

MATERIAL SAFETY DATA SHEET

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

1.1. Product identifier

KEROX PREMIA PMMA CAD-CAM DISC

Product number: -

1.2. Relevant identified uses of the substance or mixture and uses advised against Basic material for making temporary dentures, crowns, and bridges.

1.3. Details of the supplier of the safety data sheet

Manufacturer

Kerox Kereskedelmi és Ipari Kft.

Address: H-2038 Sóskút, Kerox St. 1.

Tel.: +36 23 382 006 /281

Fax: +36 23 545 215

Email: info@kerodental.net

Supplier

Kerox Kereskedelmi és Ipari Kft.

Address: H-2038 Sóskút, Kerox St. 1.

Tel.: +36 23 382 006 /281

Fax: +36 23 545 215

Email: info@kerodental.net

Responsible person: info@kerodental.net

1.4. Emergency telephone number:

Egészségügyi Toxikológiai Tájékoztató Szolgálat

(ETTSZ) 1097 Budapest, Nagyvárad tér 2.

Tel.: +36 1 476 6464, +36 80 201 199

e-mail: ettsz@okbi.antsz.hu

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]:

Not classified.

For the full text of H-statements mentioned in this Section: see Section 16.

2.2. Label elements

Hazard Pictograms:

-

Signal word:

-

Hazard statements:

-

Precautionary statements:

-

Supplemental hazard information:

-

Substances contributing of hazard identification:

-

2.3. Other hazards:

See PBT and vPvB assessment results in section 12.5.
Endocrine disrupting properties: see sections 11.2. and 12.6.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

| Component | CAS-No. | EC-No. | Index No. | REACH No. | Concentration [%] | Classification according to Regulation (EC) No. 1272/2008 [CLP] | H-statements | Special concentration limits/M factor/ATE |
|--------------------------------------|-----------|-----------|-----------|-----------|-------------------|-----------------------------------------------------------------|--------------|-------------------------------------------|
| Cross linked polymethyl methacrylate | 9011-14-7 | 618-466-4 | - | - | min. 99,86 | - | - | - |
| pigments | - | - | - | - | 0,14 | - | - | - |

For the full text of H-statements mentioned in this Section: see Section 16. The product does not contain Substances of Very High Concern (SVHC).

SECTION 4 : First aid measures

4.1. Description of first aid measures:

GENERAL INFORMATION:

In case of accident or feeling sick immediately consult a physician. Show this safety data sheet or the product label to the doctor in attendance!

FOLLOWING INGESTION:

Rinse mouth with water. If symptoms persist consult a doctor.

FOLLOWING INHALATION:

Take the injured person to fresh air, remove from the contaminated area. In case of loss of consciousness, place the victim in a stable side position. In case of respiratory failure, perform artificial respiration immediately or administer oxygen. In case of persistent symptoms or in all cases of doubt, medical assistance is required.

FOLLOWING SKIN CONTACT

Wash off with soap and plenty of water. Remove contaminated clothing. If irritation persists, consult a doctor.

FOLLOWING EYE CONTACT:

Immediately rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If irritation persists, seek medical attention.

- 4.2. Most important symptoms and effects, both acute and delayed No information available.
- 4.3. Indication of any immediate medical attention and special treatment needed.
In case of irritation or complaints, consult a doctor. Show the product label or safety data sheet to the doctor; Instructions to the physician: symptomatic observational treatment!

SECTION 5: Firefighting measures

- 5.1. Extinguishing media:
Suitable extinguishing media: Use fire extinguishing methods suitable to surrounding conditions. Water spray, foam, CO2, dry chemical.
Unsuitable extinguishing media: Use water jets only to cool the surfaces of the goods exposed to fire.
- 5.2. Special hazards arising from the substance or mixture: Not flammable.
In case of fire, the following can be released: carbon monoxide, carbon dioxide, organic decomposition products.
- 5.3. Advice for firefighters
Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots, and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.
Cool goods and containers exposed to fire with sprayed water; if possible. The product must be moved out of the danger zone; if possible, extinguishing water should not be discharged into the sewer.

SECTION 6 : Accidental release measures

- 6.1. Personal precautions, protective equipment and emergency procedures
- 6.1.1. For non-emergency personnel
Evacuate and close the affected area. Unauthorized persons must be kept away. Wear appropriate personal protective equipment.
- 6.1.2. For emergency personnel
Wear appropriate personal protective equipment. See sections 7 and 8.
- 6.2. Environmental precautions
Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. If the substance enters sewers or watercourses, the competent authority must be notified.
- 6.3. Methods and material for containment and cleaning up:
The spilled material must be collected. Avoid dust formation. Store in an acid-resistant container (polyethylene, etc.); transport in a closed container to the place of disposal.
- 6.4. Reference to other sections See sections 7, 8 and 13.

SECTION 7: Handling and storage

- 7.1. Precautions for safe handling:
Ensure adequate ventilation. Protective equipment is recommended (see section 8). For use by trained personnel only.
Avoid getting the product on the skin, eyes, or clothes, avoid inhaling the dust of the product. Do not eat, drink, or smoke during use, and wash your hands after use.
Advice on protection against fire and explosion: No special action is required.
- 7.2. Conditions for safe storage, including any incompatibilities: Keep it dry. Keep away from children.
Storage class (LGK Germany): 13
- 7.3. Specific end use(s)
Only for dental use.

SECTION 8 : Exposure controls/personal protection

8.1. Control

parameters:

Exposure limits:

There are no international exposure limits (source

GESTIS) DNEL: no information available.

PNEC: no information available

- 8.2. Exposure controls: Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday. Caution is necessary to prevent skin contact, eye contact, cloth contact and spilling into the floor.

5/2020. (II. 6.) ITM decree on the protection of the health and safety of workers exposed to chemical pathogenic factors, pursuant to Section 11(2) in the case of hazardous substances not regulated by limit values, the employer is obliged to reduce the level of exposure to the lowest level expected according to scientific and technical standards, at which level, according to the current state of science, the dangerous substance has no health-damaging effect. When using in an open system, use local exhaust where possible. If local extraction is not possible or is insufficient, adequate ventilation of the work area must be ensured.

General protective and hygienic measures

Handle material in accordance with good industrial hygiene and safety practices.

Appropriate engineering controls

Ensure adequate ventilation.

Individual protection measures, such as personal protective equipment:



a) eye/face protection

Safety eyewear and/or face protection complying with an approved standard (European Standard EN 166) should be used in case of mechanical processing of product.

b) skin protection

- i. hand protection: Not necessary for intended use. The use of chemical-resistant protective gloves according to EN 374 is recommended in case of prolonged or repeated contact.
- ii. other: body protection: Not necessary for intended use. Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

c) respiratory protection

Wear dust mask during processing, and local exhaust must be used during processing.

d) thermal hazards
No information available

Environmental exposure controls

No information available.

Personal protective equipment selections vary based on potential exposure conditions such as applications, handling practices, concentration and ventilation. Information on the selection of protective equipment for use with this material, as provided above, is based upon intended, normal usage. If there is different than normal usage of the material, it is advised to consult a safety specialist about the type of personal protective equipment and other actions that should be taken.

SECTION 9 : Physical and chemical properties

9.1. Information on basic physical and chemical properties:

| Propertie s | | Method of determinatio n | Notation |
|----------------------------------------------|---------------------------------------------|--------------------------------|----------|
| Appearance | solid disc | | |
| Colour | different | | |
| Odor | odourless | | |
| Odor threshold | no data available | | |
| Melting point/freezing point | no data available | | |
| Initial boiling point and boiling range | no data available | | |
| Flammability | not flammable | | |
| Upper/lower flammability or explosive limits | no data available | | |
| Flash point | > 250 °C | | |
| Auto-ignition temperature | no data available | | |
| Decomposition temperature | no data available | | |
| pH | not applicable | | |
| Kinematic viscosity | not applicable | | |
| Solubility | insoluble in water | | |
| Partition coefficient: n-octanol/water | not applicable | | |
| Vapor pressure | not applicable | | |
| Density and/or relative density | relative density: 1,17 g/cm ³ | | 20°C |
| Relative vapor density | no data available | | |
| Particle characteristics | solid disc | | |

9.2. Other information

9.2.1. Information with regard to physical hazard classes Not classified based on available information.

- 9.2.2. Other safety characteristics No information available.

SECTION 10 : Stability and reactivity

- 10.1. Reactivity
No information available.
- 10.2. Chemical stability
Stable under normal handling and storage conditions.
- 10.3. Possibility of hazardous reactions Not known.
- 10.4. Conditions to avoid
If exposed to high temperatures, the product may degrade, avoid temperatures of 250°C or higher.
- 10.5. Incompatible materials
No information available.
- 10.6. Hazardous decomposition products
There is no hazard in case of normal use. In case of fire, the following can be released: carbon monoxide, carbon dioxide, organic decomposition products.

SECTION 11 : Toxicological information

- 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008:

Acute toxicity:

No information available.

Skin corrosion / irritation:

Similar product has been tested according to EN ISO 10993-10 (2010):

Tests for skin irritation.

An intracutaneous irritation test by intradermal injection in the rabbit has been performed and the test article extract met the requirements of the ISO 10993-10 (2010).

Serious eye damage/irritation:

No information available.

Respiratory or skin sensitization:

Similar product has been tested according to EN ISO 10993-10 (2010): Tests for skin sensitization. According to the EN ISO 10993-10 (2010) the product did not induce delayed sensitization.

Germ cell mutagenicity:

Similar product has been tested according to EN ISO 10993-5 (2009): Tests for in vitro cytotoxicity. The test article extract met the requirements of the EN ISO 10993-5 (2009).

Carcinogenicity:

No information available.

Reproductive toxicity:

No information available.

STOT-single exposure:

No information available.

STOT-repeated exposure:

No information available.

Aspiration hazard:

No information available.

Relevant toxicological data:

No information available.

Information on likely routes of exposure:

No information available.

Symptoms related to the physical, chemical, and toxicological characteristics:

- .. Skin contact: No specific information available.
- .. Eye contact: No specific information available.
- .. Inhalation: No specific information available.
- .. Ingestion: No specific information available.
- .. Other: No information available.

Delayed and immediate effects as well as chronic effects from short- and long-term exposure:

See Section 4. 2.

Interactive effects:

No information available.

Absence of specific data:

No information available.

Mixtures:

No information available.

Mixture versus substance information:

No information available.

11.2 Information on other hazards

Endocrine disrupting properties

Cross linked polymethyl methacrylate CAS: 9011-14-7 not listed.

Other information

No information available.

SECTION 12: Ecological information

Do not allow product to reach surface water, waterways or soil.

12.1. Toxicity

No information available, no evidence of hazardous properties.

12.2. Persistence and degradability

No information available, no evidence of hazardous properties.

12.3 Bioaccumulative

potential No information available.

12.4 Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

According to Regulation 1907/2006/EC Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Annex XIII: The product does not meet the criteria for PBT and vPvB.

12.6. Endocrine disrupting properties

Cross linked polymethyl methacrylate CAS: 9011-14-7 not listed.

12.7. Other adverse effects

No information available.

SECTION 13 : Disposal considerations

13.1. Waste treatment methods

Product disposal:

Dispose of contents in accordance with local/regional/national/international regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user based on the application for which the product was used.

Suggested EWC code: 18 01 07 chemicals other than those mentioned in 18 01 06

Packaging disposal:

The handling and disposal of contaminated packaging material must be carried out in accordance with the regulations for the product.

Physical, chemical properties, which could influence waste management:

No information available.

Sewage disposal-relevant information:

No information available.

SECTION 14 : Transport information

Product is not classified as a dangerous good for transport.

ADR/RID

14.1 UN number or ID number: -

14.2 UN proper shipping name: -

14.3 Transport Hazard Class(es): -

14.4 Packing group: -

14.5 Environmental hazards: -

14.6 Special precautions for user: -

ADN

14.1 UN number or ID number: -

14.2 UN proper shipping name: -

14.3 Transport Hazard Class(es): -

14.4 Packing group: -

14.5 Environmental hazards: -

14.6 Special precautions for user: -

IMDG

14.1 UN number or ID number: -

14.2 UN proper shipping name: -

14.3 Transport Hazard Class(es): -

14.4 Packing group: -

14.5 Environmental hazards: -

14.6 Special precautions for user: -

ICAO-TI/IATA-DGR

14.1 UN number or ID number: -

14.2 UN proper shipping name: -

14.3 Transport Hazard Class(es): -

14.4 Packing group: -

14.5 Environmental hazards: -

14.6 Special precautions for user: -

14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

SECTION 15 :Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture:

EU Regulations:

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

COMMISSION REGULATION (EU) No 348/2013 of 17 April 2013 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

COMMISSION REGULATION (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance.

- 15.2. Chemical safety assessment:
Chemical safety assessment has not been carried out.

SECTION 16: Other

information

Identification of

changes

v2.0 Revision and harmonization of the data sheet in accordance with applicable international legislation.

Abbreviations and acronyms:

ATE: Acute toxicity estimate.
PBT: persistent, bioaccumulative and toxic.
vPvB: very persistent, very bioaccumulative.
LD50 lethal dose,
LC50 Lethal concentration.
EC50 Effective concentration.
EWC: European Waste Catalog.
IARC: International Agency for Research on Cancer.
RTECS: Registry of Toxic Effects of Chemical Substances.
VOC: Volatile Organic Carbon.
PNEC: Predicted no effect concentration.
LFL: Lower Inflammatory Limit.
UFL: Upper Flammability Limit.
LEL: lower explosion limit.
UEL: Upper explosion limit.
STOT: Specific Target Organ Toxicity.
LDLo: Lethal dose, low.
IC50: Inhibitory concentration.
SVHC: Substances of very high concern.
NOAEL: No-observed-adverse-effect level.
LOAEL: Lowest-observed-adverse-effect level

For the compilation of the safety data sheet, we used the data of the registration dossier.

Full text of H-statements from section 2 and 3:

-

Precautionary statements:

-

Further training advice:

No information available.

Recommended restrictions on use:

No information available.

This Safety Data Sheet was prepared based on the documentation provided by the manufacturer and complies with the requirements of Regulation (EC) No. 878/2020