

Safety Data Sheet

according to HPR, Schedule 1

Printing date 07/19/2023


Version number 9

Reviewed on 07/18/2023

1 Identification

- **Product identifier**
- **Trade name:** ***AESTHETIC INTENSIVE COLORS/ OPAQUE***
- **Application of the substance / the mixture** for characterization of denture base materials
- **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
- **Information department:**
Regulatory Affairs
info@candulor.ch
- **Emergency telephone number:**
24 Hour Emergency Assistance:
Emergency-Call USA - Infotrac: 1-800-535-5053
Emergency-Call Canada - Canutec: 1-613-996-6666
- **General SDS Assistance:**
US: 1-800-533-6825
Canada: 1-800-263-8182

2 Hazard identification

- **Classification of the substance or mixture**
Skin Sensitizer - Category 1 H317 May cause an allergic skin reaction.
- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**

GHS07
- **Signal word** Warning
- **Hazard-determining components of labeling:**
dibenzoyl peroxide
- **Hazard statements**
May cause an allergic skin reaction.
- **Precautionary statements**
Avoid breathing dust/fume/gas/mist/vapours/spray.
Do not get in eyes, on skin, or on clothing.
Wear protective gloves/protective clothing/eye protection/face protection.
Dispose of contents/container in accordance with local/regional/national/international regulations.

(Contd. on page 2)

Safety Data Sheet

according to HPR, Schedule 1

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Trade name: AESTHETIC INTENSIVE COLORS/ OPAQUE

(Contd. of page 1)

- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**

HEALTH	0	Health = 0
FIRE	1	Fire = 1
REACTIVITY	0	Reactivity = 0

- **Other hazards**

Dust generation

Particular danger of slipping on leaked/spilled product.

3 Composition/Information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** > 95% Polymethylmethacrylate

- **Dangerous components:**

CAS: 13463-67-7	titanium dioxide	0.1-1% w/w *
CAS: 14807-96-6	Talc (Mg ₃ H ₂ (SiO ₃) ₄)	0.1-1% w/w *
CAS: 94-36-0	dibenzoyl peroxide	0.1-1% w/w *

* Actual concentration ranges are withheld as a trade secret.

4 First-aid measures

- **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.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

CA

(Contd. on page 3)

Safety Data Sheet according to HPR, Schedule 1

Printing date 07/19/2023

Version number 9

Reviewed on 07/18/2023

Trade name: **AESTHETIC INTENSIVE COLORS/ OPAQUE**

(Contd. of page 2)

* 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **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.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Only adequately trained personnel should handle this product.
For use in dentistry only.
- **Information about protection against explosions and fires:** No special measures required.
- **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.
- **Specific end use(s)** No further relevant information available.

* 8 Exposure controls/ Personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**

- **Components with limit values that require monitoring at the workplace:**

CAS: 13463-67-7 titanium dioxide

EL Long-term value: 10* 3** mg/m³
*total dust; **respirable fraction; IARC 2B

EV Long-term value: 10 mg/m³
total dust

CAS: 14807-96-6 Talc (Mg₃H₂(SiO₃)₄)

EL Long-term value: 2 mg/m³
respirable

EV Long-term value: 2* mg/m³, 2 f/cc ppm
*respirable

CAS: 94-36-0 dibenzoyl peroxide

EL Long-term value: 5 mg/m³

EV Long-term value: 5 mg/m³

- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Usual hygienic measures for dental practice and dental laboratories.

(Contd. on page 4)

CA

Safety Data Sheet according to HPR, Schedule 1

Printing date 07/19/2023

Version number 9

Reviewed on 07/18/2023

Trade name: AESTHETIC INTENSIVE COLORS/ OPAQUE

(Contd. of page 3)

Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
Avoid contact with the skin.

· **Breathing equipment:** Not required.

· **Protection of hands:**



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 protection:**



Tightly sealed goggles

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Powder
Color: According to product specification

· **Odor:** Characteristic

· **Odor threshold:** Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

Melting point/Melting range: 150 °C
Boiling point/Boiling range: Undetermined.

· **Flash point:** 250 °C

· **Flammability (solid, gaseous):** Not determined.

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

Lower: Not determined.
Upper: Not determined.

(Contd. on page 5)

CA

Safety Data Sheet

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Version number 9

Reviewed on 07/18/2023

Trade name: AESTHETIC INTENSIVE COLORS/ OPAQUE

(Contd. of page 4)

· Vapor pressure:	Not applicable.
· Density at 20 °C:	1.2 g/cm ³
· Relative density	Not determined.
· Vapor density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with Water:	Nearly insoluble.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability** Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** None under normal conditions of storage and use.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Specific symptoms in biological assay:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:** No further relevant information available.

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

CAS: 14807-96-6	Talc (Mg ₃ H ₂ (SiO ₃) ₄)	3
CAS: 94-36-0	dibenzoyl peroxide	3

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.

(Contd. on page 6)

CA

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(Contd. of page 5)

- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (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.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

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

14 Transport information

- | | |
|--|--|
| · UN-Number | Void |
| · DOT/TDG, ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name | Void |
| · DOT/TDG, ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | Void |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · Class | Void |
| · Packing group | Void |
| · DOT/TDG, ADR, IMDG, IATA | Void |
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · Transport/Additional information: | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · UN "Model Regulation": | Void |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**
- **Section 355 (extremely hazardous substances):**
None of the ingredients is listed.

(Contd. on page 7)

CA

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(Contd. of page 6)

· **Section 313 (Specific toxic chemical listings):**

CAS: 94-36-0	dibenzoyl peroxide
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· **TSCA (Toxic Substances Control Act):**

CAS: 14807-96-6	Talc (Mg ₃ H ₂ (SiO ₃) ₄)
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CAS: 94-36-0	dibenzoyl peroxide
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· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS07

· **Signal word** Warning

· **Hazard-determining components of labeling:**

dibenzoyl peroxide

· **Hazard statements**

May cause an allergic skin reaction.

· **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapours/spray.

Do not get in eyes, on skin, or on clothing.

Wear protective gloves/protective clothing/eye protection/face protection.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **National regulations:**

· **Other regulations, limitations and prohibitive regulations**

The product is a medical device according to the Directive 93/42/EEC.

This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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.

· **Contact:**

· **Date of the latest revision of the safety data sheet** 07/19/2023

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

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)

NFPA: National Fire Protection Association (USA)

HMS: Hazardous Materials Identification System (USA)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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