

## 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.

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· **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: CO<sub>2</sub>, 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.

· **Dangerous components:**

CAS: 75-65-0 EINECS: 200-889-7	2-methylpropan-2-ol Flam. Liq. 2, H225; Acute Tox. 4, H332; Eye Irrit. 2, H319; STOT SE 3, H335	50-70%
CAS: 108-10-1 EINECS: 203-550-1	4-methylpentan-2-one Flam. Liq. 2, H225; Acute Tox. 4, H332; Eye Irrit. 2, H319; STOT SE 3, H335	20-40%
CAS: 94-36-0 EINECS: 202-327-6	benzoyl peroxide Unst. Expl., H200; Eye Irrit. 2, H319; Skin Sens. 1, H317; Org. Perox. E, H242	<1.5%

· **Other ingredients:**

Hydrophobic aromatic dimethacrylate

Hydrophobic aliphatic methacrylate

10-Methacryloyloxydecyl dihydrogen phosphate

GB

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**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 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:**

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:** CO<sub>2</sub>, 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.

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- **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**

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**

<b>Ingredients with limit values that require monitoring at the workplace:</b>	
<b>75-65-0 2-methylpropan-2-ol</b>	
WEL	Short-term value: 462 mg/m <sup>3</sup> , 150 ppm Long-term value: 308 mg/m <sup>3</sup> , 100 ppm
<b>108-10-1 4-methylpentan-2-one</b>	
WEL	Short-term value: 416 mg/m <sup>3</sup> , 100 ppm Long-term value: 208 mg/m <sup>3</sup> , 50 ppm Sk

- **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.

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· **Eye protection:**



Tightly sealed goggles

## SECTION 9: Physical and chemical properties

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

#### · General Information

#### · Appearance:

· <b>Form:</b>	Liquid
· <b>Colour:</b>	Colourless
· <b>Odour:</b>	Ether-like

· **pH-value:** Not applicable

#### · Change in condition

· <b>Melting point/Melting range:</b>	-83.5 °C (4-methylpentan-2-one)
· <b>Boiling point/Boiling range:</b>	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:

· <b>Lower:</b>	1.7 Vol % (4-methylpentan-2-one)
· <b>Upper:</b>	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/cm<sup>3</sup>

· **Relative density** Not determined

· **Vapour density** 3.45 g/cm<sup>3</sup> (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.

## 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.

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· **10.6 Hazardous decomposition products:** Carbon monoxide and carbon dioxide

## SECTION 11: Toxicological information

### · 11.1 Information on toxicological effects

· **Acute toxicity**  
Harmful if inhaled.

#### · LD/LC50 values relevant for classification:

##### 75-65-0 2-methylpropan-2-ol

Oral	LD50	3500 mg/kg (rat)
	LD50	399 mg/kg (mouse - intraperitoneal)

##### 108-10-1 4-methylpentan-2-one

Oral	LD50	2850 mg/kg (mouse)
		2080 mg/kg (rat)
Inhalative	LC50/4 h	8.3-16.6 mg/l (rat)

##### 94-36-0 benzoyl peroxide

Oral	LD50	5700 mg/kg (mouse)
		7710 mg/kg (rat)
	LD50	250 mg/kg (mouse - intraperitoneal)

- **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 (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:

##### 75-65-0 2-methylpropan-2-ol

LC50/48h	5500 mg/l (orange-red killifish)
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- **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.

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· **12.6 Other adverse effects** No further relevant information available.

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### 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**

Warning: Flammable liquids.

· **Danger code (Kemler):**

33

· **EMS Number:**

F-E,S-E

· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**

Not applicable.

· **Transport/Additional information:**

· **ADR**

· **Limited quantities (LQ)**

LQ4

· **Transport category**

2

· **Tunnel restriction code**

D1E

· **UN "Model Regulation":**

UN1993; FLAMMABLE LIQUID, N.O.S.; 3; II

### 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

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· **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.**