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
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]

<table>
<thead>
<tr>
<th>Classification</th>
<th>Hazard statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Tox. 4</td>
<td>H302 - Harmful if swallowed.</td>
</tr>
<tr>
<td>Skin Irrit. 2</td>
<td>H315 - Causes skin irritation.</td>
</tr>
<tr>
<td>Skin Sens. 1</td>
<td>H317 - May cause an allergic skin reaction.</td>
</tr>
<tr>
<td>Eye Irrit. 2</td>
<td>H319 - Causes serious eye irritation.</td>
</tr>
<tr>
<td>STOT SE 3</td>
<td>H335 - May cause respiratory irritation.</td>
</tr>
</tbody>
</table>

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.

Supplemental Hazard information (EU): -
Precautionary Statements - General
P102 - Keep out of reach of children.

Precautionary Statements - Prevention
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

<table>
<thead>
<tr>
<th>Substance</th>
<th>C (%)</th>
<th>Classification</th>
<th>Specific concentration limits</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Propenoic acid, 2-methyl-, 7,7(9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diy1 ester CAS N°:72869-86-4 EC N°:276-957-5 IDN N°:607-134-00-4</td>
<td>50.0% ≤C&lt; 75.0%</td>
<td>Skin Irrit. 2: H315 Eye Irrit. 2: H319 STOT SE 3: H335</td>
<td>STOT SE 3; H335: C ≥ 10 %</td>
<td>-</td>
</tr>
<tr>
<td>2-Propenoic acid, 2-methyl-1,2-ethanediylbis(oxy-2,1-ethanediyl) ester CAS N°:109-16-0 EC N°:203-652-6 IDN N°:607-134-00-4</td>
<td>25.0% &lt;C≤ 50.0%</td>
<td>Skin Irrit. 2: H315 Eye Irrit. 2: H319 STOT SE 3: H335</td>
<td>STOT SE 3; H335: C ≥ 10 %</td>
<td>-</td>
</tr>
<tr>
<td>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 IDN N°:</td>
<td>0.0% ≤C&lt; 10.0%</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>glass, oxide, chemicals CAS N°:65997-17-3 EC N°:266-046-0 IDN N°:</td>
<td>0.0% ≤C&lt; 10.0%</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2-Propenoic acid, 2-methyl-, phosphinicobis(oxy-2,1-ethanediyl) ester CAS N°:32435-46-4 EC N°:251-040-2 IDN N°:607-134-00-4</td>
<td>0.0% ≤C&lt; 10.0%</td>
<td>Skin Irrit. 2: H315 Eye Irrit. 2: H319 STOT SE 3: H335</td>
<td>STOT SE 3; H335: C ≥ 10 %</td>
<td>-</td>
</tr>
<tr>
<td>ethyl 4-dimethylaminobenzoate CAS N°:10287-53-3 EC N°:233-634-3 IDN N°:</td>
<td>0.0% ≤C&lt; 5.0%</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>di-borne-2,3-dione CAS N°:10373-78-1 EC N°:233-814-1 IDN N°:</td>
<td>0.0% ≤C&lt; 5.0%</td>
<td>Acute Tox. 4: H302 Eye Dam. 1: H318</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
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
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
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.
Advice 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**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Solid - Paste</td>
</tr>
<tr>
<td>Colour</td>
<td>white</td>
</tr>
<tr>
<td>Odour</td>
<td>Specific odor</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>Not available</td>
</tr>
<tr>
<td>PH</td>
<td>3.2</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>N / A °C</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>N / A °C</td>
</tr>
<tr>
<td>Flash point</td>
<td>N / A</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>N / A</td>
</tr>
<tr>
<td>Flammability</td>
<td>Not available</td>
</tr>
<tr>
<td>Upper/lower flammability or explosive limits</td>
<td>Not available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>N / A</td>
</tr>
<tr>
<td>Vapour density</td>
<td>N / A</td>
</tr>
<tr>
<td>Relative density</td>
<td>Insoluble</td>
</tr>
<tr>
<td>Solubility(ies):</td>
<td>Not available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water (Log KOC):</td>
<td>Not available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td></td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td></td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Explosive properties</td>
<td></td>
</tr>
</tbody>
</table>

PREVENT SEAL 4 / 8
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

10.6. Hazardous decomposition products

10.7. Additional information
Not available

SECTION 11: Toxicological information

11.1. Acute oral toxicity
Data for mixture
Species: Rat

<table>
<thead>
<tr>
<th>subendpoint</th>
<th>Operator</th>
<th>Value</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50</td>
<td>&gt;</td>
<td>5000</td>
<td>mg/kg bw</td>
</tr>
</tbody>
</table>

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.

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.