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

1.1 Product identifier

Trade name: ESTENIA C&B; OPAQUE PRIMER

Article number: 095-OPP

Registration number: Not applicable

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: Dental crown and bridge restorative material

1.3 Details of the supplier of the safety data sheet

Manufacturer:
Kuraray Europe GmbH
Philipp-Reis-Str. 4,
65795 Hattersheim am Main
Germany
Phone: +49 (0)69 305 35 840
Fax: +49 (0)69 305 35 640
E-mail: dental@kuraray.de

Supplier:
J & S Davis
5 Whitworth Road, Stevenage,
Hertfordshire, SG1 4QS
Great Britain
Tel: +44- (0) 1438 747344
Fax: +44- (0) 1438 758909
E-mail: jsdsales@js-davis.co.uk

Further information obtainable from: Manufacturer or Supplier

1.4 Emergency telephone number:
National Poisons information Service (London Centre)
Guy’s & St. Thomas’ Hospital Trust
Medical Toxicology Unit
Avonley Road
LONDON
SE14 5ER
Emergency telephone: (local) 0870 600 6266 or +44 20 7771 5394
Administrative telephone: +44 20 7 771 53 10
Facsimile number: +44 20 7 771 53 09

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

GHS02 flame

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

GHS07

Acute Tox. 4 H332 Harmful if inhaled.

Eye Irrit. 2 H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

STOT SE 3 H335 May cause respiratory irritation.

(Contd. on page 2)
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:
  2-methylpropan-2-ol
  benzoyl peroxide
  4-methylpentan-2-one

- Hazard statements
  H225 Highly flammable liquid and vapour.
  H332 Harmful if inhaled.
  H319 Causes serious eye irritation.
  H317 May cause an allergic skin reaction.
  H335 May cause respiratory irritation.

- Precautionary statements
  P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
  P241 Use explosion-proof electrical/ventilating/lighting/equipment.
  P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
  P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
  P370+P378 In case of fire: Use for extinction: CO2, powder or water spray.
  P362+P364 Take off contaminated clothing and wash it before reuse.
  P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3 Other hazards
- Results of PBT and vPvB assessment
  - PBT: Not applicable.
  - vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

- 3.1 Chemical characterisation: Substances
  None

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

<table>
<thead>
<tr>
<th>CAS</th>
<th>Description</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>75-65-0</td>
<td>2-methylpropan-2-ol, Flam. Liq. 2, H225; Acute Tox. 4, H332; Eye Irrit. 2, H319; STOT SE 3, H335</td>
<td>50-70%</td>
</tr>
<tr>
<td>108-10-1</td>
<td>4-methylpentan-2-one, Flam. Liq. 2, H225; Acute Tox. 4, H332; Eye Irrit. 2, H319; STOT SE 3, H335</td>
<td>20-40%</td>
</tr>
<tr>
<td>94-36-0</td>
<td>benzoyl peroxide, Unst. Expl., H200; Eye Irrit. 2, H319; Skin Sens. 1, H317; Org. Perox. E, H242</td>
<td>&lt;1.5%</td>
</tr>
</tbody>
</table>

- Other ingredients:
  Hydrophobic aromatic dimethacrylate
  Hydrophobic aliphatic methacrylate
  10-Methacryloyloxydecyl dihydrogen phosphate

(Contd. on page 3)
SECTION 4: First aid measures

4.1 Description of first aid measures

General information:
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

After inhalation:
Supply fresh air and 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:
Do not induce vomiting; call for medical help immediately.
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, sand, extinguishing powder. Do not use water.
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.

5.3 Advice for firefighters

Protective equipment:
Wear fully protective suit.
Mouth 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).
Dispose contaminated material as waste according to item 13.
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
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 (2-25 °C).
- Information about storage in one common storage facility: Store away from oxidising agents. Store away from reducing agents.
- Further information about storage conditions: Keep container tightly sealed. Store in cool, dry conditions in well sealed receptacles. Protect from heat and direct sunlight.

7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

<table>
<thead>
<tr>
<th>CAS Number</th>
<th>Chemical Name</th>
<th>WEL Short-term value</th>
<th>WEL Long-term value</th>
</tr>
</thead>
<tbody>
<tr>
<td>75-65-0</td>
<td>2-methylpropan-2-ol</td>
<td>462 mg/m³, 150 ppm</td>
<td>308 mg/m³, 100 ppm</td>
</tr>
<tr>
<td>108-10-1</td>
<td>4-methylpentan-2-one</td>
<td>416 mg/m³, 100 ppm</td>
<td>208 mg/m³, 50 ppm</td>
</tr>
</tbody>
</table>

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

8.2 Exposure controls

Personal protective equipment:
- General protective and hygienic measures:
  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 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 trough time has to be found out by the manufacturer of the protective gloves and has to be observed.
· Eye protection:

Tightly sealed goggles

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## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

#### General Information

- **Appearance:** Liquid
- **Colour:** Colourless
- **Odour:** Ether-like

#### pH-value:

Not applicable

#### Change in condition

- **Melting point/Melting range:** -83.5 °C (4-methylpentan-2-one)
- **Boiling point/Boiling range:** 83 °C (2-methylpropan-2-ol)

#### Flash point:

11 °C (2-methylpropan-2-ol)

#### Ignition temperature:

460.0 °C (4-methylpentan-2-one)

#### Decomposition temperature:

Not determined

#### Danger of explosion:

Product is not explosive. However, formation of explosive air/vapour mixtures are possible.

#### Explosion limits:

- **Lower:** 1.7 Vol % (4-methylpentan-2-one)
- **Upper:** 9.0 Vol % (4-methylpentan-2-one)

#### Oxidising properties

Not determined

#### Vapour pressure:

40.0 hPa (20 °C, 2-methylpropan-2-ol)

#### Density:

0.8 g/cm³

#### Relative density

Not determined

#### Vapour density

3.45 g/cm³ (4-methylpentan-2-one, air=1)

#### Evaporation rate

Not determined

#### Solubility in / Miscibility with water:

Not miscible or difficult to mix.

#### Partition coefficient (n-octanol/water):

Not determined

#### Viscosity:

Not determined

### 9.2 Other information

No further relevant information available.

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

No further relevant information available.

### 10.2 Chemical stability

- **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.
SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity
Harmful if inhaled.

LD/LC50 values relevant for classification:

<table>
<thead>
<tr>
<th>Compound</th>
<th>LD50/LC50 values</th>
</tr>
</thead>
<tbody>
<tr>
<td>75-65-0 2-methylpropan-2-ol</td>
<td>LD50 3500 mg/kg (rat)</td>
</tr>
<tr>
<td></td>
<td>LD50 399 mg/kg (mouse - intraperitoneal)</td>
</tr>
<tr>
<td>108-10-1 4-methylpentan-2-one</td>
<td>LD50 2850 mg/kg (mouse)</td>
</tr>
<tr>
<td></td>
<td>LD50 2080 mg/kg (rat)</td>
</tr>
<tr>
<td></td>
<td>Inhalative LC50/4 h 8.3-16.6 mg/l (rat)</td>
</tr>
<tr>
<td>94-36-0 benzoyl peroxide</td>
<td>Oral LD50 5700 mg/kg (mouse)</td>
</tr>
<tr>
<td></td>
<td>LD50 7710 mg/kg (rat)</td>
</tr>
<tr>
<td></td>
<td>LD50 250 mg/kg (mouse - intraperitoneal)</td>
</tr>
</tbody>
</table>

Primary irritant effect:
- Skin corrosion/irritation Based on available data, the classification criteria are not met.
- 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)
  Based on available data, the classification criteria are not met.
- 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:

<table>
<thead>
<tr>
<th>Compound</th>
<th>LC50/48h</th>
</tr>
</thead>
<tbody>
<tr>
<td>75-65-0 2-methylpropan-2-ol</td>
<td>5500 mg/l (orange-red killifish)</td>
</tr>
</tbody>
</table>

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

SECTION 14: Transport information

- 14.1 UN-Number
  - ADR, IMDG, IATA 1993
- 14.2 UN proper shipping name
  - ADR 1993 FLAMMABLE LIQUID, N.O.S. (BUTANOLS, METHYL ISOBUTYL KETONE)
  - IMDG, IATA FLAMMABLE LIQUID, N.O.S. (BUTANOLS, METHYL ISOBUTYL KETONE)
- 14.3 Transport hazard class(es)
  - ADR, 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
  - Danger code (Kemler): Warning: Flammable liquids.
  - EMS Number: F-E,S-E
- 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
  Not applicable.

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

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
  - H200 Unstable explosives.
  - H225 Highly flammable liquid and vapour.
  - H242 Heating may cause a fire.
  - H317 May cause an allergic skin reaction.
  - H319 Causes serious eye irritation.
  - H332 Harmful if inhaled.
  - H335 May cause respiratory irritation.

- Abbreviations and acronyms:
  - Unst. Expl.: Explosives – Unstable explosive
  - Flam. Liq. 2: Flammable liquids – Category 2
  - Org. Perox. E: Organic peroxides – Type E/F
  - Acute Tox. 4: Acute toxicity – Category 4
  - 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

* Data compared to the previous version altered.