

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**
- **Supplier :**
Kuraray Europe GmbH
Philipp-Reis-Str. 4,
65795 Hattersheim am Main
Germany
Phone: +49 (0)69 305 35 835
E-mail: dental.eu@kuraray.com
- **Further information obtainable from:** Supplier
- **1.4 Emergency telephone number:**
(UK) 0 800 680 0425
(GB) +44 20 35147487
(AU) +61 2 80363166
* 3E Company
* Kuraray Access Code:334674

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.
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.
Carc. 2 H351 Suspected of causing cancer.
STOT SE 3 H335-H336 May cause respiratory irritation. May cause drowsiness or dizziness.
- **Additional information :**
Medical devices as defined in Regulation (EU) 2017/745 and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (GB CLP/ GHS) usually if they are in the finished state and intended for the final user.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the GB CLP regulation.
- **Hazard pictograms**

GHS02 GHS07 GHS08
- **Signal word** Danger
- **Hazard-determining components of labelling:**
2-methylpropan-2-ol
4-methylpentan-2-one
benzoyl peroxide
- **Hazard statements**
H225 Highly flammable liquid and vapour.

(Contd. on page 2)

Trade name: ESTENIA C&B; OPAQUE PRIMER

(Contd. of page 1)

- H332 Harmful if inhaled.
 H319 Causes serious eye irritation.
 H317 May cause an allergic skin reaction.
 H351 Suspected of causing cancer.
 H335-H336 May cause respiratory irritation. May cause drowsiness or dizziness.

· **Precautionary statements**

- P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
 P240 Ground and bond container and receiving equipment.
 P241 Use explosion-proof [electrical/ventilating/lighting] equipment.
 P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
 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.
 P405 Store locked up.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Labelling of packages where the contents do not exceed 125 ml**

- **Precautionary statements** EUH066: Repeated exposure may cause skin dryness or cracking.

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
 · **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.1 Substances** None
 · **3.2 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; ⚠ Carc. 2, H351; ⚠ Acute Tox. 4, H332; Eye Irrit. 2, H319; STOT SE 3, H336, EUH066 ATE: LC50/4 h inhalative: 11 mg/l	20-40%
CAS: 94-36-0 EINECS: 202-327-6	benzoyl peroxide ⚠ Self-react. B, H241; Org. Perox. B, H241; ⚠ Eye Irrit. 2, H319; Skin Sens. 1, H317	<1.5%

· **Other ingredients:**

- Hydrophobic aromatic dimethacrylate
 Hydrophobic aliphatic dimethacrylate
 10-Methacryloyloxydecyl dihydrogen phosphate

GB

(Contd. on page 3)

Safety data sheet
according to 1907/2006/EC, Article 31

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Trade name: ESTENIA C&B; OPAQUE PRIMER

(Contd. of page 2)

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:** 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** See Section 8.**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.

(Contd. on page 4)

Trade name: ESTENIA C&B; OPAQUE PRIMER

(Contd. of page 3)

- **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:**

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

WEL	Short-term value: 462 mg/m ³ , 150 ppm Long-term value: 308 mg/m ³ , 100 ppm
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108-10-1 4-methylpentan-2-one

WEL	Short-term value: 416 mg/m ³ , 100 ppm Long-term value: 208 mg/m ³ , 50 ppm
	Sk

94-36-0 benzoyl peroxide

WEL	Long-term value: 5 mg/m ³
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· **Additional information:** The lists valid during the making were used as basis.

· **8.2 Exposure controls**

· **Appropriate engineering controls** No further data; see item 7.

· **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.

· **Hand protection**



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.

(Contd. on page 5)

Trade name: ESTENIA C&B; OPAQUE PRIMER

(Contd. of page 4)

- **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/face protection**



Tightly sealed goggles

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Physical state	Liquid
· Colour:	Colourless
· Odour:	Ether-like
· Melting point/freezing point:	-83.5 °C (4-methylpentan-2-one)
· Boiling point or initial boiling point and boiling range	83 °C (2-methylpropan-2-ol)
· Flammability	Flammable.
· Lower and upper explosion limit	
· Lower:	1.7 Vol % (4-methylpentan-2-one)
· Upper:	9.0 Vol % (4-methylpentan-2-one)
· Flash point:	11 °C (2-methylpropan-2-ol)
· Auto-ignition temperature:	460.0 °C (4-methylpentan-2-one)
· Decomposition temperature:	Not determined
· pH	Not applicable
· Viscosity:	Not determined
· Kinematic viscosity	Not applicable.
· Solubility	
· water:	Not miscible or difficult to mix.
· Partition coefficient n-octanol/water (log value)	Not determined
· Vapour pressure:	40.0 hPa (20°C, 2-methylpropan-2-ol)
· Density and/or relative density	
· Density at 20 °C:	0.9 g/cm ³
· Relative density	Not determined
· Relative vapour density	3.45 g/cm ³ (4-methylpentan-2-one, air=1)

· 9.2 Other information

· Appearance:	
· Form:	Liquid
· Important information on protection of health and environment, and on safety.	
· Explosive properties:	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· Change in condition	
· Softening point/range	
· Oxidising properties	Not determined
· Evaporation rate	Not determined
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	
Highly flammable liquid and vapour.	
· Flammable solids	Void
· Self-reactive substances and mixtures	Void

(Contd. on page 6)

Trade name: ESTENIA C&B; OPAQUE PRIMER

(Contd. of page 5)

· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

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.
- **10.6 Hazardous decomposition products:** Carbon monoxide and carbon dioxide

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **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)

- **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.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity**
Suspected of causing cancer.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure**
May cause respiratory irritation. May cause drowsiness or dizziness.
- **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.

(Contd. on page 7)

Trade name: ESTENIA C&B; OPAQUE PRIMER

(Contd. of page 6)

· **11.2 Information on other hazards**

· **Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**

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

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

· **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.

· **12.5 Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **12.6 Endocrine disrupting properties**

The product does not contain substances with endocrine disrupting properties.

· **12.7 Other adverse effects**

· **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.

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 or ID number**

· **ADR, IMDG, IATA**

1993

· **14.2 UN proper shipping name**

1993 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

(Contd. on page 8)

Trade name: ESTENIA C&B; OPAQUE PRIMER

(Contd. of page 7)

· 14.5 Environmental hazards:	
· Marine pollutant:	No
· 14.6 Special precautions for user	Warning: Flammable liquids.
· Hazard identification number (Kemler code):	33
· EMS Number:	F-E,S-E
· 14.7 Maritime transport in bulk according to IMO instruments	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**
- **Directive 94/33/EC:** Care should be taken when people under 18 handle this product.
- **Directive 94/85/EEC:** No further relevant information available.
- **Chemical safety assessment**
- **Named dangerous substances - ANNEX I** None of the ingredient is listed.
- **Seveso category** 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 (EU) No 649/2012**

· Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

· Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

None of the ingredients is listed.

- **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**

- H225 Highly flammable liquid and vapour.
- H241 Heating may cause a fire or explosion.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H332 Harmful if inhaled.
- H335 May cause respiratory irritation.
- H336 May cause drowsiness or dizziness.
- H351 Suspected of causing cancer.
- EUH066 Repeated exposure may cause skin dryness or cracking.

· **Abbreviations and acronyms:**

- ELINCS: European List of Notified Chemical Substances
- Flam. Liq. 2: Flammable liquids – Category 2
- Self-react. B: Self-reactive substances and mixtures – Type B
- Org. Perox. B: Organic peroxides – Type B

(Contd. on page 9)

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Acute Tox. 4: Acute toxicity – Category 4
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
Carc. 2: Carcinogenicity – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

· *** Data compared to the previous version altered.**

(Contd. of page 8)

GB