

# Safety Data Sheet

According to Regulation 2015 830

Version: 1 Version date: 14/11/2018 Language: EN

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

#### **1.1. Product identifier**

| Trade name / designation            | :        | SILAN-IT                                |
|-------------------------------------|----------|---|
| Article No (user)                   | :        | SILAN-IT                                |
| 1.2. Relevant identified uses of th | e substa | nce or mixture and uses advised against |
| Relevant identified uses            |          | Dental products                         |

| Relevant luentineu uses | • | Dental products   |
|-------------------------|---|-------------------|
| Uses advised against    | : | No data available |

### 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: <u>+33 1 45 91 30 06</u>       |
|          | Telefax: <u>+ 33 1 45 91 61 31</u>        |
|          | E-mail: <u>contact@itena-clinical.com</u> |

#### **1.4 Emergency Telephone Number**

In England and Wales: dial 111 (NHS 111), In Scotland: dial 111 (NHS 24), In Northern Ireland: Contact your local GP or pharmacist during normal hours. During GP Out-of-Hours (www.gpoutofhours.hscni.net/): Belfast HSC Trust, (North & West) 028 9074 4447, (South & East) 028 9079 6220 South Eastern HSC Trust, (North Down & Ards) 028 9182 2344, (Lisburn & Downpatrick) 028 9260 2204, Dalriada Urgent Care (Northern Trust area) 028 2566 3500, Southern HSC Trust 028 3839 9201, Western Urgent Care 028 7186 5195Not available

### **SECTION 2: Hazards identification**

### 2.1. Classification of the substance or mixture

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

|            | Classification | Hazard staten | Hazard statements                  |  |
|------------|----------------|---------------|------------------------------------|--|
| ۲          | Flam. Liq. 2   | H225          | Highly flammable liquid and vapour |  |
| $\diamond$ | Skin Irrit. 2  | H315          | Causes skin irritation             |  |
| $\Diamond$ | Eye Irrit. 2   | H319          | Causes serious eye irritation      |  |
| $\diamond$ | STOT SE 3      | H335          | May cause respiratory irritation   |  |

#### 2.2. Label elements

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

### Hazard pictograms

|                                      | $\checkmark$ $\checkmark$                 |
|--------------------------------------|---|
| Signal word                          | Danger                                    |
| Product identifiers                  | -   |
| Hazard Statements                    | H225 - Highly flammable liquid and vapour |
|                                      | H315 - Causes skin irritation             |
|                                      | H319 - Causes serious eye irritation      |
|                                      | H335 - May cause respiratory irritation   |
| Supplemental Hazard information (EU) | -   |

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+P352 - IF ON SKIN: Wash with plenty of 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 : Prolonged or repeated contact with skin or mucous membrane result in irritation symptoms such as redness, blistering, dermatitis, etc. May cause an allergic skin reaction.

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

### 3.1. Substances

This product does not contain any hazardous ingredients at or above regulated thresholds.

### 3.2. Mixtures

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

#### 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                 | : 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                    | : Do NOT induce vomiting. Rinse mouth immediately and drink plenty of water.   |
| Self-protection of the first aider     | : First aider: Pay attention to self-protection!   |

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)

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

Not available

### 5.4. 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

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. 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

Protective measures

Avoid contact with skin, eyes and clothes. Use only in well-ventilated areas. Avoid breathing gas / fumes / vapour / spray.

Advices on general occupational hygiene

Wash hands before breaks and after work.

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

Keep only in the original container in a cool, well-ventilated place. Keep container tightly closed. Protect from sunlight. Keep away from heat. Store at about 10 ° C

Requirements for storage rooms and vessels

Ensure adequate ventilation of the storage area.

Advice on joint storage

Keep away from food, drink and animal feedingstuffs. 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.

Further information on storage conditions

Use only non-sparking tools.

### 7.3. Specific end uses

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

### SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Not available

### 8.2. Exposure controls

#### **Appropriate engineering controls**

Technical measures and the application of suitable work processes have priority over personal protection equipment. Personal protection equipment



| Eye/face protection | : Eye glasses  |
|---------------------|--|
|                     | Suitable eye protection: Wear eye protection equipment.                |
|                     | Recommended eye protection articles: Eye glasses                       |
| Skin protection     | : Hand protection: Suitable gloves type: Wear protective gloves.       |
|                     | Hand protection: Suitable material: NR (natural rubber, natural 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: Disposable gloves

### 8.3. Additional information

| Not | avai | lab | le |
|-----|------|-----|----|
| NOU | avai | ab  | iC |

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

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

| Physical state:                          | Liquid        |
|--|---------------|
| Colour:                                  | colorless     |
| Odour:                                   | Without Odor  |
| Odour threshold:                         |               |
| PH:                                      | Not available |
| Melting point/freezing point:            |               |
| Initial boiling point and boiling range: | °C            |
| Flash point:                             | = 18 °C       |
| Evaporation rate:                        |               |
| Flammability:                            |               |
| Upper/lower flammability or explosive    |               |
| limits:                                  |               |
| Vapour pressure:                         |               |
| Vapour density:                          |               |
| Relative density:                        |               |
| Solubility(ies):                         | miscible      |
| 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

Not available

**10.2.** Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3. Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

10.4. Conditions to avoid

Heat

**10.5. Incompatible materials** 

Sulphur oxides Strong Caustics Metals Sulfites

**10.6.** Hazardous decomposition products

Not available

10.7. Additional information

Not available

### **SECTION 11: Toxicological information**

### 11.1. Acute oral toxicity

**Data for mixture** 

### Species : Rat

| subendpoint | Operator | Value | Unit     |
|-------------|----------|-------|----------|
| 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

#### 11.8. 5101 SE

Data for mixture Not available Substances Not available

### 11.9. STOT RE

Data for mixture Not available Substances Not available

### 11.10. Carcinogenicity

Data for mixture Not available

### Substances

Not available

### **11.11. Reproductive and Developmental Toxicity**

Data for mixture Not available Substances Not available

#### 11.12. genotoxicity

Data for mixture Not available Substances Not available

#### 11.13. In vitro genotoxicity

Data for mixture Not available Substances Not available

### 11.14. Respiratory sensitisation

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. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.

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. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.

### **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.

Waste treatment options: Appropriate disposal / Product: Dispose of waste according to applicable legislation.

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**

|                                  | Land transport<br>(ADR/RID)   | Inland waterway<br>transport (ADN)  | Sea transport<br>(IMDG)   | Air transport (ICAO-TI /<br>IATA-DGR)   |
|----------------------------------|---|---|---|---|
| 14.1. UN number                  | 1170  | 1170  | 1170  | 1170  |
| 14.2. UN proper shipping name    | ETHANOL (ETHYL<br>ALCOHOL) or<br>ETHANOL<br>SOLUTION (ETHYL<br>ALCOHOL<br>SOLUTION) | ETHANOL (ETHYL<br>ALCOHOL) or<br>ETHANOL<br>SOLUTION (ETHYL<br>ALCOHOL<br>SOLUTION) | ETHANOL (ETHYL<br>ALCOHOL) or<br>ETHANOL<br>SOLUTION (ETHYL<br>ALCOHOL<br>SOLUTION) | ETHANOL (ETHYL<br>ALCOHOL) or ETHANOL<br>SOLUTION (ETHYL<br>ALCOHOL SOLUTION) |
| 14.3. Transport hazard class(es) |   |   |   |   |
| Class or Division                | 3   | 3   | 3   | 3   |
| Hazard label(s)                  |   |   |   |   |
| 14.4. Packing group              | II  | I   | II  | I   |

#### 14.5. Environmental hazards

Not available

### 14.6. Special precautions for user

Not available

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

Not 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

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. Not available--]

--]

#### 15.2. Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier. For this substance/ mixture a chemical safety assessment has been elaborated. For this mixture, the relevant data of the Substances' Chemical safety assessment are integrated in the sections of the SDS.

### 15.3. Additional information

Not available

### **SECTION 16: Other information**

| Creation date: | 14/11/2018 |
|----------------|------------|
| Version date:  | 14/11/2018 |
| Printing date: | 14/11/2018 |

### 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 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 CLP: Classification, labeling and packaging 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)

| H225 | Highly flammable liquid and vapour |
|------|------------------------------------|
| H315 | Causes skin irritation             |
| H319 | Causes serious eye irritation      |
| H335 | May cause respiratory irritation   |
|      |                                    |

### 16.6. Training advice

Not available

### 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.