

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



- **1.1 Product identifier**
- **Trade name:** Esthetic Colorant
- **Article number:** 896
- **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** Colorings for dental ceramics
- **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**

Skin Corr. 1B	H314	Causes severe skin burns and eye damage.
Eye Dam. 1	H318	Causes serious eye damage.
Resp. Sens. 1	H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin Sens. 1	H317	May cause an allergic skin reaction.
Muta. 2	H341	Suspected of causing genetic defects.
Carc. 1A	H350i	May cause cancer by inhalation.
Repr. 1B	H360D	May damage the unborn child.
STOT RE 2	H373	May cause damage to organs through prolonged or repeated exposure.
Aquatic Chronic 3	H412	Harmful 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**

GHS05    GHS08

- **Signal word** Danger
- **Hazard-determining components of labelling:**  
3-aminopropyltriethoxysilane

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Nickel bromide (NiBr<sub>2</sub>), trihydrate  
 aluminum chloride hexahydrate

**· Hazard statements**

- H314 Causes severe skin burns and eye damage.
- H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- H317 May cause an allergic skin reaction.
- H341 Suspected of causing genetic defects.
- H350i May cause cancer by inhalation.
- H360D May damage the unborn child.
- H373 May cause damage to organs through prolonged or repeated exposure.
- H412 Harmful to aquatic life with long lasting effects.

**· Precautionary statements**

- P260 Do not breathe dusts or mists.
- P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
- P284 [In case of inadequate ventilation] wear respiratory protection.
- P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or 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.
- P310 Immediately call a POISON CENTER/doctor.
- P321 Specific treatment (see on this label).
- 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** Dust generation.

**· 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: 57-55-6 EINECS: 200-338-0	Propylene glycol substance with a Community workplace exposure limit	<10%
CAS: 919-30-2 EINECS: 213-048-4	3-aminopropyltriethoxysilane ⚠ Skin Corr. 1B, H314; ⚠ Acute Tox. 4, H302	<5%
CAS: 7789-49-3	Nickel bromide (NiBr <sub>2</sub> ), trihydrate ⚠ Resp. Sens. 1, H334; Muta. 2, H341; Carc. 1A, H350i; Repr. 1B, H360D; STOT RE 1, H372; ⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410; ⚠ Skin Sens. 1, H317	<3%
CAS: 7784-13-6	aluminum chloride hexahydrate ⚠ Skin Corr. 1B, H314	≤1%

**· Other ingredients:**

Water  
 Pigments  
 Dyes

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

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**SECTION 4: First aid measures**

- **4.1 Description of first aid measures**
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** 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>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.  
Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

**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).  
Contain spill, then place in a suitable container. Minimize dust generation. Do not flush to sewer or allow to enter waterways.  
Vacuum or sweep material and place in a disposal container. Provide ventilation.  
Use appropriate Personal Protective Equipment (PPE).
- **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**  
Avoid contact with skin and eyes. Do not swallow. Avoid generating dust. Do not breathe dust/fume/gas/mist/vapors/spray.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Store at room temperature.
- **Further information about storage conditions:** None.
- **7.3 Specific end use(s)** No further relevant information available.

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**SECTION 8: Exposure controls/personal protection**

**8.1 Control parameters**

<b>Ingredients with limit values that require monitoring at the workplace:</b>	
<b>57-55-6 Propylene glycol</b>	
<b>WEL</b>	Long-term value: 474* 10** mg/m <sup>3</sup> , 150* ppm *total vapour and particulates **particulates

**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:**  
 The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Suitable respiratory protective device recommended.
- **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 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**

- |   |                                    |
|---|------------------------------------|
| <b>Physical state</b>   | Liquid                             |
| <b>Colour:</b>  | According to product specification |
| <b>Odour:</b>   | Odourless                          |
| <b>Melting point/freezing point:</b>                            | Not determined                     |
| <b>Boiling point or initial boiling point and boiling range</b> | Not determined                     |
| <b>Flammability</b>   | Not determined                     |
| <b>Lower and upper explosion limit</b>                          | Not determined                     |
| <b>Lower:</b>   | Not determined                     |
| <b>Upper:</b>   | Not determined                     |

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· <b>Flash point:</b>	Not determined
· <b>Auto-ignition temperature:</b>	Not determined
· <b>Decomposition temperature:</b>	Not determined
· <b>pH</b>	Not determined
· <b>Viscosity:</b>	
· <b>Kinematic viscosity</b>	Not determined
· <b>Dynamic:</b>	Not determined
· <b>Solubility</b>	
· <b>water:</b>	Miscible
· <b>Partition coefficient n-octanol/water (log value)</b>	Not determined
· <b>Vapour pressure:</b>	Not determined
· <b>Density and/or relative density</b>	
· <b>Density:</b>	Not determined
· <b>Relative density</b>	Not determined
· <b>Relative vapour density</b>	Not determined

**9.2 Other information**

· <b>Appearance:</b>	
· <b>Form:</b>	Liquid
· <b>Important information on protection of health and environment, and on safety.</b>	
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Change in condition</b>	
· <b>Evaporation rate</b>	Not determined
· <b>Oxidising gases</b>	Void
· <b>Gases under pressure</b>	Void
· <b>Flammable liquids</b>	Void
· <b>Flammable solids</b>	Void
· <b>Self-reactive substances and mixtures</b>	Void
· <b>Pyrophoric liquids</b>	Void
· <b>Pyrophoric solids</b>	Void
· <b>Self-heating substances and mixtures</b>	Void
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
· <b>Oxidising liquids</b>	Void
· <b>Oxidising solids</b>	Void
· <b>Organic peroxides</b>	Void
· <b>Corrosive to metals</b>	Void
· <b>Desensitised explosives</b>	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** Based on available data, the classification criteria are not met.

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

**919-30-2 3-aminopropyltriethoxysilane**

Oral	LD50	1,780 mg/kg (rat)
Dermal	LD50	4,000 mg/kg (rabbit)

- **Skin corrosion/irritation** Causes severe skin burns and eye damage.
- **Serious eye damage/irritation** Causes serious eye damage.
- **Respiratory or skin sensitisation**  
May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
May cause an allergic skin reaction.
- **Germ cell mutagenicity** Suspected of causing genetic defects.
- **Carcinogenicity** May cause cancer by inhalation.
- **Reproductive toxicity** May damage the unborn child.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** May cause damage to organs through prolonged or repeated exposure.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

· **11.2 Information on other hazards**

· **Endocrine disrupting properties**

None of the ingredients is listed.

**SECTION 12: Ecological information**

- **12.1 Toxicity**
- **Aquatic toxicity:** Harmful to aquatic life with long lasting effects.
- **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** Disposal must be made according to official regulations.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

**SECTION 14: Transport information**

- |                                       |      |
|---------------------------------------|------|
| · <b>14.1 UN number or ID number</b>  |      |
| · <b>ADR, IMDG, IATA</b>              | Void |
| · <b>14.2 UN proper shipping name</b> |      |
| · <b>ADR, IMDG, IATA</b>              | Void |

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· <b>14.3 Transport hazard class(es)</b>	
· <b>ADR, ADN, IMDG, IATA</b>	
· <b>Class</b>	Void
· <b>14.4 Packing group</b>	
· <b>ADR, IMDG, IATA</b>	Void
· <b>14.5 Environmental hazards:</b>	Not applicable.
· <b>14.6 Special precautions for user</b>	Not applicable.
· <b>14.7 Maritime transport in bulk according to IMO instruments</b>	Not applicable.
· <b>UN "Model Regulation":</b>	Void

### 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.
- **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**

- H302 Harmful if swallowed.
- H314 Causes severe skin burns and eye damage.
- H317 May cause an allergic skin reaction.
- H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- H341 Suspected of causing genetic defects.
- H350i May cause cancer by inhalation.
- H360D May damage the unborn child.
- H372 Causes damage to organs through prolonged or repeated exposure.
- 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  
 Acute Tox. 4: Acute toxicity – Category 4  
 Skin Corr. 1B: Skin corrosion/irritation – Category 1B  
 Eye Dam. 1: Serious eye damage/eye irritation – Category 1  
 Resp. Sens. 1: Respiratory sensitisation – Category 1  
 Skin Sens. 1: Skin sensitisation – Category 1  
 Muta. 2: Germ cell mutagenicity – Category 2  
 Carc. 1A: Carcinogenicity – Category 1Ai  
 Repr. 1B: Reproductive toxicity – Category 1B

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**Safety data sheet**  
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STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1  
STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2  
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  
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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

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