

Printing date 07/26/2023 Version number 2 Reviewed on 07/26/2023

### 1 Identification

- · Product identifier
- Trade name: X PLEX Polymer
- · Application of the substance / the mixture Self/Hot-curing high impact material
- · 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(s) identification

· Classification of the substance or mixture

Sensitization - Skin 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



- · 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/vapors/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)

Printing date 07/26/2023 Version number 2 Reviewed on 07/26/2023

## Trade name: X PLEX Polymer

(Contd. of page 1)

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



· HMIS-ratings (scale 0 - 4)



· Other hazards

Dust generation

Particular danger of slipping on leaked/spilled product.

- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

#### 3 Composition/information on ingredients

- · Chemical characterization: Mixtures
- **Description:** > 98% polymethylmethacrylate
- · Dangerous components:

CAS: 94-36-0 dibenzoyl peroxide

<2.5%

#### 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.

- · 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 fire with alcohol resistant foam.

· Special hazards arising from the substance or mixture No further relevant information available.

(Contd. on page 3)

Printing date 07/26/2023 Version number 2 Reviewed on 07/26/2023

## Trade name: X PLEX Polymer

(Contd. of page 2)

- · Advice for firefighters
- · Protective equipment: No special measures required.

#### 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

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

Protective Action Criteria for Chemicals

· PAC-1:	
CAS: 94-36-0 dibenzoyl peroxide	15 mg/m <sup>3</sup>
· PAC-2:	
CAS: 94-36-0 dibenzoyl peroxide	$1,200 \text{ mg/m}^3$
· PAC-3:	
CAS: 94-36-0 dibenzoyl peroxide	$7,000 \text{ mg/m}^3$

### 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 section 7.
- · Control parameters

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· Components wi	.,, ,,,,,,	vuiues in	ui reuuire	momonie	ui ine woi	nviuce.

#### CAS: 94-36-0 dibenzoyl peroxide

PEL Long-term value: 5 mg/m³

REL Long-term value: 5 mg/m<sup>3</sup> TLV Long-term value: 5 mg/m<sup>3</sup>

A4

· Additional information: The lists that were valid during the creation were used as basis.

(Contd. on page 4)

Printing date 07/26/2023 Version number 2 Reviewed on 07/26/2023

## Trade name: X PLEX Polymer

(Contd. of page 3)

- · 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

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:



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:
Boiling point/Boiling range:
Undetermined.

Flash point:
Not applicable.

Flammability (solid, gaseous):
Not determined.

Decomposition temperature:
Not determined.

Product is not selfigniting.

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

(Contd. on page 5)

Printing date 07/26/2023 Version number 2 Reviewed on 07/26/2023

Trade name: X PLEX Polymer

		(Contd. of page
· Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
· Vapor pressure:	Not applicable.	
· Density at 20 °C (68 °F):	1.2 g/cm³ (10.014 lbs/gal)	
· Relative density	Not determined.	
· Vapor density	Not applicable.	
· Evaporation rate	Not applicable.	
· Solubility in / Miscibility with		
Water:	Nearly insoluble.	
· Partition coefficient (n-octanol/wo	<b>ater):</b> Not determined.	
· Viscosity:		
Dynamic:	Not applicable.	
Kinematic:	Not applicable.	
· Solvent content:		
VOC content:	0.00 %	
· 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:

Can decompose slowly with localized heating above 150°C.

- $\cdot \textit{\textit{Possibility of hazardous reactions}} \ \textit{No dangerous reactions known}.$
- · 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: 94-36-0 dibenzoyl peroxide

3

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

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Printing date 07/26/2023 Version number 2 Reviewed on 07/26/2023

Trade name: X PLEX Polymer

(Contd. of page 5)

### 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.

UN-Number	
DOT, ADR/RID/ADN, IMDG, IATA	Void
UN proper shipping name DOT, ADR/RID/ADN, IMDG, IATA	Void
Transport hazard class(es)	
DOT, ADR/RID/ADN, ADN, IMDG, IA	TA
Class	Void
Packing group	
DOT, ÄDR/RID/ADN, IMDG, IATA	Void
Environmental hazards:	Not applicable.
Special precautions for user	Not applicable.
Transport in bulk according to Annex II	l 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

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Printing date 07/26/2023 Version number 2 Reviewed on 07/26/2023

Trade name: X PLEX Polymer

(Contd. of page 6)

### 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.

· Hazardous Air Pollutants

None of the ingredients is listed.

- · Proposition 65
- · Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

- · Carcinogenic categories
- · EPA (Environmental Protection Agency)

None of the ingredients is listed.

· TLV (Threshold Limit Value)

CAS: 94-36-0 dibenzoyl peroxide

A4

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

· GHS label elements

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

· Hazard pictograms



- · 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/vapors/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 8)

Printing date 07/26/2023 Version number 2 Reviewed on 07/26/2023

Trade name: X PLEX Polymer

(Contd. of page 7)

- · 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 preparation / last revision 07/26/2023
- · 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

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)

VOC: Volatile Organic Compounds (USA, EU)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Sensitization - Skin 1: Skin sensitisation - Category 1

· \* Data compared to the previous version altered.

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