

**Safety data sheet**  
according to Regulation (EC) No 1907/2006, Article 31

Printing date 27.09.2024



Version number 3 (replaces version 2)

Revision: 25.09.2024

**SECTION 1: Identification of the substance/mixture and of the company/undertaking**

- **1.1 Product identifier**
- **Trade name: X PLEX Cold Monomer**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Self-curing high impact material
- **1.3 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
- **Further information obtainable from:**  
Regulatory Affairs  
info@candulor.ch
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, 9494 Schaan, Liechtenstein)

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
Flam. Liq. 2 H225 Highly flammable liquid and vapour.  
Skin Irrit. 2 H315 Causes skin irritation.  
Skin Sens. 1 H317 May cause an allergic skin reaction.  
STOT SE 3 H335 May cause respiratory irritation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the GB CLP regulation.
- **Hazard pictograms**  
  
GHS02 GHS07
- **Signal word** Danger
- **Hazard-determining components of labelling:**  
methyl methacrylate  
1,4-butanediol dimethacrylate
- **Hazard statements**  
H225 Highly flammable liquid and vapour.  
H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H335 May cause respiratory irritation.
- **Precautionary statements**  
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
P262 Do not get in eyes, on skin, or on clothing.

(Contd. on page 2)

## Safety data sheet

### according to Regulation (EC) No 1907/2006, Article 31

Printing date 27.09.2024

Version number 3 (replaces version 2)

Revision: 25.09.2024

**Trade name: X PLEX Cold Monomer**

(Contd. of page 1)

- P280 Wear protective gloves/protective clothing/eye protection/face protection.  
 P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].  
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 80-62-6 EINECS: 201-297-1 Reg.nr.: 01-2119452498-28-xxxx	methyl methacrylate Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	50-100%
CAS: 2082-81-7 EINECS: 218-218-1 Reg.nr.: 01-2119967415-30-XXXX	1,4-butanediol dimethacrylate Skin Sens. 1, H317	2.5-10%
CAS: 3077-12-1 EINECS: 221-359-1 Reg.nr.: 01-2120791684-40-xxxx	2,2'-[(4-methylphenyl)imino]bisethanol Eye Dam. 1, H318; Acute Tox. 4, H302; Skin Sens. 1, H317; Aquatic Chronic 3, H412	0.1-<1%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** Immediately remove any clothing soiled by the product.
- **After inhalation:**  
Supply fresh air; consult doctor in case of complaints.  
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:**  
Immediately rinse with water.  
If skin irritation continues, consult a doctor.
- **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.  
Do not induce vomiting; call for medical help immediately.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:** CO<sub>2</sub>, powder or water spray. Fight larger fire with alcohol resistant foam.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

(Contd. on page 3)

## Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 27.09.2024

Version number 3 (replaces version 2)

Revision: 25.09.2024

Trade name: **X PLEX Cold Monomer**

(Contd. of page 2)

- **Additional information** Cool endangered receptacles with water spray.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Ensure adequate ventilation.
- **6.4 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.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**  
Only adequately trained personnel should handle this product.  
Ensure good ventilation/exhaustion at the workplace.  
For use in dentistry only.
- **Information about fire - and explosion protection:**  
Keep ignition sources away - Do not smoke.  
Protect against electrostatic charges.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**  
Store in a cool location.  
Store only in the original receptacle.
- **Information about storage in one common storage facility:** Store away from oxidising agents.
- **Further information about storage conditions:**  
Keep container tightly sealed.  
Store receptacle in a well ventilated area.  
Protect from heat and direct sunlight.
- **7.3 Specific end use(s)** No further relevant information available.

### SECTION 8: Exposure controls/personal protection

#### · 8.1 Control parameters

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

**CAS: 80-62-6 methyl methacrylate**

WEL	Short-term value: 416 mg/m <sup>3</sup> , 100 ppm
	Long-term value: 208 mg/m <sup>3</sup> , 50 ppm

- **Regulatory information** WEL: EH40/2018
- **Additional information:** The lists valid during the making were used as basis.

#### · 8.2 Exposure controls

- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**  
Usual hygienic measures for dental practice and dental laboratories.  
Keep away from foodstuffs, beverages and feed.

(Contd. on page 4)

## Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 27.09.2024

Version number 3 (replaces version 2)

Revision: 25.09.2024

**Trade name: X PLEX Cold Monomer**

(Contd. of page 3)

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

Do not inhale gases / fumes / aerosols.

· **Respiratory protection:** Use suitable respiratory protective device in case of insufficient ventilation.

· **Recommended filter device for short term use:**

Filter A1

Filter A2

Filter A3

· **Hand protection**



Protective gloves (EN 374)

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

· **Material of gloves**

Butyl rubber, BR

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.

· **Not suitable are gloves made of the following materials:**

Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.

· **Eye/face protection**



Tightly sealed goggles (EN 166)

### SECTION 9: Physical and chemical properties

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

· **General Information**

· <b>Colour:</b>	Colourless
· <b>Odour:</b>	Pungent
· <b>Odour threshold:</b>	Not determined.
· <b>Melting point/freezing point:</b>	-48 °C
· <b>Boiling point or initial boiling point and boiling range</b>	101 °C
· <b>Lower and upper explosion limit</b>	
· <b>Lower:</b>	2.1 Vol %
· <b>Upper:</b>	12.5 Vol %
· <b>Flash point:</b>	10 °C
· <b>Auto-ignition temperature:</b>	430 °C
· <b>pH</b>	Not determined.
· <b>Viscosity:</b>	
· <b>Kinematic viscosity</b>	Not determined.
· <b>Dynamic:</b>	Not determined.
· <b>Solubility</b>	
· <b>water at 20 °C:</b>	1.6 g/l
· <b>Partition coefficient n-octanol/water (log value)</b>	Not determined.
· <b>Vapour pressure at 20 °C:</b>	47 hPa

(Contd. on page 5)

## Safety data sheet

### according to Regulation (EC) No 1907/2006, Article 31

Printing date 27.09.2024

Version number 3 (replaces version 2)

Revision: 25.09.2024

Trade name: **X PLEX Cold Monomer**

(Contd. of page 4)

· <b>Density and/or relative density</b>	
· <b>Density at 20 °C:</b>	0.943 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>9.2 Other information</b>	No further relevant information available.
· <b>Appearance:</b>	
· <b>Form:</b>	Fluid
· <b>Important information on protection of health and environment, and on safety.</b>	
· <b>Ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· <b>Change in condition</b>	
· <b>Evaporation rate</b>	Not determined.
· <b>Information with regard to physical hazard classes</b>	
· <b>Explosives</b>	Void
· <b>Flammable gases</b>	Void
· <b>Aerosols</b>	Void
· <b>Oxidising gases</b>	Void
· <b>Gases under pressure</b>	Void
· <b>Flammable liquids</b>	Highly flammable liquid and vapour.
· <b>Flammable solids</b>	Void
· <b>Self-reactive substances and mixtures</b>	Void
· <b>Pyrophoric liquids</b>	Void
· <b>Pyrophoric solids</b>	Void
· <b>Self-heating substances and mixtures</b>	Void
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
· <b>Oxidising liquids</b>	Void
· <b>Oxidising solids</b>	Void
· <b>Organic peroxides</b>	Void
· <b>Corrosive to metals</b>	Void
· <b>Desensitised explosives</b>	Void

### SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability** Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions**  
Forms explosive gas mixture with air.  
Reacts with strong oxidising agents.  
Exothermic polymerisation.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** None under normal conditions of storage and use.

### SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.

(Contd. on page 6)

## Safety data sheet

### according to Regulation (EC) No 1907/2006, Article 31

Printing date 27.09.2024

Version number 3 (replaces version 2)

Revision: 25.09.2024

Trade name: **X PLEX Cold Monomer**

(Contd. of page 5)

· <b>LD/LC50 values relevant for classification:</b>		
Oral	LD50	7872 mg/kg (rat)

· <b>CAS: 80-62-6 methyl methacrylate</b>		
Oral	LD50	7872 mg/kg (rat)

- **Skin corrosion/irritation**

- Causes skin irritation.

- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.

- **Respiratory or skin sensitisation**

- May cause an allergic skin reaction.

- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.

- **Carcinogenicity** Based on available data, the classification criteria are not met.

- **Reproductive toxicity** Based on available data, the classification criteria are not met.

- **STOT-single exposure**

- May cause respiratory irritation.

- **STOT-repeated exposure** Based on available data, the classification criteria are not met.

- **Aspiration hazard** Based on available data, the classification criteria are not met.

- **Additional toxicological information:** No further relevant information available.

- **11.2 Information on other hazards**

· <b>Endocrine disrupting properties</b>		
None of the ingredients is listed.		

### SECTION 12: Ecological information

- **12.1 Toxicity**

- **Aquatic toxicity:** No further relevant information available.

- **12.2 Persistence and degradability** No further relevant information available.

- **12.3 Bioaccumulative potential** No further relevant information available.

- **12.4 Mobility in soil** No further relevant information available.

- **12.5 Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

- **12.6 Endocrine disrupting properties**

- The product does not contain substances with endocrine disrupting properties.

- **12.7 Other adverse effects** No further relevant information available.

- **Additional ecological information:**

- **General notes:**

- Water hazard class 1 (German Regulation) (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.

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**

- **Recommendation**

- Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

- **Uncleaned packaging:**

- **Recommendation:** Disposal must be made according to official regulations.

GB

(Contd. on page 7)

## Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 27.09.2024



Version number 3 (replaces version 2)

Revision: 25.09.2024

Trade name: **X PLEX Cold Monomer**

(Contd. of page 6)

### SECTION 14: Transport information

<ul style="list-style-type: none"> <li>· 14.1 UN number or ID number</li> <li>· ADR/RID/ADN, IMDG, IATA</li> </ul>	<p style="text-align: center;">UN1247</p>
<ul style="list-style-type: none"> <li>· 14.2 UN proper shipping name</li> <li>· ADR/RID/ADN</li> <li>· IMDG, IATA</li> </ul>	<p style="text-align: center;">1247 METHYL METHACRYLATE MONOMER, STABILIZED</p> <p style="text-align: center;">METHYL METHACRYLATE MONOMER, STABILIZED</p>
<ul style="list-style-type: none"> <li>· 14.3 Transport hazard class(es)</li> <li>· ADR/RID/ADN</li> </ul>	<div style="text-align: center;">  </div> <ul style="list-style-type: none"> <li>· Class <span style="float: right;">3 (F1) Flammable liquids.</span></li> <li>· Label <span style="float: right;">3</span></li> </ul> <hr style="border-top: 1px dashed red;"/> <div style="text-align: center;">  </div> <ul style="list-style-type: none"> <li>· Class <span style="float: right;">3 Flammable liquids.</span></li> <li>· Label <span style="float: right;">3</span></li> </ul>
<ul style="list-style-type: none"> <li>· 14.4 Packing group</li> <li>· ADR/RID/ADN, IMDG, IATA</li> </ul>	<p style="text-align: center;">II</p>
<ul style="list-style-type: none"> <li>· 14.5 Environmental hazards:</li> <li>· Marine pollutant:</li> </ul>	<p style="text-align: center;">No</p>
<ul style="list-style-type: none"> <li>· 14.6 Special precautions for user</li> <li>· Hazard identification number (Kemler code):</li> <li>· EMS Number:</li> <li>· Stowage Category</li> <li>· Stowage Code</li> </ul>	<p style="text-align: center;">Warning: Flammable liquids.</p> <p style="text-align: center;">33</p> <p style="text-align: center;">F-E,S-D</p> <p style="text-align: center;">C</p> <p style="text-align: center;">SW1 Protected from sources of heat. SW2 Clear of living quarters.</p>
<ul style="list-style-type: none"> <li>· 14.7 Maritime transport in bulk according to IMO instruments</li> </ul>	<p style="text-align: center;">Not applicable.</p>
<ul style="list-style-type: none"> <li>· Transport/Additional information:</li> </ul>	<hr style="border-top: 1px dashed red;"/> <ul style="list-style-type: none"> <li>· ADR/RID/ADN</li> <li>· Limited quantities (LQ)</li> <li>· Excepted quantities (EQ)</li> </ul> <p style="text-align: center;">1L</p> <p style="text-align: center;">Code: E2</p> <p style="text-align: center;">Maximum net quantity per inner packaging: 30 ml</p> <p style="text-align: center;">Maximum net quantity per outer packaging: 500 ml</p> <ul style="list-style-type: none"> <li>· Transport category <span style="float: right;">2</span></li> <li>· Tunnel restriction code <span style="float: right;">D/E</span></li> </ul> <hr style="border-top: 1px dashed red;"/> <ul style="list-style-type: none"> <li>· IMDG</li> <li>· Limited quantities (LQ)</li> </ul> <p style="text-align: center;">1L</p>

(Contd. on page 8)

GB

## Safety data sheet

### according to Regulation (EC) No 1907/2006, Article 31

Printing date 27.09.2024

Version number 3 (replaces version 2)

Revision: 25.09.2024

Trade name: **X PLEX Cold Monomer**

(Contd. of page 7)

· <b>Excepted quantities (EQ)</b>	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· <b>UN "Model Regulation":</b>	UN1247, METHYL METHACRYLATE MONOMER, STABILIZED, 3, II

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5000 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50000 t
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**  
The product is a medical device according to Regulation 2017/745 on Medical Devices (MDR).
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### SECTION 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.

- **Relevant phrases**  
H225 Highly flammable liquid and vapour.  
H302 Harmful if swallowed.  
H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H318 Causes serious eye damage.  
H335 May cause respiratory irritation.  
H412 Harmful to aquatic life with long lasting effects.
- **Abbreviations and acronyms:**  
IMO: International Maritime Organization  
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)  
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)  
IMDG: International Maritime Code for Dangerous Goods  
IATA: International Air Transport Association  
GHS: Globally Harmonised System of Classification and Labelling of Chemicals  
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)  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
Flam. Liq. 2: Flammable liquids – Category 2  
Acute Tox. 4: Acute toxicity – Category 4  
Skin Irrit. 2: Skin corrosion/irritation – Category 2  
Eye Dam. 1: Serious eye damage/eye irritation – Category 1  
Skin Sens. 1: Skin sensitisation – Category 1  
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3  
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3
- **\* Data compared to the previous version altered.**