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

1.1 Product identifier
   · Trade name: Meliodent Rapid Repair Liquid

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

1.3 Details of the supplier of the safety data sheet
   · Manufacturer/Supplier:
     Kulzer GmbH
     Leipziger Straße 2, 63450 Hanau (Germany) Tel.: +49 (0)800 4372522
   · Informing department: E-Mail: msds@kulzer-dental.com

1.4 Emergency telephone number:
   Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

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.
     Skin Irrit. 2 H315 Causes skin irritation.
     Skin Sens. 1 H317 May cause an allergic skin reaction.
     STOT SE 3 H335 May cause respiratory irritation.

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:
       methyl methacrylate
       2-(2H-Benzotriazol-2-yl)-4-methylphenol
     · Hazard statements
       H225 Highly flammable liquid and vapour.
       H315 Causes skin irritation.
       H317 May cause an allergic skin reaction.
       H335 May cause respiratory irritation.
     · Precautionary statements
       P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
       P260 Do not breathe dust/fume/gas/mist/vapours/spray.
       P280 Wear protective gloves/protective clothing/eye protection/face protection.
       P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
       P370+P378 In case of fire: Use for extinction: CO2, sand, extinguishing powder.
       P403+P233 Store in a well-ventilated place. Keep container tightly closed.
SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

- Description: Product based on methacrylates

**Dangerous components:**

<table>
<thead>
<tr>
<th>CAS</th>
<th>EINECS</th>
<th>Reg.nr.</th>
<th>Description</th>
<th>Hazard Classing</th>
</tr>
</thead>
<tbody>
<tr>
<td>80-62-6</td>
<td>201-297-1</td>
<td>01-2119452498-28-0000</td>
<td>methyl methacrylate</td>
<td>Flam. Liq. 2, H225; Skin Irrit. 2, H315;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Skin Sens. 1, H317; STOT SE 3, H335</td>
</tr>
<tr>
<td>2082-81-7</td>
<td>218-218-1</td>
<td>02-2118949716-25</td>
<td>tetramethylene dimethacrylate</td>
<td>Skin Irrit. 2, H315; Eye Irrit. 2, H319;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>STOT SE 3, H335</td>
</tr>
<tr>
<td>2440-22-4</td>
<td>2119583811-34-0000</td>
<td>01-2119583811-34-0001</td>
<td>2-(2H-Benzotriazol-2-yl)-4-methylphenol</td>
<td>Acute Tox. 3, H331; Aquatic Chronic 1, H410;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Skin Sens. 1, H317</td>
</tr>
<tr>
<td>99-97-8</td>
<td>202-805-4</td>
<td></td>
<td>N.N-dimethyl-p-toluidine</td>
<td>Acute Tox. 3, H301; Acute Tox. 3, H311;</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 3, H331; STOT RE 2, H373;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Aquatic Chronic 3, H412</td>
</tr>
</tbody>
</table>

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

SECTION 4: First aid measures

4.1 Description of first aid measures

- After inhalation: Supply fresh air; consult doctor in case of symptoms.
- After skin contact: Instantly wash with water and soap and rinse thoroughly.
- After eye contact: Rinse opened eye for several minutes under running water.
- After swallowing: Rinse out mouth and then drink plenty of water.
  In case of persistent symptoms 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, sand, extinguishing powder. Do not use water.
- For safety reasons unsuitable extinguishing agents: Water.

5.2 Special hazards arising from the substance or mixture

Can form explosive gas-air mixtures.
Formation of toxic gases is possible during heating or in case of fire.
5.3 Advice for firefighters
- Protective equipment: No special measures required.
- Additional information -

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:
  Prevent material from reaching sewage system, holes and cellars.
- 6.3 Methods and material for containment and cleaning up:
  Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).
  Do not flush with water or aqueous cleansing agents.
- 6.4 Reference to other sections
  No dangerous materials are released.
  See Section 7 for information on safe handling.
  See Section 8 for information on personal protection equipment.
  See Section 13 for information on disposal.

SECTION 7: Handling and storage
- 7.1 Precautions for safe handling
  Keep containers tightly sealed.
  Ensure good interior ventilation, especially at floor level. (Fumes are heavier than air).
  Please observe the additional instructions in the product's instructions for use.
  - Information about protection against explosions and fires:
    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 containers: Store in cool location.
    Information about storage in one common storage facility: Not required.
    Further information about storage conditions:
    Store cool (not above 25 °C).
    Store in cool, dry conditions in well sealed containers.
- 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection
- Additional information about design of technical systems: No further data; see item 7.
- 8.1 Control parameters
  Components with critical values that require monitoring at the workplace:
  80-62-6 methyl methacrylate
  OELV (I) Short-term value: 510 mg/m³, 125 ppm
  Long-term value: 410 mg/m³, 100 ppm

Trade name: Meliodent Rapid Repair Liquid

| · DNELs | 80-62-6 methyl methacrylate |
| | Dermal | worker industr., l.te., syst. | 74.3 mg/Kg/d (human) |
| | Inhalative | worker industr., l.te., syst. | 210 mg/m3 (human) |
| | 2440-22-4 2-(2H-Benzotriazol-2-yl)-4-methylphenol |
| | Oral | ge.pop., l.te, syst. | 1.2 mg/Kg (nd) |
| | Dermal | worker industr., l.te., syst. | 2.5 mg/Kg/d (nd) |
| | ge.pop., l.te, syst. | 1.2 mg/Kg/d (nd) |
| | Inhalative | worker industr., l.te., syst. | 1 mg/m3 (nd) |

| · PNECs | 80-62-6 methyl methacrylate |
| | freshwater | 0.94 mg/l (aqua) |
| | 2440-22-4 2-(2H-Benzotriazol-2-yl)-4-methylphenol |
| | freshwater | 0.1 mg/l (nd) |
| | marine water | 0.01 mg/l (nd) |
| | STP | 1 mg/l (nd) |
| | sedim., dw, fre.wat. | 52.3 mg/Kg (nd) |
| | sedim., dw, mar.wat. | 5.23 mg/Kg (nd) |
| | soil,dw | 11 mg/Kg (nd) |

- Additional information: The lists that were valid during the compilation were used as basis.

- 8.2 Exposure controls
  - Personal protective equipment
    - General protective and hygienic measures
      Keep away from foodstuffs, beverages and food.
      Instantly remove any soiled and impregnated garments.
      Wash hands during breaks and at the end of the work.
      Avoid contact with the eyes and skin.
    - Breathing equipment:
      Not necessary with efficient local exhaust. If exposition to vapours is possible, use breathing protective mask (filter A).
  - Protection of hands:
    The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
    Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.
    If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.
    Solvent resistant gloves
    Check protective gloves prior to each use for their proper condition.
  - Material of gloves
    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.
**SECTION 9: Physical and chemical properties**

- **9.1 Information on basic physical and chemical properties**
  - **General Information**
    - Appearance:
      - Form: Fluid
      - Colour: Colourless
    - Smell: Characteristic
    - Odour threshold: Not determined.
  - pH-value: Not determined.
  - Change in condition
    - Melting point/Melting range: Not determined
    - Boiling point/Boiling range: 100 °C
  - Flash point: 10 °C
  - Inflammability (solid, gaseous): Not applicable.
  - Ignition temperature: 430.0 °C
  - Decomposition temperature: Not determined.
  - Self-inflammability: Product is not selfigniting.
  - Danger of explosion: Product is not explosive. However, formation of explosive air/vapour mixtures is possible.
  - Critical values for explosion:
    - Lower: 2.1 Vol %
    - Upper: 12.5 Vol %
  - Steam pressure at 20 °C: 47 hPa
  - Density at 20 °C: 0.950 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.
**Trade name:** Meliodent Rapid Repair Liquid

- **Viscosity:**
  - dynamic at 20 °C: 1 mPas
  - kinematic: Not determined

- **Solvent content:**

- **Solids content:** 1.0 %

**SECTION 10: Stability and reactivity**

- **10.1 Reactivity**
  No further relevant information available.

- **10.2 Chemical stability**
  - **Conditions to be avoided:** No decomposition if used and stored 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

  *Additional information:*
  If stored longer than recommended and/or above recommended temperature, product may polymerize generating heat.

**SECTION 11: Toxicological information**

- **11.1 Information on toxicological effects**

  - **Acute toxicity**
    Based on available data, the classification criteria are not met.

    - **LD/LC50 values that are relevant for classification:**

    | Compound                        | Oral LD50 | Dermal LD50 | Inhalative LC50/4 h |
    |---------------------------------|-----------|-------------|---------------------|
    | 80-62-6 methyl methacrylate     | >5000 mg/kg (rat) | >5000 mg/kg (rab) | 29.8 mg/l (rat) |
    | 2082-81-7 tetramethylene dimethacrylate | LD50 | 10120 mg/kg (rat) |
    | 2440-22-4 2-(2H-Benzotriazol-2-yl)-4-methylphenol | LD50 | >10000 mg/kg (rat) |
    | 99-97-8 N,N-dimethyl-p-toluidine | LD50 | >2000 mg/kg (rat) |
    | Inhalative                     | LC50/4 h  | 1400 mg/l (rat) |

  - **Primary irritant effect:**
    - **Skin corrosion/irritation**
      Causes skin irritation.
    - **Serious eye damage/irritation**
      Based on available data, the classification criteria are not met.
    - **Respiratory or skin sensitisation**
      May cause an allergic skin reaction.
CMR effects (carcinogenicity, 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
May cause respiratory irritation.

STOT-repeated exposure: Based on available data, the classification criteria are not met.

Aspiration hazard: Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:
- 2440-22-4 2-(2H-Benzotriazol-2-yl)-4-methylphenol
  EC50/72h >100 mg/l (algae)
  LC50/96h >0.17 mg/l (fish)
- 99-97-8 N,N-dimethyl-p-toluidine
  LC50/96h 100 mg/l (fish)

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:
  Do not allow product to reach ground water, water bodies or sewage system.
  Danger to drinking water if even small quantities leak into soil.

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 of together with household garbage. Do not allow product to reach sewage system.
  Small quantities can be polymerized with the matching system component(s) and the cured solid material can be disposed of with the regular garbage. Larger quantities must be disposed of following the regulations of the local authorities.

European waste catalogue
- 18 01 06 chemicals consisting of or containing dangerous substances
**Trade name:** Meliodent Rapid Repair Liquid

*Uncleaned packagings:*
*Recommendation:* Disposal must be made according to official regulations.

### SECTION 14: Transport information

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
</table>
| **14.1 UN-Number** | **ADR, IMDG, IATA**
|  | 1247 |
| **14.2 UN proper shipping name** | **ADR**
|  | 1247 METHYL METHACRYLATE MONOMER, STABILIZED, solution |
|  | **IMDG, IATA**
|  | METHYL METHACRYLATE MONOMER, STABILIZED, solution |
| **14.3 Transport hazard class(es)** | **ADR**
|  | **Class**
|  | 3 (F1) Flammable liquids. |
|  | **Label**
|  | 3 |
|  | **IMDG, IATA**
|  | **Class**
|  | 3 Flammable liquids. |
|  | **Label**
|  | 3 |
| **14.4 Packing group** | **ADR, IMDG, IATA**
|  | II |
| **14.5 Environmental hazards:** | **Marine pollutant:**
|  | No |
| **14.6 Special precautions for user** | ***Kemler Number:** Warning: Flammable liquids. 339
|  | ***EMS Number:** F-E,S-D |
| **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code** | Not applicable.
|  | **Transport/Additional information:** - |

(Contd. on page 9)
SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

These data are based on our present knowledge. However, they 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.
- H301 Toxic if swallowed.
- H311 Toxic in contact with skin.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H331 Toxic if inhaled.
- H335 May cause respiratory irritation.
- H373 May cause damage to organs through prolonged or repeated exposure.
- H410 Very 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)
- DNEL: Derived No-Effect Level (REACH)
- PNEC: Predicted No-Effect Concentration (REACH)
- 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
- Acute Tox. 3: Acute toxicity – Category 3
- 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
- STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2
- Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
- Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

* Data compared to the previous version altered.