>Vapour pressure at 20 °C:</b>	47 hPa
· <b>Density and/or relative density</b>	
· <b>Density at 20 °C:</b>	0.943 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>9.2 Other information</b>	No further relevant information available.
· <b>Appearance:</b>	
· <b>Form:</b>	Fluid
· <b>Important information on protection of health and environment, and on safety.</b>	
· <b>Ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· <b>Change in condition</b>	
· <b>Evaporation rate</b>	Not determined.
· <b>Information with regard to physical hazard classes</b>	
· <b>Explosives</b>	Void
· <b>Flammable gases</b>	Void
· <b>Aerosols</b>	Void
· <b>Oxidising gases</b>	Void
· <b>Gases under pressure</b>	Void
· <b>Flammable liquids</b>	Highly flammable liquid and vapour.
· <b>Flammable solids</b>	Void
· <b>Self-reactive substances and mixtures</b>	Void
· <b>Pyrophoric liquids</b>	Void
· <b>Pyrophoric solids</b>	Void
· <b>Self-heating substances and mixtures</b>	Void
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
· <b>Oxidising liquids</b>	Void
· <b>Oxidising solids</b>	Void
· <b>Organic peroxides</b>	Void
· <b>Corrosive to metals</b>	Void
· <b>Desensitised explosives</b>	Void

## SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability** Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions**
  - Forms explosive gas mixture with air.
  - Reacts with strong oxidising agents.
  - Exothermic polymerisation.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.

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- **10.6 Hazardous decomposition products:** None under normal conditions of storage and use.

#### 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.

- **LD/LC50 values relevant for classification:**

<b>CAS: 80-62-6 methyl methacrylate</b>
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Oral LD50	7872 mg/kg (rat)
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- **Skin corrosion/irritation**

Causes skin irritation.

- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.

- **Respiratory or skin sensitisation**

May cause an allergic skin reaction.

- **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**

May cause respiratory irritation.

- **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 toxicological information:** No further relevant information available.

- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

None of the ingredients is listed.

#### SECTION 12: Ecological information

- **12.1 Toxicity**

- **Aquatic toxicity:** No further relevant information available.

- **12.2 Persistence and degradability** No further relevant information available.

- **12.3 Bioaccumulative potential** No further relevant information available.

- **12.4 Mobility in soil** No further relevant information available.

- **12.5 Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

- **12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.

- **12.7 Other adverse effects** No further relevant information available.

- **Additional ecological information:**

- **General notes:**

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

#### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**

- **Recommendation**

Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

#### SECTION 14: Transport information

· 14.1 UN number or ID number	
· ADR/RID/ADN, IMDG, IATA	UN1247
· 14.2 UN proper shipping name	
· ADR/RID/ADN	1247 METHYL METHACRYLATE MONOMER, STABILIZED
· IMDG, IATA	METHYL METHACRYLATE MONOMER, STABILIZED
· 14.3 Transport hazard class(es)	
· ADR/RID/ADN	
	
· Class	3 (F1) Flammable liquids.
· Label	3
· IMDG, IATA	
	
· Class	3 Flammable liquids.
· Label	3
· 14.4 Packing group	
· ADR/RID/ADN, IMDG, IATA	II
· 14.5 Environmental hazards:	
· Marine pollutant:	No
· 14.6 Special precautions for user	Warning: Flammable liquids.
· Hazard identification number (Kemler code):	33
· EMS Number:	F-E,S-E
· Stowage Category	B
· Stowage Code	SW2 Clear of living quarters.
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	
· ADR/RID/ADN	
· Limited quantities (LQ)	1L
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· Transport category	2
· Tunnel restriction code	D/E

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· <b>IMDG</b>	
· <b>Limited quantities (LQ)</b>	1L
· <b>Excepted quantities (EQ)</b>	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
· <b>UN "Model Regulation":</b>	UN1247, METHYL METHACRYLATE MONOMER, STABILIZED, 3, II

#### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5000 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50000 t
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**  
The product is a medical device according to Regulation 2017/745 on Medical Devices (MDR).
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

#### SECTION 16: Other information

- **Relevant phrases**  
H225 Highly flammable liquid and vapour.  
H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H335 May cause respiratory irritation.
- **Abbreviations and acronyms:**  
IMO: International Maritime Organization  
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)  
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)  
IMDG: International Maritime Code for Dangerous Goods  
IATA: International Air Transport Association  
GHS: Globally Harmonised 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 (division of the American Chemical Society)  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
Flam. Liq. 2: Flammable liquids – Category 2  
Skin Irrit. 2: Skin corrosion/irritation – Category 2  
Skin Sens. 1: Skin sensitisation – Category 1  
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
- **\* Data compared to the previous version altered.**

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

- **1.1 Product identifier**
- **Trade name:** **SR Ivolen Polymer**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Custom tray material
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Ivoclar Vivadent AG  
Bendererstrasse 2  
9494 Schaan  
PRINCIPALITY OF LIECHTENSTEIN
- Tel: +423 235 35 35  
Fax: +423 235 33 60
- **Further information obtainable from:**  
Regulatory Affairs  
sds@ivoclar.com
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, 9494 Schaan, Liechtenstein)

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the GB CLP regulation.
- **Hazard pictograms**
- 
- GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**  
dibenzoyl peroxide
- **Hazard statements**  
H317 May cause an allergic skin reaction.
- **Precautionary statements**  
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
P262 Do not get in eyes, on skin, or on clothing.  
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.  
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **2.3 Other hazards**  
Dust generation  
Particular danger of slipping on leaked/spilled product.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

**Description:** Mixture of substances listed below with nonhazardous additions.

#### Dangerous components:

CAS: 94-36-0	dibenzoyl peroxide	I-<2.5%
EINECS: 202-327-6	Org. Perox. B, H241; Eye Irrit. 2, H319; Skin Sens. 1, H317	
Reg.nr.: 01-2119511472-50-XXXX		

**Additional information:** For the wording of the listed hazard phrases refer to section 16.

### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

**After inhalation:** Supply fresh air and to be sure call for a doctor.

**After skin contact:**

Rinse with water.

If skin irritation continues, consult a doctor.

**After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.

**After swallowing:**

Rinse out mouth and then drink plenty of water.

If symptoms persist consult doctor.

**4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

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

No further relevant information available.

### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

**Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.

**5.2 Special hazards arising from the substance or mixture** No further relevant information available.

**5.3 Advice for firefighters**

**Protective equipment:** No special measures required.

### SECTION 6: Accidental release measures

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

Avoid formation of dust.

Particular danger of slipping on leaked/spilled product.

**6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.

**6.3 Methods and material for containment and cleaning up:** Pick up mechanically.

#### 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

Only adequately trained personnel should handle this product.

For use in dentistry only.

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- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Protect from heat and direct sunlight.
- **7.3 Specific end use(s)** No further relevant information available.

## SECTION 8: Exposure controls/personal protection

### · 8.1 Control parameters

- **Ingredients with limit values that require monitoring at the workplace:**

CAS: 94-36-0 dibenzoyl peroxide

WEL Long-term value: 5 mg/m<sup>3</sup>

- **Additional information:** The lists valid during the making were used as basis.

### · 8.2 Exposure controls

- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**  
Usual hygienic measures for dental practice and dental laboratories.  
Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.  
Avoid contact with the skin.
- **Respiratory protection:** Use respiratory protective device against the effects of dust.
- **Hand protection**



Protective gloves (EN 374)

After use of gloves apply skin-cleaning agents and skin cosmetics.

### · **Material of gloves**

Nitrile rubber, NBR

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

### · **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

### · **Eye/face protection** Safety glasses

## SECTION 9: Physical and chemical properties

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

#### · General Information

- **Colour:** Beige
- **Odour:** Characteristic
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** Undetermined.
- **Boiling point or initial boiling point and boiling range** Undetermined.
- **Flammability** Not determined.

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<b>· Lower and upper explosion limit</b>	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	Not applicable.
· pH	Not applicable.
· Viscosity:	
· Kinematic viscosity	Not applicable.
· Dynamic:	Not applicable.
· Solubility	
· water:	Nearly insoluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not applicable.
· Density and/or relative density	
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not applicable.
<b>· 9.2 Other information</b>	
· Appearance:	
· Form:	Powder
<b>· Important information on protection of health and environment, and on safety.</b>	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Change in condition	
· Evaporation rate	Not applicable.
<b>· Information with regard to physical hazard classes</b>	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

## SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability** Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.

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- **10.6 Hazardous decomposition products:** None under normal conditions of storage and use.

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### 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.
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation**  
May cause an allergic skin reaction.
- **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.
- **Additional toxicological information:** No further relevant information available.
- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

None of the ingredients is listed.

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### SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**  
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

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#### SECTION 14: Transport information

· 14.1 UN number or ID number	
· ADR/RID/ADN, ADN, IMDG, IATA	Void
· 14.2 UN proper shipping name	
· ADR/RID/ADN, ADN, IMDG, IATA	Void
· 14.3 Transport hazard class(es)	
· ADR/RID/ADN, ADN, IMDG, IATA	
· Class	Void
· 14.4 Packing group	
· ADR/RID/ADN, IMDG, IATA	Void
· 14.5 Environmental hazards:	
· Marine pollutant:	No
· 14.6 Special precautions for user	Not applicable.
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· UN "Model Regulation":	Void

#### SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- National regulations:
- Other regulations, limitations and prohibitive regulations  
The product is a medical device according to Regulation 2017/745 on Medical Devices (MDR).
- 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

#### SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**  
H241 Heating may cause a fire or explosion.  
H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.
- **Abbreviations and acronyms:**  
IMO: International Maritime Organization  
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)  
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)  
IMDG: International Maritime Code for Dangerous Goods  
IATA: International Air Transport Association  
GHS: Globally Harmonised 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 (division of the American Chemical Society)  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
Org. Perox. B: Organic peroxides – Type B  
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

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*Skin Sens. 1: Skin sensitisation – Category 1*

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· **\* Data compared to the previous version altered.**

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