

Printing date 04/03/2023 Version number 1 Reviewed on 04/03/2023

### 1 Identification

- · Product identifier
- · Trade name: XPLEX BASE
- · Application of the substance / the mixture Denture base material discs for digital precessing
- · 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 The product is not classified, according to the Globally Harmonized System (GHS).
- · Label elements
- · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Classification system:
- · NFPA ratings (scale 0 4)



Health = 0Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



Health = 0Fire = 0

- · Other hazards Avoid breathing sanding dust /swarf.
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

Printing date 04/03/2023 Version number 1 Reviewed on 04/03/2023

Trade name: XPLEX BASE

(Contd. of page 1)

#### 3 Composition/information on ingredients

· Chemical characterization: Mixtures

• **Description:** > 90% polymethylmethacrylate

· Dangerous components: Void

### 4 First-aid measures

- · Description of first aid measures
- · General information: No special measures required.
- · After inhalation: Grinding dust: Supply fresh air; consult doctor in case of complaints.
- · After skin contact: Generally the product does not irritate the skin.
- · After eye contact:

Grinding dust: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

Mechanical effects only.

- · After swallowing: Grinding dust: Rinse out mouth and then drink plenty of water.
- 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.

### 6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- Environmental precautions:

No special measures required.

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.

(Contd. on page 3)

Printing date 04/03/2023 Version number 1 Reviewed on 04/03/2023

Trade name: XPLEX BASE

(Contd. of page 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.
- · 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:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- · 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.

- Breathing equipment: Use respiratory protective device against the effects of dust.
- · Recommended filter device for short term use: Filter P1
- · Protection of hands:

Protective gloves should always be worn during mechanical and thermal processing.

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

· Material of gloves

Mechanical processing:

Leather gloves

Strong gloves

· 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:

Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling).

#### 9 Physical and chemical properties

- · Information on basic physical and chemical properties
- · General Information

· Appearance:

Form: Solid

Color: According to product specification

Odor: Odorless
Odor threshold: Not determined.

· pH-value: Not applicable.

· Change in condition

Melting point/Melting range: Undetermined.
Boiling point/Boiling range: Undetermined.

(Contd. on page 4)

Printing date 04/03/2023 Version number 1 Reviewed on 04/03/2023

Trade name: XPLEX BASE

		(Contd. of pag
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.	
Vapor pressure:	Not applicable.	
Density at 20 °C (68 °F):	$\sim 1.2 \text{ g/cm}^3 (\sim 10.014 \text{ lbs/gal})$	
Relative density	Not determined.	
Vapor density	Not applicable.	
Evaporation rate	Not applicable.	
Solubility in / Miscibility with		
Water:	Insoluble.	
Partition coefficient (n-octanol/wa	ter): 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.

Can decompose slowly with localized heating above 150°C.

- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid Keep away from heat and direct sunlight.
- · Incompatible materials: acetone
- · 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.

Mechanical effects only.

- · Sensitization: No sensitizing effects known.
- · Additional toxicological information:

The product is not subject to classification according to internally approved calculation methods for preparations:

- · Carcinogenic categories
- · NTP (National Toxicology Program)

None of the ingredients is listed.

(Contd. on page 5)

Printing date 04/03/2023 Version number 1 Reviewed on 04/03/2023

Trade name: XPLEX BASE

(Contd. of page 4)

· 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.

- · 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, ADR/RID/ADN, ADN, IMDG, IATA Void
- · UN proper shipping name
- · DOT, ADR/RID/ADN, ADN, IMDG, IATA Void
- · Transport hazard class(es)
- · DOT, ADR/RID/ADN, ADN, IMDG, IATA
- · Class 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 II of

MARPOL73/78 and the IBC Code Not applicable.

(Contd. on page 6)

Printing date 04/03/2023 Version number 1 Reviewed on 04/03/2023

Trade name: XPLEX BASE

(Contd. of page 5)

• 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.

Section 313 (Specific toxic chemical listings):

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)

None of the ingredients is listed.

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

None of the ingredients is listed.

- · **GHS label elements** Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · 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 04/03/2023

(Contd. on page 7)

Printing date 04/03/2023 Version number 1 Reviewed on 04/03/2023

Trade name: XPLEX BASE

(Contd. of page 6)

#### · 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)
PRT: Persistant Bioaccumulative and Toxic

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

-US