

Version number 1

Reviewed on 04/23/2020

1 Identification

· Product identifier

• Trade name: X PLEX Hot Monomer

· Application of the substance / the mixture Denture base material

• Details of the supplier of the safety data sheet • Manufacturer/Supplier: CANDULOR AG Boulevard Lilienthal 8 CH-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

Flam. Liq. 2 H225 Highly flammable liquid and vapor.
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.

· Label elements

· GHS label elements

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

· Hazard pictograms



- · Signal word Danger
- *Hazard-determining components of labeling: methyl methacrylate ethylene glycol dimethacrylate*
- Hazard statements Highly flammable liquid and vapor. Causes skin irritation. May cause an allergic skin reaction. May cause respiratory irritation.

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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)

 $\begin{array}{c} \textbf{Health} = 1\\ Fire = 3\\ Reactivity = 0 \end{array}$

· HMIS-ratings (scale 0 - 4)



· 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

CAS: 97-90-5 ethylene glycol dimethacrylate

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.
- · Indication of any immediate medical attention and special treatment needed
- No further relevant information available.

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50-100%

2.5-<10%

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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.
- · 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.

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• 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 item 7.

- · 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 remaining constituent has no known exposure limits.

CAS: 80-62-6 methyl methacrylate

PEL Long-term value: 410 mg/m³, 100 ppm

- REL Long-term value: 410 mg/m³, 100 ppm
- TLV Short-term value: 410 mg/m³, 100 ppm Long-term value: 205 mg/m³, 50 ppm DSEN

• *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

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.

 \cdot Not suitable are gloves made of the following materials:

Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates. (Contd. on page 5)

[·] Control parameters

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• Eye protection:

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Tightly sealed goggles

Physical and chemical proper	ties
Information on basic physical and c	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)
Ignition temperature:	430 °C (806 °F)
Auto igniting:	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)
<i>Density at 20 °C (68 °F):</i>	0.943 g/cm ³ (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/wate	e r): Not determined.
Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
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. (Contd. on page 6)

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- 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)
- 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

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

13 Disposal considerations

· Waste treatment methods

· Recommendation:

Must not be disposed of together with household garbage. Do not allow product to reach sewage system. (Contd. on page 7)

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(Contd. of page 6) *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	UN1247
UN proper shipping name DOT ADR/RID/ADN IMDG, IATA	Methyl methacrylate monomer, stabilized 1247 Methyl methacrylate monomer, stabilized METHYL METHACRYLATE MONOMER, STABILIZED
Transport hazard class(es)	
DOT	
Class Label	3 Flammable liquids 3
ADR/RID/ADN	,
Class	3 (F1) Flammable liquids
Label IMDG, IATA	3
Class Label	3 Flammable liquids 3
Packing group DOT, ADR/RID/ADN, IMDG, IATA	II
Environmental hazards: Marine pollutant:	No
Special precautions for user Hazard identification number (Kemler code EMS Number:	Warning: Flammable liquids ;): 339 F-E,S-D
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

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• Transport/Additional information:	(Contd. of page
· 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
\cdot Excepted quantities (\widetilde{EQ})	Code: E2
1 1 (<i>Z</i>)	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

Suru
• 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

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• 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:

• TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

· Carcinogenic categories

· EPA (Environmental Protection Agency)

CAS: 80-62-6 methyl methacrylate

E, NL A4

CAS: 80-62-6 methyl methacrylate

·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).

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(Contd. of page 8) · Hazard pictograms GHS02 GHS07 · Signal word Danger · Hazard-determining components of labeling: methyl methacrylate ethylene glycol dimethacrylate · Hazard statements Highly flammable liquid and vapor. Causes skin irritation. May cause an allergic skin reaction. 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. · Date of preparation / last revision 05/14/2020 / -· Abbreviations and acronyms: ADR: Accord européen sur le transport 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 ACGIH: American Conference of Governmental Industrial Hygienists 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 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

Flam. Liq. 2: Flammable liquids – Category 2

Skin Irrit. 2: Skin corrosion/irritation – Category 2

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Skin Sens. 1: Skin sensitisation – Category 1 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3 (Contd. of page 9)

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