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

· Product identifier
  · Trade name: Enamelast™
  · Article number: 71122, 1001036, 1005983, 1006179, 1006557, 1009274
  · Index number: SDS 352-001.15
· Relevant identified uses of the substance or mixture and uses advised against
  Professional Dental Fluoride Varnish
· Application of the substance / the mixture

2 Hazards identification

· Classification of the substance or mixture
  · Classification according to Regulation (EC) No 1272/2008

  GHS02 flame
  Flam. Liq. 3 H226 Flammable liquid and vapour.

  GHS07
  Acute Tox. 4 H302 Harmful if swallowed.
  Acute Tox. 4 H332 Harmful if inhaled.
  Skin Irrit. 2 H315 Causes skin irritation.
  Eye Irrit. 2 H319 Causes serious eye irritation.
  Skin Sens. 1 H317 May cause an allergic skin reaction.
  Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

· Label elements
  · Labelling according to Regulation (EC) No 1272/2008
    The Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according
to Art. 1.5 (d). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.

- **Hazard pictograms** GHS02, GHS07
- **Signal word** Warning

**Hazard-determining components of labelling:**
- Sodium Fluoride
- Amaretto Flavor
- Bubble Gum Flavor
- Trans-p-Menthan-3-One
- D,L-Isomenthone
- Orange Oil
- (R)-1-Methyl-4-(1-Methylethenyl) Cyclohexane

**Hazard statements**
- H226 Flammable liquid and vapour.
- H302+H332 Harmful if swallowed or if inhaled.
- H315 Causes skin irritation.
- H319 Causes serious eye irritation.
- H317 May cause an allergic skin reaction.
- H412 Harmful to aquatic life with long lasting effects.

**Precautionary statements**
- P101 If medical advice is needed, have product container or label at hand.
- P102 Keep out of reach of children.
- P103 Read label before use.
- P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- P233 Keep container tightly closed.
- P240 Ground and bond container and receiving equipment.
- P241 Use explosion-proof [electrical/ventilating/lighting] equipment.
- P242 Use non-sparking tools.
- P243 Take action to prevent static discharges.
- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
- P264 Wash thoroughly after handling.
- P270 Do not eat, drink or smoke when using this product.
- P271 Use only outdoors or in a well-ventilated area.
- P272 Contaminated work clothing should not be allowed out of the workplace.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
- P330 Rinse mouth.
- P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
- P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P362+P364 Take off contaminated clothing and wash it before reuse.
- P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
- P321 Specific treatment (see on this label).
- P337+P313 If eye irritation persists: Get medical advice/attention.
- P370+P378 In case of fire: Use for extinction: CO2, powder or water spray.
- P403+P235 Store in a well-ventilated place. Keep cool.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

(Contd. on page 3)
Safety data sheet
generated according to 1907/2006/EC, Article 31

Printing date 09.09.2020
Revision: 19.09.2018

Trade name: Enamelast™

- Additional information:
  - EUH032 Contact with acids liberates very toxic gas.
- Other hazards
- Results of PBT and vPvB assessment
  - PBT: Not applicable.
  - vPvB: Not applicable.

3 Composition/information on ingredients

- Chemical characterisation: Mixtures
- Description: Mixture of substances listed below with nonhazardous additions.

- Dangerous components:

<table>
<thead>
<tr>
<th>CAS</th>
<th>EINECS</th>
<th>Ingredient</th>
<th>Hazard phrases</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>64-17-5</td>
<td>200-578-6</td>
<td>Ethyl Alcohol</td>
<td>Flam. Liq. 2, H225</td>
<td>&gt;25≤50%</td>
</tr>
<tr>
<td>8050-15-5</td>
<td>232-476-2</td>
<td>Hydrogenated Rosin</td>
<td>Aquatic Chronic 3, H412</td>
<td>&gt;2.5≤10%</td>
</tr>
<tr>
<td>7681-49-4</td>
<td>231-667-8</td>
<td>Sodium Fluoride</td>
<td></td>
<td>5%</td>
</tr>
<tr>
<td>89-78-1</td>
<td>201-939-0</td>
<td>Bubble Gum Flavor</td>
<td>Flam. Liq. 2, H225; Skin Irrit. 2, H315;</td>
<td>&lt;5%</td>
</tr>
<tr>
<td>89-80-5</td>
<td>201-941-1</td>
<td>Menthol</td>
<td>Skin Irrit. 2, H315; Eye Irrit. 2, H319</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>8008-57-9</td>
<td>307-891-8</td>
<td>Strawberry Flavor</td>
<td>Flam. Liq. 3, H226; Skin Irrit. 2, H315;</td>
<td>&lt;2%</td>
</tr>
<tr>
<td>5989-27-5</td>
<td>227-813-5</td>
<td>Trade Secret</td>
<td>Skin Corr. 1A, H314</td>
<td>≤2.5%</td>
</tr>
<tr>
<td>491-07-6</td>
<td>207-727-4</td>
<td>D,L-Isomenthone</td>
<td></td>
<td>≤2.5%</td>
</tr>
<tr>
<td>89-80-5</td>
<td>201-941-1</td>
<td>Trans-p-Menthanol-3-One</td>
<td>Skin Irrit. 2, H315; Skin Sens. 1, H317</td>
<td>≤2.5%</td>
</tr>
<tr>
<td>8008-57-9</td>
<td>307-891-8</td>
<td>Orange Oil</td>
<td>Flam. Liq. 3, H226; Asp. Tox. 1, H304; Aquatic Chronic 2, H411; Skin Irrit. 2, H315; Skin Sens. 1, H317</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>5989-27-5</td>
<td>227-813-5</td>
<td>(R)-1-Methyl-4-(1-Methylethenyl) Cyclohexane</td>
<td>Flam. Liq. 3, H226; Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Skin Irrit. 2, H315; Skin Sens. 1, H317</td>
<td>≤2.5%</td>
</tr>
</tbody>
</table>

Additional information: For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

- Description of first aid measures
- General information:
  - Immediately remove any clothing soiled by the product.
  - Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
5 Firefighting measures

- Extinguishing media
- Suitable extinguishing agents: CO₂ powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- For safety reasons unsuitable extinguishing agents: Water with full jet

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures
  Mount respiratory protective device.
  Wear protective equipment. Keep unprotected persons away.
- Environmental precautions:
  Do not allow product to reach sewage system or any water course.
  Inform respective authorities in case of seepage into water course or sewage system.
  Do not allow to enter sewers/surface or ground water.
- Methods and material for containment and cleaning up:
  Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
  Dispose contaminated material as waste according to item 13.
  Ensure adequate ventilation.
- Reference to other sections
  See Section 7 for information on safe handling.
  See Section 8 for information on personal protection equipment.
  See Section 13 for disposal information.

7 Handling and storage

- Handling:
- Precautions for safe handling:
  Ensure good ventilation/exhaustion at the workplace.
  Prevent formation of aerosols.
- Information about fire - and explosion protection:
  Keep ignition sources away - Do not smoke.
Trade name: Enamelast™

(Contd. of page 4)

51.0.1 Protect against electrostatic charges.

· Conditions for safe storage, including any incompatibilities

· Storage:
  · Requirements to be met by storerooms and receptacles: No special requirements.
  · Information about storage in one common storage facility: Do not store together with acids.
  · Further information about storage conditions:
    See product labelling.
    Keep container tightly sealed.
  · Specific end use(s) Professional Dental Fluoride Varnish

8 Exposure controls/personal protection

· Additional information about design of technical facilities: No further data; see item 7.

· Control parameters

· Ingredients with limit values that require monitoring at the workplace:

<table>
<thead>
<tr>
<th>CAS Number</th>
<th>Substance</th>
<th>WEL (Great Britain) Long-term value</th>
</tr>
</thead>
<tbody>
<tr>
<td>64-17-5</td>
<td>Ethyl Alcohol</td>
<td>1920 mg/m³, 1000 ppm</td>
</tr>
</tbody>
</table>

· Additional information: The lists valid during the making were used as basis.

· Exposure controls

· Personal protective equipment:

· General protective and hygienic measures:
  Keep away from foodstuffs, beverages and feed.
  Immediately remove all soiled and contaminated clothing.
  Wash hands before breaks and at the end of work.
  Avoid contact with the eyes and skin.

· Respiratory protection:
  In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· Protection of hands:

Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves
  The selection of suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material
  The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection:

Tightly sealed goggles

(Contd. on page 6)
9 Physical and chemical properties

- Information on basic physical and chemical properties
  - General Information
    - Appearance:
      - Form: Viscous Liquid
      - Colour: White
    - Odour:
      - Odour threshold: Flavor Dependent
    - Odour threshold:
      - Not determined.
  - pH-value:
    - Not applicable (non-aqueous)
  - Change in condition
    - Melting point/freezing point:
      - Undetermined.
    - Initial boiling point and boiling range:
      - Undetermined.
  - Flash point:
    - 23 °C
  - Flammability (solid, gas):
    - Not applicable.
  - Decomposition temperature:
    - Not determined.
  - Auto-ignition temperature:
    - Product is not selfigniting.
  - Explosive properties:
    - Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
  - Explosion limits:
    - Lower: Not determined.
    - Upper: Not determined.
  - Vapour pressure:
    - Not determined.
  - Density at 20 °C:
    - 0.96-1.03 g/cm³
  - Relative density:
    - Not determined.
  - Vapour density:
    - Not determined.
  - Evaporation rate:
    - Not determined.
  - Solubility in / Miscibility with water:
    - Not miscible or difficult to mix.
  - Partition coefficient: n-octanol/water:
    - Not determined.
  - Viscosity:
    - Dynamic:
      - Not determined.
    - Kinematic:
      - Not determined.
  - Solvent content:
    - Organic solvents:
      - <30 %
    - VOC (EC):
      - 32.3-36.75 %
  - Solids content:
    - <50.0 %
  - Other information:
    - No further relevant information available.

10 Stability and reactivity

- Reactivity: No further relevant information available.
51.0.1 Chemical stability

- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

### 11 Toxicological information

#### Information on toxicological effects

- **Acute toxicity**
  - Harmful if swallowed or if inhaled.
  - **LD/LC50 values relevant for classification:**

<table>
<thead>
<tr>
<th></th>
<th>Oral LD50</th>
<th>Dermal LD50</th>
<th>Inhalative LC50/4 h</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>989 mg/kg</td>
<td>3,500 mg/kg</td>
<td>440 mg/l (mouse)</td>
</tr>
</tbody>
</table>

- **64-17-5 Ethyl Alcohol**
  - **Oral LD50**
    - 5,600 mg/kg (Guinea pig)
    - 3,400 mg/kg (mouse)
    - 7,060 mg/kg (rat)
  - **Inhalative LC50/4 h**
    - >10,000 mg/l (Fish)
    - 39 mg/l (mouse)
    - 20,000 mg/l (rat)

- **7681-49-4 Sodium Fluoride**
  - **Oral LD50**
    - 52 mg/kg (mouse)
  - **Dermal LC50 Fish (static)**
    - 17 mg/l (Fish)
  - **Dermal LD50**
    - 175 mg/kg (rat)

- **8050-15-5 Hydrogenated Rosin**
  - **Oral LD50**
    - >5,000 mg/kg (Guinea pig)
    - >5,000 mg/kg (rat)

- **5949-29-1 Citric Acid Monohydrate**
  - **Oral LD50**
    - 5,790 mg/kg (mouse)

- **5989-27-5 (R)-1-Methyl-4-(1-Methylethenyl) Cyclohexane**
  - **Oral LD50**
    - 4,400 mg/kg (rat)

- **Primary irritant effect:**
  - **Skin corrosion/irritation**
    - Causes skin irritation.
  - **Serious eye damage/irritation**
    - Causes serious eye irritation.
  - **Respiratory or skin sensitisation**
    - May cause an allergic skin reaction.
  - **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
    - **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
    - **Carcinogenicity** Based on available data, the classification criteria are not met.
    - **Reproductive toxicity** Based on available data, the classification criteria are not met.
  - **STOT-single exposure** Based on available data, the classification criteria are not met.
Trade name: Enamelast™

12 Ecological information

· Toxicity
  · Aquatic toxicity:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity</th>
<th>EC50</th>
<th>Algae Toxicity (static)</th>
</tr>
</thead>
<tbody>
<tr>
<td>64-17-5 Ethyl Alcohol</td>
<td></td>
<td>272 mg/kg (Algae)</td>
<td>7 mg/l (Algae)</td>
</tr>
<tr>
<td>7681-49-4 Sodium Fluoride</td>
<td></td>
<td>98 mg/kg (daphnia)</td>
<td></td>
</tr>
<tr>
<td>8050-15-5 Hydrogenated Rosin</td>
<td></td>
<td>Oral EL50 27 mg/l (daphnia)</td>
<td>LL50 &gt;1,000 mg/l (Fish)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>72-hour EL50 &gt;1,000 mg/l (Algae)</td>
<td></td>
</tr>
</tbody>
</table>

· Persistence and degradability No further relevant information available.
· Behaviour in environmental systems:
· Bioaccumulative potential No further relevant information available.
· Mobility in soil No further relevant information available.
· Ecotoxic effects:
· Remark: Harmful to fish
· Additional ecological information:
· General notes:
· Results of PBT and vPvB assessment
· PBT: Not applicable.
· vPvB: Not applicable.
· Other adverse effects No further relevant information available.

13 Disposal considerations

· Waste treatment methods
· Recommendation
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
Harmful to aquatic organisms

· European waste catalogue
· HP3 Flammable
· HP4 Irritant - skin irritation and eye damage
· HP6 Acute Toxicity
· HP12 Release of an acute toxic gas
· HP14 Ecotoxic
## 14 Transport information

<table>
<thead>
<tr>
<th><strong>· UN-Number</strong></th>
<th>UN1986</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>· UN proper shipping name</strong></td>
<td>ADR 1986 ALCOHOLS, FLAMMABLE, TOXIC, N.O.S. (Ethyl Alcohol, SODIUM FLUORIDE)</td>
</tr>
<tr>
<td><strong>· IMDG, IATA</strong></td>
<td>ALCOHOLS, FLAMMABLE, TOXIC, N.O.S. (Ethyl Alcohol, SODIUM FLUORIDE)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>· Transport hazard class(es)</strong></th>
<th>ADR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>· Class</strong></td>
<td>3 Flammable liquids.</td>
</tr>
<tr>
<td><strong>· Label</strong></td>
<td>3+6.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>· IMDG</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>· Class</strong></td>
<td>3 Flammable liquids.</td>
</tr>
<tr>
<td><strong>· Label</strong></td>
<td>3/6.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>· IATA</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>· Class</strong></td>
<td>3 Flammable liquids.</td>
</tr>
<tr>
<td><strong>· Label</strong></td>
<td>3 (6.1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>· Packing group</strong></th>
<th>ADR, IMDG, IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>· Packing group</strong></td>
<td>II</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>· Environmental hazards:</strong></th>
<th>Not applicable.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>· Special precautions for user</strong></td>
<td>Warning: Flammable liquids. 63</td>
</tr>
<tr>
<td><strong>· Hazard identification number (Kemler code):</strong></td>
<td>F-E,S-D</td>
</tr>
<tr>
<td><strong>· EMS Number:</strong></td>
<td>B</td>
</tr>
<tr>
<td><strong>· Stowage Category</strong></td>
<td>SW2 Clear of living quarters.</td>
</tr>
<tr>
<td><strong>· Stowage Code</strong></td>
<td>Not applicable.</td>
</tr>
</tbody>
</table>
Trade name: Enamelast™

<table>
<thead>
<tr>
<th>Transport/Additional information:</th>
</tr>
</thead>
<tbody>
<tr>
<td>· ADR</td>
</tr>
<tr>
<td>· Limited quantities (LQ)</td>
</tr>
<tr>
<td>1L</td>
</tr>
<tr>
<td>Code: E2</td>
</tr>
<tr>
<td>· Excepted quantities (EØ)</td>
</tr>
<tr>
<td>Maximum net quantity per inner packaging: 30 ml</td>
</tr>
<tr>
<td>Maximum net quantity per outer packaging: 500 ml</td>
</tr>
<tr>
<td>· Transport category</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>· Tunnel restriction code</td>
</tr>
<tr>
<td>D/E</td>
</tr>
<tr>
<td>· IMDG</td>
</tr>
<tr>
<td>· Limited quantities (LQ)</td>
</tr>
<tr>
<td>1L</td>
</tr>
<tr>
<td>Code: E2</td>
</tr>
<tr>
<td>· Excepted quantities (EØ)</td>
</tr>
<tr>
<td>Maximum net quantity per inner packaging: 30 ml</td>
</tr>
<tr>
<td>Maximum net quantity per outer packaging: 500 ml</td>
</tr>
<tr>
<td>· UN &quot;Model Regulation&quot;:</td>
</tr>
<tr>
<td>UN 1986 ALCOHOLS, FLAMMABLE, TOXIC, N.O.S. (ETHYL ALCOHOL, SODIUM FLUORIDE), 3 (6.1), II</td>
</tr>
</tbody>
</table>

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture
· Directive 2012/18/EU
· Seveso category P5c FLAMMABLE LIQUIDS
· Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t
· Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t
· REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
· Chemical safety assessment:
  Device is biocompatible when used as directed by dental professionals per ISO 10993-1

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Relevant phrases
  H225 Highly flammable liquid and vapour.
  H226 Flammable liquid and vapour.
  H301 Toxic if swallowed.
  H302 Harmful if swallowed.
  H304 May be fatal if swallowed and enters airways.
  H310 Fatal in contact with skin.
  H314 Causes severe skin burns and eye damage.
  H315 Causes skin irritation.
  H317 May cause an allergic skin reaction.
  H319 Causes serious eye irritation.
  H332 Harmful if inhaled.
  H335 May cause respiratory irritation.
  H400 Very toxic to aquatic life.
  H410 Very toxic to aquatic life with long lasting effects.
  H411 Toxic to aquatic life with long lasting effects.
  H412 Harmful to aquatic life with long lasting effects.
Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
VOC: Volatile Organic Compounds (USA, EU)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Flam. Liq. 2: Flammable liquids – Category 2
Flam. Liq. 3: Flammable liquids – Category 3
Acute Tox. 3: Acute toxicity - oral – Category 3
Acute Tox. 4: Acute toxicity - oral – Category 4
Acute Tox. 2: Acute toxicity - dermal – Category 2
Skin Corr. 1A: Skin corrosion/irritation – Category 1A
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
Asp. Tox. 1: Aspiration hazard – Category 1
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3