

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

#### 1.1. Product identifier

Trade name / designation : DENTOTEMP Base.  
 Article No (user) : DT-2.10 / DTCA2-20 / DTCA1-5 / DTCA4-VP.

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

Relevant identified uses : Dental products.

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

Supplier : ITENA CLINICAL  
 Street: 83, Avenue Foch  
 Postal code / City: 75116 Paris  
 Country: France  
 Telephone: [+33 1 45 91 30 06](tel:+33145913006)  
 Telefax: [+ 33 1 45 91 61 31](tel:+33145916131)  
 E-mail: [contact@itena-clinical.com](mailto:contact@itena-clinical.com)





#### 1.4 Emergency Telephone Number

Not available

### SECTION 2: Hazards identification


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

Classification according to Regulation (EC) No. 1272/2008 [CLP]

	Classification	Hazard statements	
	Skin Irrit. 2	H315	Causes skin irritation.
	Skin Sens. 1	H317	May cause an allergic skin reaction.
	Eye Irrit. 2	H319	Causes serious eye irritation.
	STOT SE 3	H335	May cause respiratory irritation.

#### 2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms	
Signal word	Warning
Product identifiers	-
Hazard Statements	H315 - Causes skin irritation. H317 - May cause an allergic skin reaction. H319 - Causes serious eye irritation. H335 - May cause respiratory irritation.
Supplemental Hazard information (EU)	-
Precautionary Statements - General	-
Precautionary Statements - Prevention	P102 - Keep out of reach of children. P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Precautionary Statements - Response

Precautionary Statements - Storage

Precautionary Statements - Disposal

P260 - Do not breathe 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.

P302+P350 - IF ON SKIN: Gently wash with plenty of soap and water.

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P403 - Store in a well-ventilated place.

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### 2.3. Other hazards

Adverse human health effects and symptoms : Prolonged or repeated contact with skin or mucous membrane result in irritation symptoms such as redness, blistering, dermatitis, etc. People who are sensitive to methacrylate may have an allergic reaction.

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Substance	C (%)	Classification	Specific concentration limits	Note
2-Propenoic acid, 2-methyl-, 1,2-ethanediylbis(oxy-, 2,1-ethanediyl) ester CAS N°:109-16-0 EC N°:203-652-6 IDX N°:607-134-00-4	10.0% ≤C≤ 20.0%	Skin Irrit. 2: H315 Eye Irrit. 2: H319 STOT SE 3: H335	STOT SE 3; H335: C ≥ 10 %	-
2-hydroxyethyl methacrylate CAS N°:868-77-9 EC N°:212-782-2 IDX N°:607-124-00-X	10.0% ≤C≤ 20.0%	Skin Irrit. 2: H315 Eye Irrit. 2: H319 Skin Sens. 1: H317	-	-
Talc (Mg <sub>3</sub> H <sub>2</sub> (SiO <sub>3</sub> ) <sub>4</sub> ) CAS N°:14807-96-6 EC N°:238-877-9 IDX N°:	0.0% ≤C≤ 5.0%	-	-	-
ethyl 4-dimethylaminobenzoate CAS N°:10287-53-3 EC N°:233-634-3 IDX N°:	0.0% ≤C≤ 5.0%	-	-	-
titanium dioxide CAS N°:13463-67-7 EC N°:236-675-5 IDX N°:	0.0% ≤C≤ 5.0%	-	-	-
diiron trioxide CAS N°:1309-37-1 EC N°:215-168-2 IDX N°:	0.0% ≤C≤ 5.0%	-	-	-
Silica, amorphous, fumed, cryst.-free CAS N°:112945-52-5 EC N°: IDX N°:	0.0% ≤C≤ 5.0%	Met. Corr. 1: H290	-	-

### 3.2. Mixtures

Not available

### 3.3. Remark

Text phrases and H- EUH-: see section 16.

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

General information	:	In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).
Following inhalation	:	Remove person to fresh air and keep comfortable for breathing. In case of respiratory tract irritation, consult a physician.
Following skin contact	:	In case of skin irritation, consult a physician. After contact with skin, wash immediately with plenty of water and soap. In case of skin reactions, consult a physician.
Following eye contact	:	In case of eye irritation consult an ophthalmologist. Rinse immediately carefully and thoroughly with eye-bath or water.
Following ingestion	:	IF SWALLOWED: Immediately call a POISON CENTER or doctor.

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

Not available

### 4.3. Indication of any immediate medical attention and special treatment needed

Notes for the doctor	:	Treat symptomatically.
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## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media	:	Extinguishing powder. Carbon dioxide (CO <sub>2</sub> ). Water spray.
Unsuitable extinguishing media	:	Strong water jet.

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

Not available

### 5.3. Advice for firefighters

Not available

### 5.4. Additional information

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

Provide adequate ventilation.

### 6.2. Environmental precautions

Do not allow to enter into surface water or drains.

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

Treat the recovered material as prescribed in the section on waste disposal. Collect in closed and suitable containers for disposal. Clean contaminated objects and areas thoroughly observing environmental regulations. Water (with cleaning agent). Wipe up with absorbent material (eg. cloth, fleece). Ventilate affected area.

### 6.4. Reference to other sections

Safe handling: see section 7. Disposal: see section 13. Personal protection equipment: see section 8.

### 6.5. Additional information

Not available

## SECTION 7: Handling and Storage

### 7.1. Precautions for safe handling

No special measures are necessary.

Protective measures

Avoid contact with skin, eyes and clothes. Sewers and ducts must be protected against the entry of the product. Avoid breathing dust.

Advices on general occupational hygiene

In the immediate working surroundings there must be: Provide eye shower and label its location conspicuously.

When using do not eat, drink, smoke, sniff. Remove contaminated, saturated clothing immediately.

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

Ensure adequate ventilation of the storage area. Keep container tightly closed. Store in a well-ventilated place. Keep/store only in original container. Keep out of direct sunlight, open flames and areas of contamination. Avoid storing the product prolonged at temperatures above 75 ° F (24 ° C).

## 7.3. Specific end uses

Observe instructions for use.

# SECTION 8: Exposure controls / personal protection

## 8.1. Control parameters

Not available

## 8.2. Exposure controls

### Appropriate engineering controls

See section 7. No additional measures necessary.

### Personal protection equipment



Eye/face protection	:	Wear eye protection equipment. Suitable eye protection: Eye glasses. Eye glasses with side protection.
Skin protection	:	Disposable gloves. Hand protection: Suitable material: Latex. Hand protection: Additional hand protection measures.: Use gloves only once. Hand protection: Remark: 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. Breakthrough times and swelling properties of the material must be taken into consideration. Hand protection: Wear protective gloves.
Respiratory protection	:	Usually no personal respirative protection necessary.
Environmental exposure controls		See section 7. No additional measures necessary.

## 8.3. Additional information

Not available

# SECTION 9: Physical and chemical Properties

## 9.1. Information on basic physical and chemical properties

Physical state:	Solid - Paste
Colour:	white
Odour:	Specific odor
Odour threshold:	Not available
PH:	
Melting point/freezing point:	
Initial boiling point and boiling range:	N / A °C
Flash point:	N / A °C
Evaporation rate:	N / A
Flammability:	
Upper/lower flammability or explosive limits:	Not available
Vapour pressure:	
Vapour density:	
Relative density:	
Solubility(ies):	Insoluble
Partition coefficient: n-octanol/water	

(Log KOC):

Auto-ignition temperature:

Decomposition temperature:

Viscosity:

Explosive properties:

Oxidising properties:

## 9.2. Other safety information

Not available

## SECTION 10: Stability and Reactivity

### 10.1. Reactivity

No data available.

### 10.2. Chemical stability

The product is stable with storage at normal ambient temperatures.

### 10.3. Possibility of hazardous reactions

No hazardous reaction when handled and stored as recommended provisions.

### 10.4. Conditions to avoid

Heat. UV exposure.

### 10.5. Incompatible materials

Free radicals. Reducing agents. Heavy metal ions.

### 10.6. Hazardous decomposition products

Carbon dioxide. Carbon monoxide. Acrylic decomposition products.

### 10.7. Additional information

Not available

## SECTION 11: Toxicological information

### 11.1. Acute oral toxicity

Data for mixture

Species : Rat

subendpoint	Operator	Value	Units
LD50	>	5000	mg/kg bw

Substances

Not available

### 11.2. Acute skin toxicity

Data for mixture

Not available

Substances

Not available

### 11.3. Acute inhalation toxicity

Data for mixture

Not available

Substances

Not available

### 11.4. Skin corrosion

Data for mixture

Not available

Substances

Not available

### 11.5. Eye damage

Data for mixture

Not available

**Substances**

Not available

**11.6. Skin sensitisation**

**Data for mixture**

Not available

**Substances**

Not available

**11.7. STOT RE**

**Data for mixture**

Not available

**Substances**

Not available

**11.8. STOT SE**

**Data for mixture**

Not available

**Substances**

Not available

**11.9. Carcinogenicity**

**Data for mixture**

Not available

**Substances**

Not available

**11.10. Reproductive and Developmental Toxicity**

**Data for mixture**

Not available

**Substances**

Not available

**11.11. genotoxicity**

**Data for mixture**

Not available

**Substances**

Not available

**Additional information**

No information available.

**Substances**

Not available

**Data for mixture**

No information available.

## **SECTION 12: Ecological information**

**12.1. Toxicity**

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

**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

No data available.

#### 12.6. Other adverse effects

No data available.

#### 12.7. Additional ecotoxicological information

Not available

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Product/Packaging disposal

Waste codes / waste designations according to EWC / AVV: The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

Properties of waste which render it hazardous: Irritant. Harmful.

Waste treatment options: Appropriate disposal / Product: Dispose of waste according to applicable legislation. May be disposed of in landfill or incinerator in accordance with local, state, or federal regulations.

Waste treatment options: Appropriate disposal / Package: Handle contaminated packages in the same way as the substance itself. Dispose of waste according to applicable legislation.

#### 13.2. Additional information

Not available

### SECTION 14: Transport information

#### 14.1. UN number

No data available.

#### 14.2. UN proper shipping name

No data available.

#### 14.3. Transport hazard class(es)

No data available.

#### 14.4. Packing group

No data available.

#### 14.5. Environmental hazards

No data available.

#### 14.6. Special precautions for user

No data available.

#### 14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No data available.

#### 14.8. Additional information

Not available

### SECTION 15: Regulatory information

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

EU legislation

This product is a medical device according to Directive 93/42.

Not available

#### 15.2. Chemical Safety Assessment

No data available.

#### 15.3. Additional information

Not available

## SECTION 16: Other information

Creation date: 29/03/2017  
Version date: 29/03/2017  
Printing date: 22/05/2017

### 16.1. Indication of changes

Not applicable (first edition of the MSDS).

### 16.2. Abbreviations and acronyms

ADN / ADNR: Regulations concerning the transport of dangerous substances in barges on the waterways. ADR / RID: European Agreement concerning the International Carriage of Dangerous Goods by Road / Regulations concerning the international carriage of dangerous goods by rail. CAS: Chemical Abstract Service Number. CLP: Classification, labeling and packaging. IATA: International Air Transport Association. IMDG: International Maritime Dangerous Goods Code. DPD Dangerous Preparation Directive. UN number: United Nations number. No EC: European Commission Number. VPvB: very persistent and very bioaccumulative substances.

### 16.3. Key literature references and sources for data

No data available.

### 16.4. Classification for mixtures and used evaluation method according to regulation (EC) 1272/2008 [CLP]

Classification of the mixture is in accordance with the evaluation method described in Regulation (EC) No 1272/2008.

### 16.5. Relevant R-, H- and EUH-phrases (Number and full text)

H290	May be corrosive to metals.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

### 16.6. Training advice

Refer to Sections 4, 5, 6, 7 and 8 of this safety data sheet.

### 16.7. Additional information

Not available

The information given in this Safety Data Sheet is based on our present knowledge and on European and national regulations. This Safety Data Sheet describes safety requirements relative to identified uses, it doesn't guarantee all the product properties particularly in the case of non identified uses. The product mustn't be used for any uses other than those identified under heading 1. Since the user's working conditions are not known by us, it is the responsibility of the user to take all necessary measures to comply with legal requirements for specific uses and avoid negative health effects.



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

#### 1.1. Product identifier

Trade name / designation : DENTOTEMP Catalyst.  
 Article No (user) : DT-2.10 / DTCA2-20 / DTCA1-5 / DTCA4-VP.

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

Relevant identified uses : Dental products.

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

Supplier : ITENA CLINICAL  
 Street: 83, Avenue Foch  
 Postal code / City: 75116 Paris  
 Country: France  
 Telephone: [+33 1 45 91 30 06](tel:+33145913006)  
 Telefax: [+ 33 1 45 91 61 31](tel:+33145916131)  
 E-mail: [contact@itena-clinical.com](mailto:contact@itena-clinical.com)





#### 1.4 Emergency Telephone Number

Not available

### SECTION 2: Hazards identification


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

Classification according to Regulation (EC) No. 1272/2008 [CLP]

	Classification	Hazard statements	
	Skin Irrit. 2	H315	Causes skin irritation.
	Skin Sens. 1	H317	May cause an allergic skin reaction.
	Eye Irrit. 2	H319	Causes serious eye irritation.
	STOT SE 3	H335	May cause respiratory irritation.

#### 2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms	
Signal word	Warning
Product identifiers	-
Hazard Statements	H315 - Causes skin irritation. H317 - May cause an allergic skin reaction. H319 - Causes serious eye irritation. H335 - May cause respiratory irritation.
Supplemental Hazard information (EU)	-
Precautionary Statements - General	-
Precautionary Statements - Prevention	P102 - Keep out of reach of children. P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Precautionary Statements - Response

Precautionary Statements - Storage

Precautionary Statements - Disposal

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.

P302+P350 - IF ON SKIN: Gently wash with plenty of soap and water.

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P403 - Store in a well-ventilated place.

-

### 2.3. Other hazards

Adverse human health effects and symptoms : Prolonged or repeated contact with skin or mucous membrane result in irritation symptoms such as redness, blistering, dermatitis, etc. People who are sensitive to methacrylate may have an allergic reaction.

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Substance	C (%)	Classification	Specific concentration limits	Note
2-Propenoic acid, 2-methyl-, 1,2-ethanediybis(oxy-2,1-ethanediy) ester CAS N°:109-16-0 EC N°:203-652-6 IDX N°:607-134-00-4	25.0% ≤C≤ 50.0%	Eye Irrit. 2: H319 Skin Irrit. 2: H315 STOT SE 3: H335	STOT SE 3; H335: C ≥ 10 %	-
Silica, amorphous, fumed, cryst.-free CAS N°:112945-52-5 EC N°: IDX N°:	0.0% ≤C≤ 5.0%	Met. Corr. 1: H290	-	-
dibenzoyl peroxide CAS N°:94-36-0 EC N°:202-327-6 IDX N°:617-008-00-0	0.0% ≤C≤ 5.0%	Skin Sens. 1: H317 Eye Irrit. 2: H319	-	-

### 3.2. Mixtures

Not available

### 3.3. Remark

Text phrases and H- EUH-: see section 16.

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

General information : In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

Following inhalation : Remove person to fresh air and keep comfortable for breathing. In case of respiratory tract irritation, consult a physician.

Following skin contact : In case of skin irritation, consult a physician. After contact with skin, wash immediately with plenty of water and soap. In case of skin reactions, consult a physician.

Following eye contact : In case of eye irritation consult an ophthalmologist. Rinse immediately carefully and thoroughly with eye-bath or water.

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

Not available

### 4.3. Indication of any immediate medical attention and special treatment needed

Notes for the doctor : Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media : Extinguishing powder. Carbon dioxide (CO<sub>2</sub>). Water spray.

Unsuitable extinguishing media : Strong water jet.

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

Not available

## 5.3. Advice for firefighters

Not available

## 5.4. Additional information

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

Provide adequate ventilation.

## 6.2. Environmental precautions

Do not allow to enter into surface water or drains.

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

Treat the recovered material as prescribed in the section on waste disposal. Collect in closed and suitable containers for disposal. Clean contaminated objects and areas thoroughly observing environmental regulations. Ventilate affected area. Wipe up with absorbent material (eg. cloth, fleece).

## 6.4. Reference to other sections

Safe handling: see section 7. Disposal: see section 13. Personal protection equipment: see section 8.

## 6.5. Additional information

Not available

# SECTION 7: Handling and Storage

## 7.1. Precautions for safe handling

No special measures are necessary.

Protective measures

Avoid contact with skin, eyes and clothes. Sewers and ducts must be protected against the entry of the product. Avoid breathing dust.

Advices on general occupational hygiene

In the immediate working surroundings there must be: Provide eye shower and label its location conspicuously.

Remove contaminated, saturated clothing immediately. When using do not eat, drink, smoke, sniff.

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

Ensure adequate ventilation of the storage area. Keep/store only in original container. Keep container tightly closed in a cool, well-ventilated place. Keep out of direct sunlight, open flames and areas of contamination. Avoid storing the product too long at temperatures above 75 ° F (24 ° C).

## 7.3. Specific end uses

Observe instructions for use.

# SECTION 8: Exposure controls / personal protection

## 8.1. Control parameters

Not available

## 8.2. Exposure controls

### Appropriate engineering controls

See section 7. No additional measures necessary.

### Personal protection equipment



Eye/face protection

: Wear eye protection equipment.  
Suitable eye protection: Eye glasses. Eye glasses with side protection.

Skin protection

: Hand protection: Suitable material: Latex.  
Hand protection: Additional hand protection measures.: Use gloves only once.  
Hand protection: Remark: 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. Breakthrough times and swelling properties of the material must be taken into consideration.

Hand protection: Wear protective gloves.

Respiratory protection : Usually no personal respiratory protection necessary.

Environmental exposure controls

See section 7. No additional measures necessary.

### 8.3. Additional information

Not available

## SECTION 9: Physical and chemical Properties

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

<b>Physical state:</b>	Solid - Paste
<b>Colour:</b>	Pink
<b>Odour:</b>	Specific odor
<b>Odour threshold:</b>	Not available
<b>PH:</b>	
<b>Melting point/freezing point:</b>	N / A
<b>Initial boiling point and boiling range:</b>	N / A °C
<b>Flash point:</b>	N / A °C
<b>Evaporation rate:</b>	N / A
<b>Flammability:</b>	
<b>Upper/lower flammability or explosive limits:</b>	Not available
<b>Vapour pressure:</b>	
<b>Vapour density:</b>	
<b>Relative density:</b>	
<b>Solubility(ies):</b>	Insoluble
<b>Partition coefficient: n-octanol/water (Log KOC):</b>	
<b>Auto-ignition temperature:</b>	
<b>Decomposition temperature:</b>	
<b>Viscosity:</b>	
<b>Explosive properties:</b>	
<b>Oxidising properties:</b>	

### 9.2. Other safety information

Not available

## SECTION 10: Stability and Reactivity

### 10.1. Reactivity

No data available.

### 10.2. Chemical stability

The product is stable with storage at normal ambient temperatures.

### 10.3. Possibility of hazardous reactions

No hazardous reaction when handled and stored as recommended provisions.

### 10.4. Conditions to avoid

Heat. UV exposure.

### 10.5. Incompatible materials

Free radicals. Reducing agents. Heavy metal ions.

### 10.6. Hazardous decomposition products

Carbon dioxide. Carbon monoxide. Acrylic decomposition products.

## 10.7. Additional information

Not available

## SECTION 11: Toxicological information

### 11.1. Acute oral toxicity

Data for mixture

Species : Rat

subendpoint	Operator	Value	Units
LD50	>	5000	mg/kg bw

Substances

Not available

### 11.2. Acute skin toxicity

Data for mixture

Not available

Substances

Not available

### 11.3. Acute inhalation toxicity

Data for mixture

Not available

Substances

Not available

### 11.4. Skin corrosion

Data for mixture

Not available

Substances

Not available

### 11.5. Eye damage

Data for mixture

Not available

Substances

Not available

### 11.6. Skin sensitisation

Data for mixture

Not available

Substances

Not available

### 11.7. STOT RE

Data for mixture

Not available

Substances

Not available

### 11.8. STOT SE

Data for mixture

Not available

Substances

Not available

### 11.9. Carcinogenicity

Data for mixture

Not available

Substances

Not available

#### 11.10. Reproductive and Developmental Toxicity

##### Data for mixture

Not available

##### Substances

Not available

#### 11.11. genotoxicity

##### Data for mixture

Not available

##### Substances

Not available

#### Additional information

No information available.

##### Substances

Not available

##### Data for mixture

No information available.

## SECTION 12: Ecological information

#### 12.1. Toxicity

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

#### 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

No data available.

#### 12.6. Other adverse effects

No data available.

#### 12.7. Additional ecotoxicological information

Not available

## SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Product/Packaging disposal

Waste codes / waste designations according to EWC / AVV: The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

Properties of waste which render it hazardous: Irritant. Harmful.

Waste treatment options: Appropriate disposal / Product: Dispose of waste according to applicable legislation. Delivery to an approved waste disposal company. May be disposed of in landfill or incinerator in accordance with local, state, or federal regulations.

Waste treatment options: Appropriate disposal / Package: Handle contaminated packages in the same way as the substance itself. Dispose of waste according to applicable legislation.

#### 13.2. Additional information

Not available

## SECTION 14: Transport information

### 14.1. UN number

No data available.

### 14.2. UN proper shipping name

No data available.

### 14.3. Transport hazard class(es)

No data available.

### 14.4. Packing group

No data available.

### 14.5. Environmental hazards

No data available.

### 14.6. Special precautions for user

No data available.

### 14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No data available.

### 14.8. Additional information

Not available

## SECTION 15: Regulatory information

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

EU legislation

This product is a medical device according to EC Directive 93/42.

Not available

### 15.2. Chemical Safety Assessment

No data available.

### 15.3. Additional information

Not available

## SECTION 16: Other information

Creation date: 05/04/2017

Version date: 05/04/2017

Printing date: 22/05/2017

### 16.1. Indication of changes

Not applicable (first edition of the MSDS).

### 16.2. Abbreviations and acronyms

ADN / ADN: Regulations concerning the transport of dangerous substances in barges on the waterways. ADR / RID: European Agreement concerning the International Carriage of Dangerous Goods by Road / Regulations concerning the international carriage of dangerous goods by rail. CAS: Chemical Abstract Service Number. CLP: Classification, labeling and packaging. IATA: International Air Transport Association. IMDG: International Maritime Dangerous Goods Code. DPD Dangerous Preparation Directive. UN number: United Nations number. No EC: European Commission Number. VPvB: very persistent and very bioaccumulative substances.

### 16.3. Key literature references and sources for data

No data available.

### 16.4. Classification for mixtures and used evaluation method according to regulation (EC) 1272/2008 [CLP]

Classification of the mixture is in accordance with the evaluation method described in Regulation (EC) No 1272/2008.

### 16.5. Relevant R-, H- and EUH-phrases (Number and full text)

H290	May be corrosive to metals.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

#### 16.6. Training advice

Refer to Sections 4, 5, 6, 7 and 8 of this safety data sheet.

#### 16.7. Additional information

Not available

The information given in this Safety Data Sheet is based on our present knowledge and on european and national regulations. This Safety Data Sheet describes safety requirements relative to identified uses, it doesn't guarantee all the product properties particularly in the case of non identified uses. The product mustn't be used for any uses other than those identified under heading 1. Since the user's working conditions are not known by us, it is the responsibility of the user to take all necessary measures to comply with legal requirements for specific uses and avoid negative health effects.