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Safety Data Sheet according to HPR, Schedule 1

Printing date 08/03/2022 Reviewed on 08/03/2022

1 Identification

- · Product identifier
 - · Trade name: PalaXpress liquid

- · Application of the substance / the mixture Manufacture of dental prothesis
- · Details of the supplier of the safety data sheet
 - Manufacturer/Supplier:

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

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

2 Hazard identification

Classification of the substance or mixture

Flammable Liquids - Category 2

Skin Irritation - Category 2

Skin Sensitizer - Category 1

Reproductive Toxicity - Category 2

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H361 Suspected of damaging fertility or the

unborn child.

Specific Target Organ Toxicity - Single Exposure - H335 May cause respiratory irritation.

Category 3

· 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

1,4-butandioldimethacrylate

· Hazard statements

Highly flammable liquid and vapour.

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, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Avoid breathing dust/fume/gas/mist/vapours/spray.

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.

If skin irritation or rash occurs: Get medical advice/attention.

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- · Additional information:
- 1 % of the mixture consists of an ingredient or ingredients of unknown acute toxicity.
- · Classification system
 - · NFPA ratings for USA (scale 0-4)



· HMIS-Ratings (Scale 0-4)



Health = 1 Fire = 3 Reactivity = 2

· Other hazards -

3 Composition/Information on ingredients

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

· Dangerous components:		
80-62-6	methyl methacrylate	>90% w/w
	Flammable Liquids - Category 2, H225 Skin Irritation - Category 2, H315; Skin Sensitizer - Category 1, H317; Specific Target Organ Toxicity - Single Exposure - Category 3, H335	
2082-81-7	1,4-butandioldimethacrylate Skin Sensitizer - Category 1B, H317	<i>≥1-≤</i> 5% w/w *
63393-96-4	Quaternary ammonium compounds, tri-C8-10-alkylmethyl, chlorides Acute Toxicity (Oral) - Category 3, H301 Reproductive Toxicity - Category 2, H361 Skin Corrosion - Category 1C, H314; Serious Eye Damage - Category 1, H318 Flammable Liquids - Category 4, H227	≥0,1-<0,5% w/w *
	p-Mentha-1,4-diene Flammable Liquids - Category 3, H226 Reproductive Toxicity - Category 2, H361	≥0,1-<0,5% w/w *

^{*} Actual concentration ranges are withheld as a trade secret.

4 First-aid measures

- · Description of first aid measures
 - · After inhalation Supply fresh air; consult doctor in case of complaints.
 - · After skin contact 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.

If symptoms persist consult doctor.

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[·] Additional information For the wording of the listed hazard phrases refer to section 16.



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- · Information for doctor
 - · Most important symptoms and effects, both acute and delayed Allergic reactions
 - 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, sand, extinguishing powder. Do not use water.
 - For safety reasons unsuitable extinguishing agents Water.
- · Special hazards arising from the substance or mixture

Can form explosive gas-air mixtures.

Formation of toxic gases is possible during heating or in case of fire.

- · Advice for firefighters
 - · Protective equipment: No special measures required.
- · Additional information -

6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

- Environmental precautions: Prevent seepage into sewage system, workpits and cellars.
- Methods and material for containment and cleaning up:

Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues).

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.

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7 Handling and storage

- · Handling
 - Precautions for safe handling

Keep receptacles tightly sealed.

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

Ensure good interior ventilation, especially at floor level. (Fumes are heavier than air).

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.
 - · Information about storage in one common storage facility: Not required.
 - Further information about storage conditions:

Keep cool, if possible (not above 25 °C).

Store in cool, dry conditions in well sealed receptacles.

· Specific end use(s) No further relevant information available.

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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:

80-62-6 methyl methacrylate

EL STEL: 100 ppm TWA: 50 ppm

S(D)

EV STEL: 100 ppm TWA: 50 ppm

· Additional information: The lists that were valid during the creation were used as basis.

· Exposure controls

Personal protective equipment

· General protective and hygienic measures

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.

Breathing equipment:

Not necessary with efficient local exhaust. If exposition to vapours is possible, use breathing protective mask (filter A).

Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

If skin contact cannot be avoided, protective gloves are recommended to

avoid possible sensitization.

Solvent resistant gloves

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: Tightly sealed goggles.
- · Body protection: Light weight protective clothing

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Information on basic physical and che	emical properties
· General Information	
· Appearance:	
· Form:	Fluid
· Color: · Odor:	Colorless
· Odor: · Odor threshold:	Ester-like Not determined.
· pH-value:	Mixture is non-soluble (in water).
•	mixture to their columns (in mater).
· Change in condition · Melting point/Melting range:	undetermined
Boiling point/Boiling range:	100,3 °C (212,5 °F)
· Flash point:	10 °C (50 °F)
Flammability (solid, gaseous)	Not applicable.
Ignition temperature:	430 °C (806 °F)
Decomposition temperature:	Not determined.
· Auto igniting:	Product is not selfigniting.
· Danger of explosion:	Product is not explosive. However, formation 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):	0,946 g/cm³ (7,89437 lbs/gal)
· Relative density	Not determined.
Vapor density	Not determined.
Evaporation rate	Not determined.
Solubility in / Miscibility with	
· Water:	Not miscible or difficult to mix
· Partition coefficient (n-octanol/wat	er): Not determined.
· Viscosity:	
dynamic at 20 °C (68 °F):	1 mPas
· kinematic:	Not determined.
Solvent content:	
· Water:	<0,1 %
· Solids content:	0,3 %
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

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· Additional information:

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Product might polymerize after considerable exceeding of recommended storage time or temperature.

11 Toxicological information

- · Information on toxicological effects
 - · Acute toxicity:

•	Addit toxicity.				
	· LD/LC50 values that are relevant for classification:				
80-0	80-62-6 methyl methacrylate				
Ora	1	LD50	~7.900 mg/kg (rat) weight of evidence		
Der	mal l	LD50	>5.000 mg/kg (guinea pig) (OECD 402)		
Inha	alative l	LC50/4 h	29,8 mg/l (rat)		
208	2082-81-7 1,4-butandioldimethacrylate				
Ora	nl I	LD50	10.066 mg/kg (rat) (OECD 401)		
633	63393-96-4 Quaternary ammonium compounds, tri-C8-10-alkylmethyl, chlorides				
Ora	nl I	LD50	200 mg/kg (ATE)		
			>200-<2.000 mg/kg (rat) (OECD 401)		
99-8	99-85-4 p-Mentha-1,4-diene				
Ora	nl I	LD50	>2.000 mg/kg (rat) (OECD 423)		
Der	mal l	LD50	>2.000 mg/kg (rat) (OECD 402)		

- · Primary irritant effect:
 - · on the skin: Irritant to skin and mucous membranes.
- · Sensitization: Sensitization possible through skin contact.
- · Additional toxicological information: Irritant
 - · Carcinogenic categories
 - · IARC (International Agency for Research on Cancer)

80-62-6 methyl methacrylate

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· NTP (National Toxicology Program)

None of the ingredients is listed.

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

12 Ecological information

· Toxicity

· Aquatic t	•
80-62-6 meth	nyl methacrylate
EC50/21d	49 mg/L (daphnia) (OECD 211)
EC50/48h	69 mg/l (daphnia) (EPA OTS 797.1300)
NOEC / 21d	37 mg/l (daphnia) (OECD 211)
ErC50 / 72 h	>110 mg/l (algae) (OECD 201)
NOEC / 72h	110 mg/l (algae) (OECD 201)
NOEC / 48h	48 mg/l (daphnia) (EPA OTS 797.1300)
EbC50 / 72h	>110 mg/l (algae) (OECD 201)

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NOEC/ 35d	9,4 mg/L (fish) (OECD 210)
LC50/ 35d	33,7 mg/L (fish) (OECD 210)
2082-81-7 1,	4-butandioldimethacrylate
EC50/21d	14,1 mg/L (daphnia) (OECD 211)
EC50/48h	32,5 mg/l (fish)
NOEC / 21d	5,09 mg/l (daphnia) (OECD 211)
ErC50 / 72 h	9,79 mg/l (algae) (OECD 201)
NOEC / 72h	2,11 mg/l (algae) (OECD 201)
NOEC / 48h	25 mg/l (fish)
ErC10/72h	4,35 mg/L (algae) (OECD 201)
63393-96-4 (Quaternary ammonium compounds, tri-C8-10-alkylmethyl, chlorides
EC50/48h	0,16 mg/l (daphnia) (OECD 202)
LC50/96h	0,15 mg/l (fish) (OECD 203)
ErC50 / 72 h	0,29 mg/l (algae) (OECD 201)
ErC10/72h	0,138 mg/L (algae) (OECD 201)
99-85-4 p-Me	entha-1,4-diene
EC50/72h	>10,82 mg/l (algae) (OECD 201)
EC50/48h	10,189 mg/l (daphnia) (OECD 202)
LC50/96h	2,792 mg/l (fish) (OECD 203)
· Persistence	and degradability
80-62-6 metl	hyl methacrylate
biodegradabi	lity 94 % /14d (not defined) (OECD 301C)
2082-81-7 1,	4-butandioldimethacrylate
	lity 84 % /28d (not defined) (OECD 310)
	Quaternary ammonium compounds, tri-C8-10-alkylmethyl, chlorides
	lity 10-<20 % /60d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)
	entha-1,4-diene
biodegradabi	lity 27 % /28d (not defined) (OECD 301F; ISO 9408/ EEC 92/69/V, C.4-D)

- Behavior in environmental systems:
 - · **Bioaccumulative potential** No further relevant information available. · **Mobility in soil** No further relevant information available.
- Additional ecological information:
 - General notes:

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

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

 - · vPvB: Not applicable.
- 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.

Disposal must be made according to official regulations.

- · Uncleaned packagings:
 - Recommendation:

Disposal must be made according to official regulations. Non contaminated packagings can be used for recycling.

14 Trans	port info	rmation
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· UN-Number	
· DOT/TOG ADD IMOG IATA	1 IN1124

· UN proper shipping name

· ÞOŤ/TDG Methyl methacrylate monomer, stabilized solution 1247 Methyl methacrylate monomer, stabilized solution · ADR

METHYL METHACRYLATE MONOMER. · IMDG, IATA

STABILIZED solution

- · Transport hazard class(es)
 - · DOT/TDG (Transport dangerous goods):



· Class 3 Flammable liquids

· Label

· ADR



· Class 3 (F1) Flammable liquids

· Label

IMDG, IATA



· Class 3 Flammable liquids

· Label

· Packing group · DOT/TDG, ADR, IMDG, IATA II

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· Environmental hazards:

Marine pollutant: No

· Special precautions for user Warning: Flammable liquids

Hazard identification number (Kemler

code): 339 · EMS Number: F-E.S-D · Stowage Category

· 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

Excepted quantities (EQ) Code: E2

Maximum net quantity per inner packaging: 30

Maximum net quantity per outer packaging: 500

· IMDG

· Limited quantities (LQ) 1L

· Excepted quantities (ÉQ) Code: E2

Maximum net quantity per inner packaging: 30

Maximum net quantity per outer packaging: 500

UN "Model Regulation": UN 1247 METHYL METHACRYLATE MONOMER,

STABILIZED SOLUTION, 3, II

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture No further relevant information available.
 - · Sara
 - · SARA Section 355 (extremely hazardous substances)

None of the ingredients is listed.

· 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

H225 Highly flammable liquid and vapour. H226 Flammable liquid and vapour.

H227 Combustible liquid.

H301 Toxic if swallowed.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

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H335 May cause respiratory irritation. H361 Suspected of damaging fertility or the unborn child.

· Date of the latest revision of the safety data sheet 08/03/2022 / 3

· Abbreviations and acronyms:

IMDG: International Maritime Code for Dangerous Goods DOT: US Department of Transportation

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
PVB: very Persistent and very Bioaccumulative

vPvB: very Persistent and very Bioaccumulative

* Data compared to the previous version altered.