

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

Printing date 13.04.2022

Version number 1

Revision date: 01.04.2022

**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 35835  
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**

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	H350 May cause cancer.
Repr. 1B	H360 May damage fertility or the unborn child.
STOT RE 1	H372 Causes 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 Directive 93/42/EEC 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 (CLP/GHS) usually if they are in the finished state and intended for the final user.

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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**  
  
GHS08
- **Signal word** Danger
- **Hazard-determining components of labelling:**  
nickel bromide (NiBr<sub>2</sub>), trihydrate  
Organoiodine compound
- **Hazard statements**  
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

(Contd. on page 2)

GB

## Safety data sheet

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**Trade name: Esthetic Colorant**

(Contd. of page 1)

- H317 May cause an allergic skin reaction.
- H341 Suspected of causing genetic defects.
- H350 May cause cancer.
- H360 May damage fertility or the unborn child.
- H372 Causes damage to organs through prolonged or repeated exposure.
- H412 Harmful to aquatic life with long lasting effects.

**Precautionary statements**

- P101 If medical advice is needed, have product container or label at hand.
- P102 Keep out of reach of children.
- P103 Read label before use.
- P260 Do not breathe dust/fume/gas/mist/vapours/spray.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P284 [In case of inadequate ventilation] wear respiratory protection.
- P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- P308+P313 IF exposed or concerned: Get medical advice/attention.
- P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
- P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.
- 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 ⚠ Acute Tox. 4, H302	<10%
CAS: 7789-49-3	Nickel bromide (NiBr <sub>2</sub> ), trihydrate ⚠ Resp. Sens. 1, H334; Muta. 2, H341; Carc. 1A, H350; Repr. 1B, H360; STOT RE 1, H372; ⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410; ⚠ Skin Sens. 1, H317	<5%
CAS: 919-30-2 EINECS: 213-048-4	3-aminopropyltriethoxysilane ⚠ Skin Corr. 1B, H314; ⚠ Acute Tox. 4, H302	<5%
CAS: 64-17-5 EINECS: 200-578-6	ethanol ⚠ Flam. Liq. 2, H225	<5%
CAS: 64-02-8 EINECS: 200-573-9	tetrasodium ethylenediaminetetraacetate ⚠ Eye Dam. 1, H318; ⚠ Acute Tox. 4, H302	<3%
	vanadate liquid ⚠ Skin Corr. 1B, H314; ⚠ Acute Tox. 4, H332	<1%
	Organoiodine compound ⚠ Skin Corr. 1, H314; Eye Dam. 1, H318; ⚠ Skin Sens. 1, H317	<1%

- **Other ingredients:** Water

### SECTION 4: First aid measures

**4.1 Description of first aid measures**

- **After inhalation:** Supply fresh air; consult doctor in case of complaints.

(Contd. on page 3)

**Trade name: Esthetic Colorant**

(Contd. of page 2)

- **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.

GB

(Contd. on page 4)

**Trade name: Esthetic Colorant**

(Contd. of page 3)

## SECTION 8: Exposure controls/personal protection

### · 8.1 Control parameters

#### · **Ingredients with limit values that require monitoring at the workplace:**

##### **57-55-6 Propylene glycol**

WEL	Long-term value: 474* 10** mg/m <sup>3</sup> , 150* ppm *total vapour and particulates **particulates
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##### **64-17-5 ethanol**

WEL	Long-term value: 1920 mg/m <sup>3</sup> , 1000 ppm
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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:**

The usual precautionary measures are to be adhered to when handling chemicals.

· **Respiratory protection:** Suitable respiratory protective device recommended.

· **Hand protection**

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** Safety glasses

## SECTION 9: Physical and chemical properties

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

#### · **General Information**

· **Physical state**

Fluid

· **Colour:**

According to product specification

· **Odour:**

Odourless

· **Odour threshold:**

Not determined

· **Melting point/freezing point:**

Not determined

· **Boiling point or initial boiling point and boiling range**

Not determined

· **Flammability**

Not determined

· **Lower and upper explosion limit**

· **Lower:**

Not determined

· **Upper:**

Not determined

· **Flash point:**

Not determined

· **Auto-ignition temperature:**

Not determined

· **Decomposition temperature:**

Not determined

· **pH**

Not determined

· **Viscosity:**

· **Kinematic viscosity**

Not determined

(Contd. on page 5)

**Trade name: Esthetic Colorant**

(Contd. of page 4)

· <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>Vapour density</b>	Not determined

· <b>9.2 Other information</b>	
· <b>Appearance:</b>	
· <b>Form:</b>	Liquid
· <b>Important information on protection of health and environment, and on safety.</b>	
· <b>Ignition temperature:</b>	Not determined
· <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**  
Void

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

**64-17-5 ethanol**

Oral	LD50	3,450 mg/kg (mouse)
		7,060 mg/kg (rat)

(Contd. on page 6)

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**Trade name: Esthetic Colorant**

(Contd. of page 5)

Inhalative	LC50/4 h	20,000 mg/l (rat)
	LD50	3,600 mg/kg (rat - intraperitoneal)
<b>919-30-2 3-aminopropyltriethoxysilane</b>		
Oral	LD50	1,780 mg/kg (rat)
Dermal	LD50	4,000 mg/kg (rabbit)

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **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.
- **Reproductive toxicity**  
May damage fertility or the unborn child.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Causes 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:** No further relevant information available.
- **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

- **14.1 UN number or ID number**
- **ADR, IMDG, IATA** Void

(Contd. on page 7)

## Safety data sheet

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(Contd. of page 6)

· <b>14.2 UN proper shipping name</b> · <b>ADR, IMDG, IATA</b>	Void
· <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.
- **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.

- **Abbreviations and acronyms:**
- ELINCS: European List of Notified Chemical Substances
- Flam. Liq. 2: Flammable liquids – Category 2
- Acute Tox. 4: Acute toxicity – Category 4
- Skin Corr. 1: Skin corrosion/irritation – Category 1
- 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 1A
- Repr. 1B: Reproductive toxicity – Category 1B
- STOT RE 1: Specific target organ toxicity (repeated exposure) – 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
- Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3