



Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

1 Identification

· **Product identifier**

· **Trade name:** **Palatray XL**

· **Application of the substance / the mixture** Auxiliary for manufacture of dental prothesis

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

Tel.: +49 (0)800 4372522

· **Information department:**

Tel. +1 (800) 431-1785 Fax: +1 (800) 522-1545

e-mail: customer.servicehkna@kulzer-dental.com

· **Emergency telephone number:**

Emergency CONTACT (24-Hour-Number)

GBK/Infotrac ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

2 Hazard(s) identification

· **Classification of the substance or mixture**

Skin Sens. 1 H317 May cause an allergic skin reaction.

Repr. 2 H361 Suspected of damaging fertility or the unborn child.

· **Label elements**

· **GHS label elements**

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

· **Hazard pictograms**



GHS07 GHS08

· **Signal word** Warning

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

4,4'-isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, esters with acrylic acid
triethylen glycol dimethacrylate

· **Hazard statements**

May cause an allergic skin reaction.

Suspected of damaging fertility or the unborn child.

· **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapors/spray

Wear protective gloves.

Specific treatment (see on this label).

Wash contaminated clothing before reuse.

IF exposed or concerned: Get medical advice/attention.

Store locked up.

(Contd. on page 2)

USA



Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

Trade name: Palatray XL

(Contd. of page 1)

- **Classification system**
- **NFPA ratings for USA (scale 0-4)**



- **HMIS-Ratings (Scale 0-4)**



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

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Composition based on methacrylates

- **Dangerous components:**

	Aliphatic urethane acrylate Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	5-10%
55818-57-0	4,4'-isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, esters with acrylic acid Skin Sens. 1, H317	5-10%
109-16-0	triethylen glycol dimethacrylate Skin Sens. 1B, H317	5-10%
75980-60-8	diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide Repr. 2, H361	< 1%

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

4 First-aid measures

- **Description of first aid measures**
- **General information** No special measures required.
- **After skin contact** Generally the product does not irritate the skin.
- **After eye contact** Rinse opened eye for several minutes under running water.
- **After swallowing**
Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.
- **Information for doctor**
- **Most important symptoms and effects, both acute and delayed**
No further relevant information available.

(Contd. on page 3)



Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

Trade name: Palatray XL

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

(Contd. of page 2)

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.
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
 - **Protective equipment:** No special measures required.
- **Additional information** -

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:**
Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues).
- **Reference to other sections**
No dangerous substances are released.
See Section 8 for information on personal protection equipment.
-

7 Handling and storage

- **Handling**
 - **Precautions for safe handling** No special measures required.
 - **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
 - **Storage**
 - **Requirements to be met by storerooms and receptacles:** No special requirements.
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:** Keep cool, if possible (not above 25 °C).
- **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.

(Contd. on page 4)



Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

Trade name: Palatray XL

(Contd. of page 3)

· **Exposure controls**

· **Personal protective equipment**

· **General protective and hygienic measures**

Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.

· **Breathing equipment:** Not required.

· **Protection of hands:**

If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.

Check protective gloves prior to each use for their proper condition.
recommended

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **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.

· **For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:**

Butyl rubber, BR

Nitrile rubber, NBR

· **Eye protection:** Not absolutely necessary.

· **Body protection:** Light weight protective clothing

9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

· **Form:**

Chips

· **Color:**

Red

· **Odor:**

Weak, characteristic

· **Odor threshold:**

Not determined.

· **pH-value:**

Not applicable.

· **Change in condition**

· **Melting point/Melting range:**

undetermined

· **Boiling point/Boiling range:**

101 °C (214 °F)

· **Flash point:**

> 150 °C (> 302 °F)

· **Flammability (solid, gaseous)**

Not determined.

· **Ignition temperature:**

· **Decomposition temperature:**

Not determined.

· **Auto igniting:**

Product is not selfigniting.

(Contd. on page 5)



Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

Trade name: Palatray XL

(Contd. of page 4)

· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
· Lower:	Not determined.
· Upper:	Not determined.
· Vapor pressure at 20 °C (68 °F):	40 hPa (30 mm Hg)
· Density at 20 °C (68 °F):	1.880 g/cm ³ (15.689 lbs/gal)
· Relative density	Not determined.
· Vapor density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with	
· Water:	Insoluble
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
· dynamic:	Not applicable.
· kinematic:	Not applicable.
· Solvent content:	
· Solids content:	77.3 %
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Possibility of hazardous reactions** No dangerous reactions known
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** none
- **Additional information:**
Product might polymerize after considerable exceeding of recommended storage time or temperature.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

· LD/LC50 values that are relevant for classification:		
Aliphatic urethane acrylate		
Oral	LD50	>5000 mg/kg (rat)
55818-57-0 4,4'-isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, esters with acrylic acid		
Oral	LD50	>5000 mg/kg (rat) (OECD 401)
Dermal	LD50	>5000 mg/kg (rabbit)
Sensitization	Sensib.	(human)

(Contd. on page 6)



Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

Trade name: Palatray XL

(Contd. of page 5)

		sensib. (mouse) (LLNA)
68909-20-6 hochdisperse Kieselsäure		
Oral	LD50	>5000 mg/kg (rat)
109-16-0 triethylen glycol dimethacrylate		
Oral	LD50	> 5000 mg/kg (rat)
Dermal	LD50	> 2000 mg/kg (mouse)
75980-60-8 diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide		
Oral	LD50	> 5000 mg/kg (rat)

· **Primary irritant effect:**

· **on the skin:** No irritant effect.

· **on the eye:** No irritating effect.

· **Sensitization:** Sensitizing effect by skin contact is possible with prolonged exposure.

· **Additional toxicological information:**

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

· **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:**

55818-57-0 4,4'-isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, esters with acrylic acid

EC50/72h | > 110 mg/l (algae) (OECD 201)

LC50/96h | > 79 mg/l (fish) (OECD 203)

109-16-0 triethylen glycol dimethacrylate

EC50/72h | > 100 mg/l (algae)

75980-60-8 diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide

EC50/48h | 10 100 mg/l (algae)

10 - 100 mg/l (daphnia)

· **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.

(Contd. on page 7)



Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

Trade name: Palatray XL

(Contd. of page 6)

- **Additional ecological information:**
 - **General notes:**
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**
Small quantities can be polymerized by light and the cured solid material can be disposed of with the regular garbage. Larger quantities must be disposed of following the regulations of the local authorities.
- **Uncleaned packagings:**
 - **Recommendation:** Packaging can be reused or recycled after cleaning.

14 Transport information

· UN-Number	
· DOT, ADR, ADN, IMDG, IATA	Void
· UN proper shipping name	
· DOT, ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
· DOT, ADR, ADN, IMDG, IATA	
· Class	Void
· Packing group	
· DOT, ADR, 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.
· Transport/Additional information:	-
· UN "Model Regulation":	Void

USA
(Contd. on page 8)



Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

Trade name: Palatray XL

(Contd. of page 7)

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.

· **TSCA (Toxic Substances Control Act)** Medical devices are exempted from TSCA.

· **Carcinogeny categories**

· **TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

· **GHS label elements**

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

· **Hazard pictograms**



GHS07 GHS08

· **Signal word** Warning

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

4,4'-isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, esters with acrylic acid
triethylen glycol dimethacrylate

· **Hazard statements**

May cause an allergic skin reaction.
Suspected of damaging fertility or the unborn child.

· **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapors/spray
Wear protective gloves.
Specific treatment (see on this label).
Wash contaminated clothing before reuse.
IF exposed or concerned: Get medical advice/attention.
Store locked up.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Relevant phrases**

H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H361 Suspected of damaging fertility or the unborn child.

· **Date of preparation / last revision** 06/03/2017 / 2

(Contd. on page 9)



Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

Trade name: Palatray XL

(Contd. of page 8)

· **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
- OSHA: Occupational Safety & Health
- TLV: Threshold Limit Value
- PEL: Permissible Exposure Limit
- REL: Recommended Exposure Limit
- Skin Irrit. 2: Skin corrosion/irritation – Category 2
- Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
- Skin Sens. 1: Skin sensitisation – Category 1
- Skin Sens. 1B: Skin sensitisation – Category 1B
- Repr. 2: Reproductive toxicity – Category 2
- STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

· *** Data compared to the previous version altered.**

USA