

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

1.1. Product identifier

Trade name / designation : PREVENT SEAL.
 Article No (user) : PVSEAL-1.2.

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






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
 Acute Tox. 4	H302 Harmful if swallowed.
 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	H302 - Harmful if swallowed. 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. 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.
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	P403 - Store in a well-ventilated place.
Precautionary Statements - Disposal	-

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. May cause irritation to the eyes, skin and respiratory problems when the product is present at high concentrations. 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-, 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl ester CAS N°:72869-86-4 EC N°:276-957-5 IDX N°:607-134-00-4	50.0% ≤C< 75.0%	Skin Irrit. 2: H315 Eye Irrit. 2: H319 STOT SE 3: H335	STOT SE 3; H335: C ≥ 10 %	-
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	25.0% <C≤ 50.0%	Skin Irrit. 2: H315 Eye Irrit. 2: H319 STOT SE 3: H335	STOT SE 3; H335: C ≥ 10 %	-
2-[(2-methyl-1-oxoallyl)oxy]ethyl 1,3-dihydro-1,3-dioxoisobenzofuran-5-carboxylate CAS N°:70293-55-9 EC N°:274-547-0 IDX N°:	0.0% ≤C< 10.0%	-	-	-
glass, oxide, chemicals CAS N°:65997-17-3 EC N°:266-046-0 IDX N°:	0.0% ≤C< 10.0%	-	-	-
2-Propenoic acid, 2-methyl-, phosphinicobis(oxy-2,1-ethanediyl) ester CAS N°:32435-46-4 EC N°:251-040-2 IDX N°:607-134-00-4	0.0% ≤C< 10.0%	Skin Irrit. 2: H315 Eye Irrit. 2: H319 STOT SE 3: H335	STOT SE 3; H335: C ≥ 10 %	-
ethyl 4-dimethylaminobenzoate CAS N°:10287-53-3 EC N°:233-634-3 IDX N°:	0.0% ≤C< 5.0%	-	-	-
dl-bornane-2,3-dione CAS N°:10373-78-1 EC N°:233-814-1 IDX N°:	0.0% ≤C< 5.0%	Acute Tox. 4: H302 Eye Dam. 1: H318	-	-

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.
- 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: Call a POISON CENTER or physician if you feel unwell.

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 : Foam. 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

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).

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

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. Wash contaminated clothing prior to re-use. When using do not eat, drink, smoke, sniff.

7.2. Conditions for safe storage, including any incompatibilities

Store in a well-ventilated place. Keep/store only in original container. Keep container tightly closed in a cool, well-ventilated place.

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



Skin protection

- : Hand protection: Suitable gloves type: 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.

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:	3.2
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:	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

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. Exposition aux UV.

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

Not available

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: Harmful. Irritant.

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 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: 10/04/2017
Version date: 10/04/2017
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)

H302	Harmful if swallowed.
H315	Causes skin irritation.
H318	Causes serious eye damage.
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.