

1 Identification


- **Product identifier**
- **Trade name:** ***X PLEX Hot Monomer***
- **Application of the substance / the mixture** *Hot-Curing High Impact Denture Base 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**

Flammable Liquids 2	H225 Highly flammable liquid and vapor.
Skin Irritation 2	H315 Causes skin irritation.
Sensitization - Skin 1	H317 May cause an allergic skin reaction.
Toxic to Reproduction 2	H361 Suspected of damaging fertility or the unborn child.
Specific Target Organ Toxicity - Single Exposure 3	H335 May cause respiratory irritation.
- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**

GHS02 GHS07 GHS08
- **Signal word** *Danger*
- **Hazard-determining components of labeling:**
*methyl methacrylate
p-Mentha-1,4-diene
ethylene glycol dimethacrylate*
- **Hazard statements**
*Highly flammable liquid and vapor.
Causes skin irritation.*

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May cause an allergic skin reaction.

Suspected of damaging fertility or the unborn child.

May cause respiratory irritation.

· **Precautionary statements**

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

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.

If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



· **HMIS-ratings (scale 0 - 4)**

HEALTH	1	Health = 1
FIRE	3	Fire = 3
REACTIVITY	0	Reactivity = 0

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

· **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 80-62-6	methyl methacrylate	50-100%
CAS: 97-90-5	ethylene glycol dimethacrylate	2.5-10%
CAS: 99-85-4	p-Mentha-1,4-diene	<2.5%

4 First-aid measures

· **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; immediately call for medical help.

· **Information for doctor:**

· **Most important symptoms and effects, both acute and delayed** No further relevant information available.

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- **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.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.
- **Additional information** Cool endangered receptacles with water spray.

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:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.
- **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: 80-62-6	methyl methacrylate	17 ppm
CAS: 97-90-5	ethylene glycol dimethacrylate	9.9 mg/m ³

- **PAC-2:**

CAS: 80-62-6	methyl methacrylate	120 ppm
CAS: 97-90-5	ethylene glycol dimethacrylate	110 mg/m ³

- **PAC-3:**

CAS: 80-62-6	methyl methacrylate	570 ppm
CAS: 97-90-5	ethylene glycol dimethacrylate	650 mg/m ³

7 Handling and storage

- **Handling:**
- **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 protection against explosions and fires:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.

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- **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 oxidizing agents.
- **Further information about storage conditions:**
Keep receptacle tightly sealed.
Store receptacle in a well ventilated area.
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:**
The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.
At this time, the other constituents have no known exposure limits.

CAS: 80-62-6 methyl methacrylate

PEL	Long-term value: 410 mg/m ³ , 100 ppm
REL	Long-term value: 410 mg/m ³ , 100 ppm
TLV	Short-term value: 100 ppm Long-term value: 50 ppm DSEN, 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.
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.
- **Breathing equipment:** Use suitable respiratory protective device in case of insufficient ventilation.
- **Recommended filter device for short term use:**
Filter A1
Filter A2
Filter A3
- **Protection of hands:**



Protective gloves

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

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- **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 protection:**



Tightly sealed goggles

9 Physical and chemical properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

· Form:	Fluid
· Color:	Colorless
· Odor:	Pungent
· Odor threshold:	Not determined.

- **pH-value:** Not determined.

- **Change in condition**

· Melting point/Melting range:	-48 °C (-54.4 °F)
· Boiling point/Boiling range:	101 °C (213.8 °F)

- **Flash point:** 10 °C (50 °F)

- **Auto igniting:** 430 °C (806 °F)

- **Ignition temperature:** Product is not selfigniting.

- **Danger of explosion:** Product is not explosive. However, formation of explosive air/vapor mixtures are possible.

- **Explosion limits:**

· Lower:	2.1 Vol %
· Upper:	12.5 Vol %

- **Vapor pressure at 20 °C (68 °F):** 47 hPa (35.3 mm Hg)

- **Density at 20 °C (68 °F):** 0.943 g/cm³ (7.869 lbs/gal)

- **Relative density** Not determined.

- **Vapor density** Not determined.

- **Evaporation rate** Not determined.

- **Solubility in / Miscibility with**

· **Water at 20 °C (68 °F):** 1.6 g/l

- **Partition coefficient (n-octanol/water):** Not determined.

- **Viscosity:**

· **Dynamic:** Not determined.

· **Kinematic:** Not determined.

- **Other information** No further relevant information available.

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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**
 - Forms explosive gas mixture with air.
 - Reacts with strong oxidizing agents.
 - Exothermic polymerization.
- **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:**
- | | | |
|---|------|------------------|
| · LD/LC50 values that are relevant for classification: | | |
| CAS: 80-62-6 methyl methacrylate | | |
| Oral | LD50 | 7872 mg/kg (rat) |
- **Specific symptoms in biological assay:**
 - **on the skin:** Irritant to skin and mucous membranes.
 - **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: 80-62-6 methyl methacrylate

3

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

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· **Other adverse effects** No further relevant information available.

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13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Must not be disposed of 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 packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- **UN-Number**
- **DOT, ADR/RID/ADN, IMDG, IATA** UN1247
- **UN proper shipping name**
- **DOT** Methyl methacrylate monomer, stabilized
- **ADR/RID/ADN** 1247 Methyl methacrylate monomer, stabilized
- **IMDG, IATA** METHYL METHACRYLATE MONOMER, STABILIZED
- **Transport hazard class(es)**
- **DOT**
- 
- **Class** 3 Flammable liquids
- **Label** 3
- **ADR/RID/ADN**
- 
- **Class** 3 (F1) Flammable liquids
- **Label** 3
- **IMDG, IATA**
- 
- **Class** 3 Flammable liquids
- **Label** 3
- **Packing group**
- **DOT, ADR/RID/ADN, IMDG, IATA** II
- **Environmental hazards:**
- **Marine pollutant:** No
- **Special precautions for user** Warning: Flammable liquids
- **Hazard identification number (Kemler code):** 339

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· EMS Number:	F-E,S-D
· Stowage Category	B
· Stowage Code	SW2 Clear of living quarters.
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR/RID/ADN	
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· IMDG	
· Limited quantities (LQ)	1L
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN1247, Methyl methacrylate monomer, stabilized, 3, II

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: 80-62-6 methyl methacrylate

· TSCA (Toxic Substances Control Act):
All components have the value ACTIVE.

· Hazardous Air Pollutants
CAS: 80-62-6 methyl methacrylate

· 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)
CAS: 80-62-6 methyl methacrylate E, NL

· TLV (Threshold Limit Value)
CAS: 80-62-6 methyl methacrylate A4

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- **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**



GHS02 GHS07 GHS08

- **Signal word** Danger

- **Hazard-determining components of labeling:**

methyl methacrylate

p-Mentha-1,4-diene

ethylene glycol dimethacrylate

- **Hazard statements**

Highly flammable liquid and vapor.

Causes skin irritation.

May cause an allergic skin reaction.

Suspected of damaging fertility or the unborn child.

May cause respiratory irritation.

- **Precautionary statements**

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

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.

If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

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

- **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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

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*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**Flammable Liquids 2: Flammable liquids – Category 2**Skin Irritation 2: Skin corrosion/irritation – Category 2**Sensitization - Skin 1: Skin sensitisation – Category 1**Toxic to Reproduction 2: Reproductive toxicity – Category 2**Specific Target Organ Toxicity - Single Exposure 3: Specific target organ toxicity (single exposure) – Category 3**** Data compared to the previous version altered.**

US