

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

Printing date 07.08.2023

Version number 9 (replaces version 8)

Revision: 18.07.2023

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

- **1.1 Product identifier**
- **Trade name:** **AESTHETIC INTENSIVE COLORS/ OPAQUE**
- **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** for characterization of denture base materials
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
CANDULOR AG  
Boulevard Lilienthal 8  
8152 Glattpark (Opfikon)  
SWITZERLAND  
  
Tel. +41 (0) 44 805 9000  
Fax +41 (0) 44 805 9090
- **Further information obtainable from:**  
Regulatory Affairs  
info@candulor.ch
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, 9494 Schaan, Liechtenstein)

### SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
The product is not classified, according to the GB CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008 Void**
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Precautionary statements**  
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
P262 Do not get in eyes, on skin, or on clothing.  
P280 Wear protective gloves/protective clothing/eye protection/face protection.  
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Additional information:**  
Contains dibenzoyl peroxide. May produce an allergic reaction.  
Safety data sheet available on request.  
Warning! Hazardous respirable dust may be formed when used. Do not breathe dust.
- **2.3 Other hazards**  
Dust generation  
Particular danger of slipping on leaked/spilled product.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
- **Description:** > 95% polymethylmethacrylate

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**· Dangerous components:**

CAS: 13463-67-7 EINECS: 236-675-5 Reg.nr.: 01-2119489379-17-0018	titanium dioxide	<2.5%
CAS: 14807-96-6 EINECS: 238-877-9	Talc (Mg <sub>3</sub> H <sub>2</sub> (SiO <sub>3</sub> ) <sub>4</sub> ) substance with a Community workplace exposure limit	<2.5%
CAS: 94-36-0 EINECS: 202-327-6 Reg.nr.: 01-2119511472-50-XXXX	dibenzoyl peroxide Org. Perox. B, H241; Eye Irrit. 2, H319; Skin Sens. 1, H317	0.1-<1%

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Rinse with water.
- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:**  
Rinse out mouth and then drink plenty of water.  
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.
- **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**  
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:** Pick up mechanically.
- **6.4 Reference to other sections**  
No dangerous substances are released.  
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**  
Only adequately trained personnel should handle this product.  
For use in dentistry only.

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- **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:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** 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:**

**CAS: 13463-67-7 titanium dioxide**

WEL	Long-term value: 10* 4** mg/m <sup>3</sup> *total inhalable **respirable
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**CAS: 14807-96-6 Talc (Mg<sub>3</sub>H<sub>2</sub>(SiO<sub>3</sub>)<sub>4</sub>)**

WEL	Long-term value: 1 mg/m <sup>3</sup>
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**CAS: 94-36-0 dibenzoyl peroxide**

WEL	Long-term value: 5 mg/m <sup>3</sup>
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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 section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**  
Usual hygienic measures for dental practice and dental laboratories.  
Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.  
Avoid contact with the skin.
- **Respiratory protection:** Not required.
- **Hand protection**



Protective gloves (EN 374)

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.

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· Eye/face protection



Tightly sealed goggles (EN 166)

**SECTION 9: Physical and chemical properties**

## · 9.1 Information on basic physical and chemical properties

## · General Information

· Colour:	According to product specification
· Odour:	Characteristic
· Odour threshold:	Not determined.
· Melting point/freezing point:	150 °C
· Boiling point or initial boiling point and boiling range	Undetermined.
· Flammability	Not determined.
· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	250 °C
· pH	Not applicable.
· Viscosity:	
· Kinematic viscosity	Not applicable.
· Dynamic:	Not applicable.
· Solubility	
· water:	Nearly insoluble.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not applicable.
· Density and/or relative density	
· Density at 20 °C:	1.2 g/cm <sup>3</sup>
· Relative density	Not determined.
· Vapour density	Not applicable.

## · 9.2 Other information

· Appearance:	
· Form:	Powder
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Change in condition	
· Evaporation rate	Not applicable.

## · Information with regard to physical hazard classes

· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void

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- |  |      |
|--|------|
| · <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** Stable under normal handling and storage conditions.
- **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:** None under normal conditions of storage and use.

### 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.
- **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** 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** Based on available data, the classification criteria are not met.
- **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.
- **Additional toxicological information:** No further relevant information available.
- **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.

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- **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**  
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

- |   |  |
|---|--|
| · <b>14.1 UN number or ID number</b>                                  | Void   |
| · <b>ADR/RID/ADN, ADN, IMDG, IATA</b>                                 | Void   |
| · <b>14.2 UN proper shipping name</b>                                 | Void   |
| · <b>ADR/RID/ADN, ADN, IMDG, IATA</b>                                 | Void   |
| · <b>14.3 Transport hazard class(es)</b>                              | Void   |
| · <b>ADR/RID/ADN, ADN, IMDG, IATA</b>                                 | Void   |
| · <b>Class</b>  | Void   |
| · <b>14.4 Packing group</b>   | Void   |
| · <b>ADR/RID/ADN, IMDG, IATA</b>                                      | Void   |
| · <b>14.5 Environmental hazards:</b>                                  |  |
| · <b>Marine pollutant:</b>  | No   |
| · <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>Transport/Additional information:</b>                            | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · <b>UN "Model Regulation":</b>                                       | Void   |

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**  
The product is a medical device according to the Directive 93/42/EEC.
- **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**

*H241 Heating may cause a fire or explosion.*

*H317 May cause an allergic skin reaction.*

*H319 Causes serious eye irritation.*

· **Classification according to Regulation (EC) No 1272/2008**

*The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.*

· **Abbreviations and acronyms:**

*ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)*

*IMDG: International Maritime Code for Dangerous Goods*

*IATA: International Air Transport Association*

*GHS: Globally Harmonised System of Classification and Labelling of Chemicals*

*EINECS: European Inventory of Existing Commercial Chemical Substances*

*ELINCS: European List of Notified Chemical Substances*

*CAS: Chemical Abstracts Service (division of the American Chemical Society)*

*PBT: Persistent, Bioaccumulative and Toxic*

*vPvB: very Persistent and very Bioaccumulative*

*Org. Perox. B: Organic peroxides – Type B*

*Eye Irrit. 2: Serious eye damage/eye irritation – Category 2*

*Skin Sens. 1: Skin sensitisation – Category 1*

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

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