

## Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (amended by Regulation (EU) No. 2015/830)

Version date: 03/04/2017 Version: 1 Language: EN

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

#### 1.1. Product identifier

Trade name / designation PROVITEMP Base. PTEMP1-10. Article No (user)

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

Relevant identified uses Dental product.

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 Telefax: + 33 1 45 91 61 31 E-mail: 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 stat	ements
<b>(</b>	Skin Irrit. 2	H315	Causes skin irritation.
<b>(</b>	Eye Irrit. 2	H319	Causes serious eye irritation.
	STOT SE 3	H335	May cause respiratory irritation.

#### 2.2. Label elements

Hazard pictograms

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

Signal word **Product identifiers** 

**Hazard Statements** H315 - Causes skin irritation.

> 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.

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.

PROVITEMP Base 1/8 Precautionary Statements - Response 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.

Precautionary Statements - Storage Precautionary Statements - Disposal P403 - Store in a well-ventilated place.

#### 2.3. Other hazards

Adverse human health effects and symptoms

Inhalation of dust may cause irritation of the respiratory system. 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 allergy.

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

#### 3.1. Substances

Substance	C (%)	Classification	Specific concentration limits	Note
Poly(oxy-1,2-ethanediyl), .alpha.,.alpha.'-	25.0% ≤C≤	-	-	-
[(1-methylethylidene)di-4,1-	50.0%			
phenylene]bis[.omega[(2-methyl-1-oxo-				
2-propen-1-yl)oxy]-				
CAS N°:41637-38-1				
EC N°:				
IDX N°:	0.00/ .0.			
ethyl 4-dimethylaminobenzoate	0.0% ≤C≤	-	-	-
CAS N°:10287-53-3	10.0%			
EC N°:233-634-3				
IDX N°:	0.00/ 404	Ov. Cal. 3: U272		
potassium nitrate CAS N°:7757-79-1	0.0% ≤C≤ 5.0%	Ox. Sol. 3: H272	-	-
EC N°:231-818-8	5.0%			
IDX N°:				
	0.00/ <c< td=""><td>Mot Corr 1.11200</td><td></td><td></td></c<>	Mot Corr 1.11200		
Silica, amorphous, fumed, crystfree CAS N°:112945-52-5	0.0% ≤C< 5.0%	Met. Corr. 1: H290	-	-
EC N°:	3.070			
IDX N°:				

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

advice.

Following inhalation : Remove person to fresh air and keep comfortable for breathing. In case of respiratory tract

irritation, consult a physician. Provide fresh air.

Following skin contact : Wash with soap and water. In case of skin irritation, 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.

PROVITEMP Base 2 / 8

## **SECTION 5: Firefighting measures**

#### 5.1. Extinguishing media

Suitable extinguishing media : Extinguishing powder. Carbon dioxide (CO2). 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

Ensure that waste is collected and contained. 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. 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. Wear personal protective clothing (see section 8). 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. Wash contaminated clothing immediately.

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

Ensure adequate ventilation of the storage area. Keep in a cool, well-ventilated place. Keep container tightly closed and in a well-ventilated place. Keep only in the original container in a cool, well-ventilated place. Avoid prolonged storage at temperatures above 24 ° C. Store away from light, open flame and contamination.

## 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** 

Not available

Personal protection equipment





PROVITEMP Base 3 / 8

Eye/face protection Wear eye protection equipment.

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

Hand protection: Suitable gloves type: Disposable gloves. Skin protection

Hand protection: Suitable material: Latex.

Hand protection: Additional hand protection measures.: Do not wear gloves near machines

and rotating tools. 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.

Body protection: No special measures are necessary. Usually no personal respirative protection necessary.

Environmental exposure controls

See section 7. No additional measures necessary.

8.3. Additional information

Respiratory protection

Not available

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

## 9.1. Information on basic physical and chemical properties

Physical state: Solid - Paste Colour: Yellow / gold Odour: Specific odor Odour threshold: Not available

Melting point/freezing point:

N/A°C Initial boiling point and boiling range: N/A°C Flash point: **Evaporation rate:** N/A

Flammability:

Upper/lower flammability or explosive

Not available

limits:

Vapour pressure:

N/A 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.

PROVITEMP Base 4/8

## 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

Conclusion

Dryness and possible irritation in case of prolonged exposure.

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

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#### 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

PROVITEMP Base 6 / 8

## **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, and 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 in accordance with EEC Directive 93/42.

Not available

**15.2. Chemical Safety Assessment** 

No data available.

15.3. Additional information

Not available

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## **SECTION 16: Other information**

 Creation date:
 03/04/2017

 Version date:
 03/04/2017

 Printing date:
 22/05/2017

## 16.1. Indication of changes

Not applicable (first edition of the MSDS).

## 16.2. Abbreviations and acronyms

ADN / 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)

H272 May intensify fire; oxidiser. H290 May be corrosive to metals.

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 responsability of the user to take all necessary measures to comply with legal requirements for specific uses and avoid negative health effects.

PROVITEMP Base 8 / 8



# **PROVITEMP** Catalyst

## Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (amended by Regulation (EU) No. 2015/830)

Version date: 04/04/2017 Version: 1 Language: EN

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

#### 1.1. Product identifier

Trade name / designation PROVITEMP Catalyst.

PTEMP1-10. Article No (user)

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

Relevant identified uses Dental product.

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 Telefax: + 33 1 45 91 61 31 E-mail: 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 stat	ements
<b>(</b>	Skin Irrit. 2	H315	Causes skin irritation.
<b>(</b>	Eye Irrit. 2	H319	Causes serious eye irritation.
	STOT SE 3	H335	May cause respiratory irritation.

#### 2.2. Label elements

Hazard pictograms

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

Signal word **Product identifiers** 

**Hazard Statements** H315 - Causes skin irritation.

> 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.

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.

**PROVITEMP Catalyst** 1/8 Precautionary Statements - Response 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.

Precautionary Statements - Storage Precautionary Statements - Disposal P403 - Store in a well-ventilated place.

#### 2.3. Other hazards

Adverse human health effects and symptoms

Inhalation of dust may cause irritation of the respiratory system. 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
Poly(oxy-1,2-ethanediyl), .alpha.,.alpha.'-	25.0% ≤C≤	-	-	-
[(1-methylethylidene)di-4,1-	50.0%			
phenylene]bis[.omega[(2-methyl-1-oxo-				
2-propen-1-yl)oxy]-				
CAS N°:41637-38-1				
EC N°:				
IDX N°:				
dibenzoyl peroxide	0.0% ≤C<	Skin Sens. 1: H317	-	-
CAS N°:94-36-0	5.0%	Eye Irrit. 2: H319		
EC N°:202-327-6				
IDX N°:617-008-00-0				
Silica, amorphous, fumed, crystfree	0.0% ≤C<	Met. Corr. 1: H290	-	-
CAS N°:112945-52-5	5.0%			
EC N°:				
IDX N°:				

## 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 : Wash with soap and water. In case of skin irritation, consult a physician. After contact with

skin, wash immediately with plenty of water and soap. In case of skin irritation, 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.

PROVITEMP Catalyst 2 / 8

## **SECTION 5: Firefighting measures**

#### 5.1. Extinguishing media

Suitable extinguishing media : Extinguishing powder. Carbon dioxide (CO2). 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

Use personal protection equipment. Provide adequate ventilation. Remove all sources of ignition.

#### 6.2. Environmental precautions

Not available

#### 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. 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. Wear personal protective clothing (see section 8). Sewers and ducts must be protected against the entry of the product. Avoid breathing dust. Keep away from sources of heat (e.g. hot surfaces), sparks and open flames. Keep away from sources of ignition - No smoking. Do not breathe gas/fumes/vapour/spray.

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. Avoid contact with skin, eyes and clothes. When using do not eat, drink, smoke, sniff.

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

Keep in a cool, well-ventilated place. Keep container tightly closed. Keep/store only in original container. Avoid prolonged storage at temperatures above 24 ° C. Store away from light, open flames, and contamination.

## 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** 

Not available

**Personal protection equipment** 





PROVITEMP Catalyst 3 / 8

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.

Not available

Hand protection: Wear protective gloves.

Body protection: No special measures are necessary. Usually no personal respirative protection necessary.

Respiratory protection

8.3. Additional information

Not available

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

## 9.1. Information on basic physical and chemical properties

Physical state:Solid - PasteColour:whiteOdour:Specific odorOdour threshold:Not available

PH:

Melting point/freezing point:

Initial boiling point and boiling range: N / A  $^{\circ}$ C Flash point: N / A  $^{\circ}$ C Evaporation rate: N / A

Flammability:

Upper/lower flammability or explosive

limits:

Vapour pressure:

Vapour density: N / A

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

Not available

## 10.3. Possibility of hazardous reactions

No hazardous reaction when handled and stored as recommended provisions.

10.4. Conditions to avoid

Heat. UV exposure.

PROVITEMP Catalyst 4 / 8

## 10.5. Incompatible materials

Free radicals. Reducing agents. Heavy metal ions.

## 10.6. Hazardous decomposition products

Carbon dioxide. Carbon monoxide. Acrylic decomposition products.

: Rat

## 10.7. Additional information

Not available

## **SECTION 11: Toxicological information**

## 11.1. Acute oral toxicity

#### **Data for mixture**

Species

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

PROVITEMP Catalyst 5 / 8

## 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**

 $Prolonged\ or\ repeated\ contact\ with\ skin\ or\ mucous\ membrane\ result\ in\ irritation\ symptoms\ such\ as\ redness,\ blistering,\ dermatitis,\ etc.$ 

**Substances** 

Not available

**Data for mixture** 

Prolonged or repeated contact with skin or mucous membrane result in irritation symptoms such as redness, blistering, dermatitis, etc.

## **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

The product has not been tested.

## **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, and federal regulations.

PROVITEMP Catalyst 6 / 8

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 in accordance with EEC 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:
 04/04/2017

 Version date:
 04/04/2017

 Printing date:
 22/05/2017

16.1. Indication of changes

Not applicable (first edition of the MSDS).

16.2. Abbreviations and acronyms

ADN / 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.

PROVITEMP Catalyst 7 / 8

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

H290 May be corrosive to metals.

H317 May cause an allergic skin reaction.
H319 Causes serious eye 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 responsability of the user to take all necessary measures to comply with legal requirements for specific uses and avoid negative health effects.

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