

*** SECTION 1: Identification of the substance/mixture and of the company/undertaking****· 1.1 Product identifier**

· Trade name: ESTENIA C&B ; CR SEP III

· Article number: 095-CS3

· 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 materials

· 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:

[United Kingdom] National Poisons Information Service (NPIS): +44 (0)344 892 0111 Only for NHS and other healthcare professionals

3E Company; (UK) 0 800 680 0425 (GB) +44 20 35147487 (AU) +61 2 80363166 *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.

Skin Irrit. 2 H315 Causes skin irritation.

STOT SE 3 H336 May cause drowsiness or dizziness.

Asp. Tox. 1 H304 May be fatal if swallowed and enters airways.

Aquatic Acute 1 H400 Very toxic to aquatic life.

Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.

· 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



GHS09

· Signal word Danger**· Hazard-determining components of labelling:**

cyclohexane

· Hazard statements

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H336 May cause drowsiness or dizziness.

H304 May be fatal if swallowed and enters airways.

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H410 Very toxic to aquatic life with long lasting effects.

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.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.
P321 Specific treatment (see on this label).
P331 Do NOT induce vomiting.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P362+P364 Take off contaminated clothing and wash it before reuse.
P405 Store locked up.
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**3.2 Mixtures**

- Description:** Mixture of substances listed below with nonhazardous additions.

Dangerous components:

CAS: 110-82-7	cyclohexane	> 90%
EINECS: 203-806-2	Flam. Liq. 2, H225; Asp. Tox. 1, H304; Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Skin Irrit. 2, H315; STOT SE 3, H336	

- Other ingredients:** Cycloolefin polymer

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.**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.

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· 5.3 Advice for firefighters**· Protective equipment:**

Wear self-contained respiratory protective device.

Wear fully protective suit.

SECTION 6: Accidental release measures**· 6.1 Personal precautions, protective equipment and emergency procedures** See Section 8.**· 6.2 Environmental precautions:**

Inform respective authorities in case of seepage into water course or sewage system.

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 section 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:****110-82-7 cyclohexane**WEL (Great Britain) Short-term value: 1050 mg/m³, 300 ppmLong-term value: 350 mg/m³, 100 ppmIOELV (EU) Long-term value: 700 mg/m³, 200 ppm**· Additional information:** The lists valid during the making were used as basis.**· 8.2 Exposure controls****· Appropriate engineering controls** No further data; see section 7.

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· 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.

· 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/face protection Safety glasses*** SECTION 9: Physical and chemical properties****· 9.1 Information on basic physical and chemical properties**

· Physical state	Liquid
· Colour:	Transparent
· Odour:	Oil-like
· Melting point/freezing point:	6.4 °C (cyclohexane)
· Boiling point or initial boiling point and boiling range	81 °C (cyclohexane)
· Flammability	Flammable.
· Lower and upper explosion limit	
· Lower:	1.2 Vol % (cyclohexane)
· Upper:	8.3 Vol % (cyclohexane)
· Flash point:	-18 °C (cyclohexane)
· Auto-ignition temperature:	260.0 °C (cyclohexane)
· Decomposition temperature:	Not determined
· pH	Not determined
· Viscosity:	Not determined
· Kinematic viscosity	Not applicable.
· Solubility	
· water:	Not miscible or difficult to mix.
· Partition coefficient n-octanol/water (log value)	Not applicable
· Vapour pressure:	104.0 hPa (20°C, cyclohexane)
· Density and/or relative density	
· Density:	0.8 g/cm³ (cyclohexane)
· Relative density	Not determined
· Relative vapour density	2.9 g/cm³ (cyclohexane, air=1)

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· 9.2 Other information	
· 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	
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Highly flammable liquid and vapour.
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· 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

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SECTION 11: Toxicological information

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

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

- LD/LC50 values relevant for classification:**

110-82-7 cyclohexane

Oral	LD50	813 mg/kg (mouse)
		12705 mg/kg (rat)

- Skin corrosion/irritation**

Causes skin irritation.

- Serious eye damage/irritation** Based on available data, the classification criteria are not met.

- Respiratory or skin sensitisation** 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 drowsiness or dizziness.

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

- Aspiration hazard**

May be fatal if swallowed and enters airways.

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· 11.2 Information on other hazards**· Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information**· 12.1 Toxicity****· Aquatic toxicity:**

Very toxic to aquatic life.

Very toxic to aquatic life with long lasting effects.

110-82-7 cyclohexane

LC50/48h | 9 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**· Remark:** Very toxic for fish**· Additional ecological information:****· General notes:**

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

Also poisonous for fish and plankton in water bodies.

Very toxic for aquatic organisms

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**

1145

· 14.2 UN proper shipping name**· ADR**1145 CYCLOHEXANE solution,
ENVIRONMENTALLY HAZARDOUS

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· 14.3 Transport hazard class(es)

· ADR, IMDG



· Class

3 Flammable liquids.

· Label

3

· IATA



· Class

3 Flammable liquids.

· Label

3

· 14.4 Packing group

· ADR, IMDG, IATA

II

· 14.5 Environmental hazards:

Product contains environmentally hazardous substances: cyclohexane

· Marine pollutant:

Symbol (fish and tree)

· Special marking (ADR):

Symbol (fish and tree)

· 14.6 Special precautions for user

Warning: Flammable liquids.

· Hazard identification number (Kemler code):

33

· EMS Number:

F-E,S-D

· 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":

UN 1145 CYCLOHEXANE SOLUTION, 3, II,
ENVIRONMENTALLY HAZARDOUS

* SECTION 15: Regulatory information

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

· Poisons Act

· Regulated explosives precursors

None of the ingredients is listed.

· Regulated poisons

None of the ingredients is listed.

· Reportable explosives precursors

None of the ingredients is listed.

· Reportable poisons

None of the ingredients is listed.

· Directive 94/33/EC: Care should be taken when people under 18 handle this product.

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- **Directive 94/85/EEC:** No further relevant information available.
- **Named dangerous substances - ANNEX I** None of the ingredient is listed.
- **Seveso category**
FLAMMABLE LIQUIDS
Hazardous to the Aquatic Environment
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 100 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 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.

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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.
H304 May be fatal if swallowed and enters airways.
H315 Causes skin irritation.
H336 May cause drowsiness or dizziness.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
- **Abbreviations and acronyms:**
ELINCS: European List of Notified Chemical Substances
Flam. Liq. 2: Flammable liquids – Category 2
Skin Irrit. 2: Skin corrosion/irritation – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
Asp. Tox. 1: Aspiration hazard – Category 1
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

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

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