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

- **1.1 Product identifier**
  - **Trade name:** Fluor Protector

- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
  - No further relevant information available.

- **Application of the substance / the mixture**
  - Protective varnish containing fluoride

- **1.3 Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:** Ivoclar Vivadent AG
    - Bendererstrasse 2
    - FL-9494 Schaan
    - PRINCIPALITY OF LIECHTENSTEIN
  - **Tel:** +423 235 35 35
  - **Fax:** +423 235 33 60

- **Further information obtainable from:**
  - Regulatory Affairs
  - sds@ivoclarvivadent.com

- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

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**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
  - **Classification according to Regulation (EC) No 1272/2008**
    - Flam. Liq. 2 H225 Highly flammable liquid and vapour.
    - Eye Irrit. 2 H319 Causes serious eye irritation.
    - Skin Sens. 1 H317 May cause an allergic skin reaction.
    - STOT SE 3 H336 May cause drowsiness or dizziness.

- **2.2 Label elements**
  - **Labelling according to Regulation (EC) No 1272/2008**
    - The product is classified and labelled according to the CLP regulation.

- **Hazard pictograms**
  - GHS02
  - GHS07

- **Signal word** Danger

- **Hazard-determining components of labelling:**
  - ethyl acetate
  - polyisocyanate

- **Hazard statements**
  - H225 Highly flammable liquid and vapour.
  - H319 Causes serious eye irritation.
  - H317 May cause an allergic skin reaction.
  - H336 May cause drowsiness or dizziness.

- **Precautionary statements**
  - P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
  - P280 Wear protective gloves/protective clothing/eye protection/face protection.
  - P260 Do not breathe vapours.
  - P233 Keep container tightly closed.

(Contd. on page 2)
SECTION 3: Composition/information on ingredients

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

Dangerous components:
- CAS: 141-78-6 ethyl acetate
  Flam. Liq. 2, H225; Eye Irrit. 2, H319; Stord SE 3, H336
  50-100%
- CAS: 105-68-0 isopentyl propionate
  Flam. Liq. 3, H226
  10-<25%
- CAS: 53317-61-6 polyisocyanate
  Eye Irrit. 2, H319; Skin Sens. 1, H317
  10-<25%

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

SECTION 4: First aid measures

4.1 Description of first aid measures
- After inhalation:
  Supply fresh air and to be sure call for a doctor.
  In case of unconsciousness place patient stably in side position for transportation.
- After skin contact:
  Immediately wash with water and soap and rinse thoroughly.
- After eye contact:
  Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- After swallowing:
  Rinse out mouth and then drink plenty of water.
  If symptoms persist consult doctor.

4.2 Most important symptoms and effects, both acute and delayed
No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed
No further relevant information available.

SECTION 5: Firefighting measures

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

5.2 Special hazards arising from the substance or mixture
No further relevant information available.

(Contd. on page 3)
Trade name: Fluor Protector

5.3 Advice for firefighters
- Protective equipment: Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures
  Wear protective equipment. Keep unprotected persons away.
- 6.2 Environmental precautions: Do not allow to enter sewers/surface or ground water.
- 6.3 Methods and material for containment and cleaning up:
  Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
  Ensure adequate ventilation.
  Do not flush with water or aqueous cleansing agents.
- 6.4 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.

SECTION 7: Handling and storage

- 7.1 Precautions for safe handling
  Only adequately trained personnel should handle this product.
  Ensure good ventilation/exhaustion at the workplace.
  Prevent formation of aerosols.
- Information about fire - and explosion protection:
  Keep ignition sources away - Do not smoke.
  Protect against electrostatic charges.
- 7.2 Conditions for safe storage, including any incompatibilities
- Storage:
  Requirements to be met by storerooms and receptacles:
  Store in a cool location.
  Store only in the original receptacle.
  Information about storage in one common storage facility: Not required.
- Further information about storage conditions:
  Keep container tightly sealed.
  Store in cool, dry conditions in well sealed receptacles.
  Store receptacle in a well ventilated area.
- 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- Additional information about design of technical facilities: No further data; see item 7.
- 8.1 Control parameters
- Ingredients with limit values that require monitoring at the workplace:
  141-78-6 ethyl acetate
  - WEL: Short-term value: 400 ppm
  - Long-term value: 200 ppm
- Additional information: The lists valid during the making were used as basis.
8.2 Exposure controls

- Personal protective equipment:
  - General protective and hygienic measures:
    Usual hygienic measures for dental practice.
    Keep away from foodstuffs, beverages and feed.
    Immediately remove all soiled and contaminated clothing
    Wash hands before breaks and at the end of work.
    Do not inhale gases / fumes / aerosols.
    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
  Butyl rubber, BR
  The selection of the 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 break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- Eye protection:

  Tightly sealed goggles

SECTION 9: Physical and chemical properties

- 9.1 Information on basic physical and chemical properties
  - General Information

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form</td>
<td>Fluid</td>
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<tr>
<td>Colour</td>
<td>Clear</td>
</tr>
<tr>
<td>Odour</td>
<td>Fruit-like</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>Not determined.</td>
</tr>
<tr>
<td>pH-value</td>
<td>Not determined.</td>
</tr>
</tbody>
</table>

  - Change in condition

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting point/Melting range</td>
<td>Undetermined.</td>
</tr>
<tr>
<td>Boiling point/Boiling range</td>
<td>Undetermined.</td>
</tr>
</tbody>
</table>

(Contd. on page 5)
Safety data sheet  
according to 1907/2006/EC, Article 31  

Trade name: Fluor Protector

- Flash point: 9 °C
- Ignition temperature: 460 °C
- Self-igniting: Product is not self-igniting.
- Danger of explosion: Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
- Explosion limits:
  Lower: 2.1 Vol %
  Upper: 11.5 Vol %
- Vapour pressure at 20 °C: 97 hPa
- Density at 20 °C: 0.869 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.
- 9.2 Other information: No further relevant information available.

SECTION 10: Stability and reactivity

- 10.1 Reactivity: No further relevant information available.
- 10.2 Chemical stability: Stable under normal handling and storage conditions.
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- 10.3 Possibility of hazardous reactions: No dangerous reactions known.
- 10.4 Conditions to avoid: No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- 10.6 Hazardous decomposition products: None under normal conditions of storage and use.

SECTION 11: Toxicological information

- 11.1 Information on toxicological effects
- Acute toxicity:
  - LD/LC50 values relevant for classification:
    - 141-78-6 ethyl acetate
      - Oral: LD50 5620 mg/kg (rabbit)
      - Inhalative: LC50/4 h 1600 mg/l (rat)
  - Primary irritant effect:
    - on the skin: No irritant effect.
    - on the eyes: Irritating effect.
  - Sensitisation: Sensitisation possible through skin contact.
  - Additional toxicological information: No further relevant information available.
SECTION 12: Ecological information

· 12.1 Toxicity
  · Aquatic toxicity: No further relevant information available.

· 12.2 Persistence and degradability No further relevant information available.

· 12.3 Bioaccumulative potential No further relevant information available.

· 12.4 Mobility in soil No further relevant information available.

· Additional ecological information:
  · General notes:
    Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
    Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

· 12.5 Results of PBT and vPvB assessment
  · PBT: Not applicable.
  · vPvB: Not applicable.

· 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

· 13.1 Waste treatment methods
  · Recommendation
    Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue
  · 18 01 06* chemicals consisting of or containing dangerous substances

· Uncleaned packaging:
  · Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

· 14.1 UN-Number
  · ADR, IMDG, IATA 1173

· 14.2 UN proper shipping name
  · ADR
    1173 ETHYL ACETATE
  · IMDG, IATA
    ETHYL ACETATE

· 14.3 Transport hazard class(es)
  · ADR

  · Class 3 (F1) Flammable liquids.
  · Label 3

  · IMDG, IATA

  · Class 3 Flammable liquids.
Trade name: **Fluor Protector**

**SECTION 14: Transportation**

- **Label**
- **ADR, IMDG, IATA**
- **Packing group** II
- **Environmental hazards:**
  - Marine pollutant: No
- **Special precautions for user** Warning: Flammable liquids.
- **Danger code (Kemler):** 33
- **EMS Number:** F-E, S-E
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.
- **Transport/Additional information:**
  - **ADR**
  - **Limited quantities (LQ)** LQ4
  - **Transport category** 2
  - **Tunnel restriction code** D/E
  - **UN "Model Regulation":** UN1173, ETHYL ACETATE, 3, II

**SECTION 15: Regulatory information**

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - **National regulations:**
  - **Other regulations, limitations and prohibitive regulations**
    - The product is a medical device according to the Directive 93/42/EEC.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

**SECTION 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.
  - H317 May cause an allergic skin reaction.
  - H319 Causes serious eye irritation.
  - H336 May cause drowsiness or dizziness.
- **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)
  - LC50: Lethal concentration, 50 percent
  - LD50: Lethal dose, 50 percent
  - Flam. Liq.: Flammable liquids
  - Eye Irrit.: Serious eye damage/eye irritation
  - STOT SE: Specific target organ toxicity - Single exposure
- **Data compared to the previous version altered.**