

Version number 8

Reviewed on 07/26/2023

1 Identification

- · Product identifier
- · Trade name: C-PLAST Polymer
- · Application of the substance / the mixture Custom tray 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.

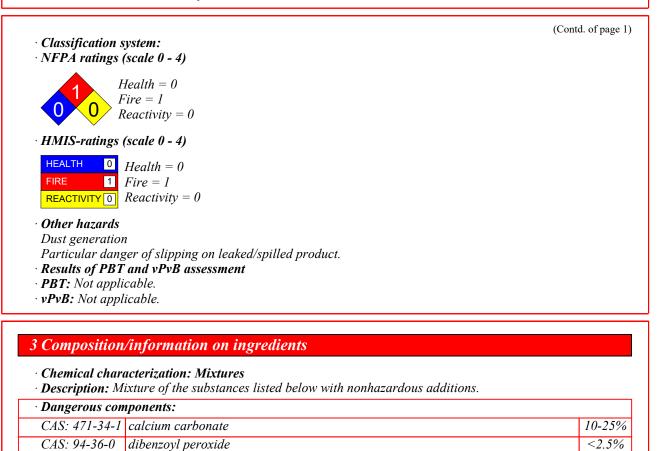
(Contd. on page 2)

Printing date 07/26/2023

Version number 8

Reviewed on 07/26/2023

Trade name: C-PLAST Polymer



4 First-aid measures

- · Description of first aid measures
- *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 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.

(Contd. on page 3)

Printing date 07/26/2023

Version number 8

Reviewed on 07/26/2023

Trade name: C-PLAST Polymer

(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
- 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 section 7.

· Control parameters

• Components with limit values that require monitoring at the workplace:			
CAS: 471-34-1 calcium carbonate			
PEL Long-term value: 15* 5** mg/m ³ *total dust **respirable fraction			
REL Long-term value: 10* 5** mg/m ³ *total dust **respirable fraction			
TLV TLV withdrawn			
CAS: 94-36-0 dibenzoyl peroxide			
PEL Long-term value: 5 mg/m ³			
REL Long-term value: 5 mg/m ³			
TLV Long-term value: 5 mg/m ³ A4			
• 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.

(Contd. on page 4)

US

Printing date 07/26/2023

Version number 8

Reviewed on 07/26/2023

(Contd. of page 3)

Trade name: C-PLAST Polymer

• *Breathing equipment:* Use respiratory protective device against the effects of dust. • *Protection of hands:*



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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 Nitrile rubber, NBR 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

Information on basic physical and	chemical properties	
General Information		
Appearance: Form:	Powder	
Color:	Beige	
Odor:	Characteristic	
Odor threshold:	Not determined.	
pH-value:	Not applicable.	
-	Not determined.	
Change in condition		
Melting point/Melting range:	Undetermined.	
Boiling point/Boiling range:	Undetermined.	
Flash point:	250 °C (482 °F)	
Flammability (solid, gaseous):	Not determined.	
Ignition temperature:	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:	Not determined.	
Relative density	Not determined.	
Vapor density	Not applicable.	
Evaporation rate	Not applicable.	
Solubility in / Miscibility with		
Water:	Nearly insoluble.	

Printing date 07/26/2023

Version number 8

Reviewed on 07/26/2023

Trade name: C-PLAST Polymer

		(Contd. of pag
· Partition coefficient (n-octan	ol/water): 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: 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: Sensitization possible through skin contact.
- Additional toxicological information: No further relevant information available.

· Carcinogenic categories

· IARC (International Agency for Research on Cancer)

CAS: 94-36-0 dibenzoyl peroxide

· NTP (National Toxicology Program)

None of the ingredients is listed.

OSHA-Ca (Occupational Safety & Health Administration)

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:

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.

(Contd. on page 6)

3

US

Printing date 07/26/2023

Version number 8

Reviewed on 07/26/2023

Trade name: C-PLAST Polymer

(Contd. of page 5)

· 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.

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

Section 313 (Specific toxic chemical listings):

CAS: 94-36-0 dibenzoyl peroxide

• TSCA (Toxic Substances Control Act):

CAS: 471-34-1 calcium carbonate

CAS: 94-36-0 dibenzoyl peroxide

(Contd. on page 7)

US

Printing date 07/26/2023

· Proposition 65

Version number 8

Reviewed on 07/26/2023

Trade name: C-PLAST Polymer

(Contd. of page 6)

A4

-			
· 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

· 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.

· 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

(Contd. on page 8)

Printing date 07/26/2023

Version number 8

Reviewed on 07/26/2023

Trade name: C-PLAST Polymer

(Contd. of page 7)

US

· 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.