

Safety Data Sheet

section

1 Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name/designation : PROVITEMP.
Article No (user) : PTEMP1-10/PTEMP2-VP.
UFI : UA68H0R0K20TY76V

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

Uses advised against : No data available.

1.3 Details of the supplier of the safety data sheet

Supplier : Name: ITENA CLINICAL
Street: Central Parc, Bat B - 97 Allée de la Louve
Postal code/City: 93420 Villepinte
Country: France
Telephone: +33(0)1 45 91 30 06
E-mail: Contact@itena-clinical.com

1.4 Emergency Telephone Number

WORLD:

section

2 Hazards identification

2.1 Classification of the substance or mixture

Classification according to the regulation (EC) n°1272/2008 (CLP) and its amendments

Hazards identification:

H241	Org. Perox. B	Heating may cause a fire or explosion.
H272	Ox. Sol. 3	May intensify fire; oxidiser.
H350	Carc. 1A	May cause cancer.
H360	Repr. 1B	May damage fertility or the unborn child.
H412	Aquatic Chronic 3	Harmful to aquatic life with long lasting effects

2.2 Label elements

Label elements according to the regulation (EC) n°1272/2008 (CLP) and its amendments

Labelling

Hazard pictograms



Signal word

Danger

Hazard Statements

H241 Heating may cause a fire or explosion.
H272 May intensify fire; oxidiser.
H350 May cause cancer.
H360 May damage fertility or the unborn child.

H412 Harmful to aquatic life with long lasting effects

Precautionary Statements - Prevention

- P201 Obtain special instructions before use.
 P202 Do not handle until all safety precautions have been read and understood.
 P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
 P220 Keep/Store away from clothing/.../combustible materials.
 P234 Keep only in original container.
 P235 Keep cool.
 P240 Ground and bond container and receiving equipment.
 P273 Avoid release to the environment.
 P280 Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary Statements - Response

- P308+P313 IF exposed or concerned: Get medical advice/attention.
 P370+P378 In case of fire: Use... to extinguish.
 P370+P380+ In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion.
 P375
 P370+P380+ P370+P380+P375+P378-li
 P375+P378

Precautionary Statements - Storage

- P403 Store in a well-ventilated place.
 P405 Store locked up.
 P410 Protect from sunlight.
 P411 Store at temperatures not exceeding ... °C/...°F.
 P420 Store away from other materials.

Precautionary Statements - Disposal

- P501 Dispose of contents/container to ...

Contains

Silica, amorphous, fumed, cryst.-free, ethyl 4-dimethylaminobenzoate

2.3 Other hazards

According to Regulation (EU) 1907/2006, no substances are assessed as PBT or vPvB.

According to Regulation (EU) 2017/2100 or Regulation (EU) 2018/605, no substances are known to have endocrine disrupting properties.

3 Composition/information on ingredients

3.2 Mixtures

In accordance with the product knowledge, no nanomaterials have been identified.

The mixture does not contain any substances classified as Substances of Very High Concern (SVHC) by the European Chemicals Agency (ECHA) under article 57 of REACH: <http://echa.europa.eu/fr/candidate-list-table>.

Substance	Concentration (%)	Specific concentration limits	Classification
Poly(oxy-1,2-ethanediyl), .alpha.,.alpha.'-[(1-methylethylidene)di-4,1-phenylene]bis[.omega.-[(2-methyl-1-oxo-2-propen-1-yl)oxy]-			
CAS N° EC N° IDX N° Registration number	41637-38-1 C= 40.275%		H413 Aquatic Chronic 4
Silica, amorphous, fumed, cryst.-free			
CAS N° EC N°	112945-52-5 C= 2.5%		H332 Acute Tox. 4 INHALATION

IDX N° Registration number				H350 Carc. 1A
ethyl 4-dimethylaminobenzoate				
CAS N° EC N° IDX N° Registration number	10287-53-3 233-634-3	C= 1.05%		H360 Repr. 1B H411 Aquatic Chronic 2
dibenzoyl peroxide				
CAS N° EC N° IDX N° Registration number	94-36-0 202-327-6 617-008-00-0 01- 2119511472- 50-XXXX	C= 0.5%		H241 Org. Perox. B H317 Skin Sens. 1 H319 Eye Irrit. 2
D-gluconic acid, compound with N,N''-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1)				
CAS N° EC N° IDX N° Registration number	18472-51-0 242-354-0	C= 0.02%	M=10 M(Chronic)=1	H318 Eye Dam. 1 H400 Aquatic Acute 1 H410 Aquatic Chronic 1

Remark

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

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).

Do not leave affected person unattended.

Remove victim out of the danger area.

Keep affected person warm, still and covered.

Remove the affected person from the danger zone and lay down.

Following inhalation:

Remove person to fresh air and keep comfortable for breathing.

Following skin contact:

Wash with soap and water.

Remove contaminated, saturated clothing immediately.

Following eye contact:

In case of eye irritation consult an ophthalmologist.

Rinse immediately carefully and thoroughly with eye-bath or water.

Following ingestion:

Never give anything by mouth to an unconscious person or a person with cramps.

IF SWALLOWED: Rinse mouth.

Do NOT induce vomiting.

Self-protection of the first aider:

First aider: Pay attention to self-protection!.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11.

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:

Foam.

Extinguishing powder.

Carbon dioxide (CO₂).

Sand.

Unsuitable extinguishing media:

Strong water jet.

5.2 **Special hazards arising from the substance or mixture**

Formation of toxic gases is possible during heating or in case of fire.

5.3 **Advice for firefighters**

Wear a self-contained breathing apparatus and chemical protective clothing.

Additional information

Do not inhale vapors and fumes.

Co-ordinate fire-fighting measures to the fire surroundings.

Move undamaged containers from immediate hazard area if it can be done safely.

Use caution when applying carbon dioxide in confined spaces. carbon dioxide can displace oxygen.

Use water spray jet to protect personnel and to cool endangered containers.

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.

Remove persons to safety.

Provide adequate ventilation.

Use appropriate respiratory protection.

6.2 **Environmental precautions**

Ensure that waste is collected and contained.

In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

Avoid release to the environment.

Cover drains.

Ensure all waste water is collected and treated via a waste water treatment plant.

Do not allow to enter into soil/subsoil.

Do not allow to enter into surface water or drains.

Retain contaminated washing water and dispose it.

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.

6.4 Reference to other sections

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

Additional information

Not available

7 Handling and Storage

7.1 Precautions for safe handling

Avoid exposure - obtain special instructions before use.

PROTECTIVE MEASURES:

Avoid contact with skin, eyes and clothes.

Keep away from sources of heat (e.g. hot surfaces), sparks and open flames.

Provide earthing of containers, equipment, pumps and ventilation facilities.

Use only in well-ventilated areas.

If local exhaust ventilation is not possible or not enough, the entire work area must be ventilated by technical means.

Only allow access to authorised staff.

Sewers and ducts must be protected against the entry of the product.

Provide for retaining containers, eg. floor pan without outflow.

Provide adequate ventilation as well as local exhaustion at critical locations.

Dust should be exhausted directly at the point of origin.

Advices on general occupational hygiene:

Wash hands before breaks and after work.

Remove contaminated, saturated clothing immediately.

Work in well ventilated zones or use proper respiratory protection.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry, cool, and well-ventilated place.

Keep container in upright position in order to prevent leakage.

Requirements for storage rooms and vessels:

Protect from sunlight.

Ensure adequate ventilation of the storage area.

Keep only in original container.

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Store locked up.

Use isolated drainage to prevent discharge to soil.

Advice on joint storage:

Keep away from food, drink and animal feedingstuffs.

Store away from other materials.

Keep away from clothing and other combustible materials.

Keep only in the original container in a cool, well-ventilated place, away from highly flammable substances.

7.3 Specific end uses

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

8 Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits:

Substance	Value	Unit	Type
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No data available

Biological limit values:

Not available

Exposure limits at intended use:

Not available

Remark:

Not available

8.2 Exposure controls

Appropriate engineering controls:

Technical measures and the application of suitable work processes have priority over personal protection equipment. Provide adequate ventilation as well as local exhaust at critical locations.

Individual protection measures, such as personal protective equipment:



Eye/face protection

- : **Suitable eye protection:**
No data available.

Skin protection

- : **Hand protection:**

Suitable gloves type:

Wear protective gloves.

Suitable material:

Butyl caoutchouc (butyl rubber).

Additional hand protection measures:

Do not wear gloves near machines and rotating tools.

Use gloves only once.

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.

Body protection:

Suitable protective clothing:

Lab coat.

Respiratory protection

: **Respiratory protection necessary at:**
 If technical exhaust or ventilation measures are not possible or insufficient, respiratory protection must be worn.
Suitable respiratory protection apparatus:
 Wear respiratory protection.
Remark:
 The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product. If the concentration is exceeded, self-contained breathing apparatus must be used.
 Observe the wear time limits as specified by the manufacturer.
 Use only respiratory protection equipment with CE-symbol including four digit test number.

Environmental exposure controls:

Not available

Consumer exposure controls:

Not available

Additional information

Not available

section **9 Physical and chemical Properties**

9.1 Information on basic physical and chemical properties

Physical state	: Solid
Colour	: Yellow
Odour	: Specific Odor
pH	: Not applicable
Melting point/freezing point	: Not available
Initial boiling point and boiling range	: Not applicable
Flash point	: Not applicable
Flammability	: Not available
Upper/lower flammability or explosive limits	: Not applicable
Vapour pressure	: Not available
Vapour density	: Not applicable
Relative density	: Not available
Solubility(ies)	: Not available
Partition coefficient n-octanol/water (log value)	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
Dynamic viscosity	: Not available
Kinematic viscosity	: Not available
Oxidising properties	: Not available
Solubility in other Solvents	: Not available
Particle characteristics	: Not available

9.2 Other safety information

Information concerning to the classes of physical hazards

Not available

Other security characteristics

Not available

10 Stability and Reactivity

10.1 Reactivity

No data available.

10.2 Chemical stability

The product is stable when stored at normal ambient temperatures.

10.3 Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

10.4 Conditions to avoid

No data available.

10.5 Incompatible materials

No data available.

10.6 Hazardous decomposition products

Does not decompose when used for intended uses.

Additional information

Not available

11 Toxicological information

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

Acute oral toxicity:

The product is not classified.

Substances:

Not available

Acute dermal toxicity:

The product is not classified.

Substances:

Not available

Acute inhalation toxicity:

The product is not classified.

Substances:

Not available

Skin corrosion/irritation:

The product is not classified.

Substances:

Not available

Serious eye damage/irritation:

The product is not classified.

Substances:

Not available

Skin sensitisation:

The product is not classified.

Substances:

Not available

Specific target organ toxicity (repeated exposure):

The product is not classified.

Substances:

Not available

Specific target organ toxicity (single exposure):

The product is not classified.

Substances:

Not available

Carcinogenicity:

The product is classified Carc. 1A according to the referenced regulation.

May cause cancer.

Substances:

Not available

Reproductive toxicity:

The product is classified Repr. 1B according to the referenced regulation.

May damage fertility or the unborn child.

Substances:

Not available

Germ cell mutagenicity:

The product is not classified.

Substances:

Not available

Sensitisation to the respiratory tract:

The product is not classified.

Substances:

Not available

Additional information:

Not available

11.2 Information on other hazards

Endocrine disrupting properties:

According to Regulation (EU) 2017/2100 or Regulation (EU) 2018/605, no substances are known to have endocrine disrupting properties.

12 Ecological information

12.1 Toxicity

Harmful to aquatic life with long lasting effects.

Substances:

Not available

12.2 Persistence and degradability

The product has not been tested.

Substances:

Not available

12.3 Bioaccumulative potential

The product has not been tested.

Substances:

Not available

12.4 Mobility in soil

The product has not been tested.

Substances:

Not available

12.5 Results of PBT and vPvB assessment

According to Regulation (EU) 1907/2006, no substances are assessed as PBT or vPvB.

12.6 Endocrine disrupting properties

According to Regulation (EU) 2017/2100 or Regulation (EU) 2018/605, no substances are known to have endocrine disrupting properties.

12.7 Other adverse effects

Not available

Additional ecotoxicological information

Not available

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.

Waste treatment options:

Appropriate disposal/Product:

Waste requiring special supervision.

Dispose of waste according to applicable legislation.

Delivery to an approved waste disposal company.

Appropriate disposal/Package:

Non-contaminated packages must be recycled or disposed of.

Contaminated packing must be completely emptied and can be reused after proper cleaning.

Packing which cannot be properly cleaned must be disposed of.

Handle contaminated packages in the same way as the substance itself.

Dispose of waste according to applicable legislation.

Remark:

For recycling, contact manufacturer.

Collect the waste separately.

Consult the appropriate authorities about waste disposal.

Do not mix with other wastes.

The waste is to be kept separate from other types of waste until its disposal.

Concerning the waste it has to be checked, whether a transport authorisation is required.

Additional information

Not available

14 Transport information

14.1 UN number

Not available

14.2 UN proper shipping name

Not available

14.3 Transport hazard class(es)

Not available

14.4 Packing group

Not available

14.5 Environmental hazards

Not available

14.6 Special precautions for user

Not available

14.7 Bulk shipping according to IMO instruments

Not available

Additional information

Not available

15 Regulatory information

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

This SDS has been established in accordance with REACH regulation, including its amendments: REACH Regulation (EC) No 1907/2006.

This SDS has been established in accordance with CLP regulation, including its amendments: CLP Regulation EC No. 1272/2008.

EU legislation:

Other regulations (EU):

Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances [Seveso-III-Directive]:

"Organic peroxides type A or type B. The total quantity likely to be present in the installation being: 1. greater than or equal to 50 kgA 2. Greater than or equal to 1 kg but less than 50 kgD Low threshold quantity within the meaning of article R. 511-10: 10 t High threshold quantity within the meaning of article R. 511-10: 10 t".

"Oxidizing solids categories 1, 2 or 3. The total quantity likely to be present in the installation being: 1. greater than or equal to 50 t.....A 2. Greater than or equal to 2 t but less than 50 t.....D Low threshold quantity as defined in article R. 511-10: 50 t High threshold quantity as defined in article R. 511-10: 200 t".

National regulations:

Cosmetic Ingredient Hotlist:

Substance	CAS	EC
dibenzoyl peroxide	94-36-0	202-327-6
D-gluconic acid, compound with N,N''-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1)	18472-51-0	242-354-0

Occupational Exposure Limit Values (long term) - Canada (Ontario):

Substance	CAS	EC
dibenzoyl peroxide	94-36-0	202-327-6

Occupational Exposure Limit Values (long term) - Canada (Quebec):

Substance	CAS	EC
dibenzoyl peroxide	94-36-0	202-327-6

Occupational Exposure Limit Values (long term) - NZ:

Substance	CAS	EC
dibenzoyl peroxide	94-36-0	202-327-6

Occupational Exposure Limit Values (long term) - Singapore:

Substance	CAS	EC
dibenzoyl peroxide	94-36-0	202-327-6

Occupational Exposure Limit Values (long term) - US (NIOSH):

Substance	CAS	EC
dibenzoyl peroxide	94-36-0	202-327-6

Occupational Exposure Limit Values (long term) - US (OSHA):

Substance	CAS	EC
dibenzoyl peroxide	94-36-0	202-327-6

U.S. - NY - RTK :

Substance	CAS	EC
dibenzoyl peroxide	94-36-0	202-327-6

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

Additional information

Not available

16 Other information

Indication of changes

Not applicable (first edition of the MSDS).

Abbreviations and acronyms

CAS: Chemical Abstract Service Number.

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.

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.

CLP: Classification, labeling and packaging.

VPvB: very persistent and very bioaccumulative substances.

Key literature references and sources for data

No data available.

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

Complies with ATP 18, Regulation (EU) n°2022/692.

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

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

H241	Org. Perox. B	Heating may cause a fire or explosion.
H272	Ox. Sol. 3	May intensify fire; oxidiser.
H317	Skin Sens. 1	May cause an allergic skin reaction.
H318	Eye Dam. 1	Causes serious eye damage
H319	Eye Irrit. 2	Causes serious eye irritation
H332	Acute Tox. 4 INHALATION	Harmful if inhaled.
H350	Carc. 1A	May cause cancer.
H360	Repr. 1B	May damage fertility or the unborn child.
H400	Aquatic Acute 1	Very toxic to aquatic life.
H410	Aquatic Chronic 1	Very toxic to aquatic life with long lasting effects.
H411	Aquatic Chronic 2	Toxic to aquatic life with long lasting effects.
H412	Aquatic Chronic 3	Harmful to aquatic life with long lasting effects
H413	Aquatic Chronic 4	May cause long lasting harmful effects to aquatic life.

Training advice

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

Additional information

Creation date: 28/08/2023

Version date: 28/08/2023

Printing date: 02/04/2024

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.