

## Safety Data Sheet according to HPR, Schedule 1

Printing date 05/14/2020


Version number 1

Reviewed on 05/14/2020

### 1 Identification

- **Product identifier**
- **Trade name:** ***X PLEX Polymer***
- **Application of the substance / the mixture** *Denture base material*
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
CANDULOR AG  
Boulevard Lilienthal 8  
CH-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.*

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



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



- **Other hazards**

Dust generation

Particular danger of slipping on leaked/spilled product.

### 3 Composition/Information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** > 98% polymethylmethacrylate

- **Dangerous components:**

CAS: 94-36-0	dibenzoyl peroxide	0.1-1% w/w *
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\* 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 and to be sure call for a doctor.  
In case of unconsciousness place patient stably in side position for transportation.
- **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:**  
CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fire with 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.

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### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **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**  
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: 94-36-0 dibenzoyl peroxide

EL TWA: 5 mg/m<sup>3</sup>EV TWA: 5 mg/m<sup>3</sup>

- **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.  
Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.  
Avoid contact with the skin.
- **Breathing equipment:** Use respiratory protective device against the effects of dust.
- **Protection of hands:**



Protective gloves

After use of gloves apply skin-cleaning agents and skin cosmetics.

- **Material of gloves**  
Butyl rubber, BR  
Chloroprene rubber, CR

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Natural rubber, NR

Fluorocarbon rubber (Viton)

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **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:** Safety glasses

### 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:** Not applicable.

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

· **Decomposition temperature:** 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.

· **Vapor pressure:** Not applicable.

· **Density at 20 °C:** 1.2 g/cm<sup>3</sup>

· **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.

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- **Chemical stability** Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided:**  
Can decompose slowly with localized heating above 150°C.
- **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:**
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**
- **Carcinogenic categories**

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

CAS: 9011-14-7	polymethylmethacrylate	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.
- **Additional ecological information:**
- **General notes:** Not hazardous for water.
- **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**
- **DOT/TDG, ADR, IMDG, IATA**                      Void

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**Trade name: X PLEX Polymer**

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· <b>UN proper shipping name</b> · <b>DOT/TDG, ADR, IMDG, IATA</b>	Void
· <b>Transport hazard class(es)</b> · <b>DOT, ADR, ADN, IMDG, IATA</b> · <b>Class</b>	Void
· <b>Packing group</b> · <b>DOT/TDG, ADR, IMDG, IATA</b>	Void
· <b>Environmental hazards:</b>	Not applicable.
· <b>Special precautions for user</b>	Not applicable.
· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</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

### 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.

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

CAS: 94-36-0 dibenzoyl peroxide

· **TSCA (Toxic Substances Control Act):**

All components have the value ACTIVE.

· **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.

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- **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.

- **Date of the latest revision of the safety data sheet** 05/14/2020 / -
- **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)  
HMIS: Hazardous Materials Identification System (USA)  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative

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