SAFETY DATA SHEETS

This SDS packet was issued with item: 074486387

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

074486379

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1 Identification	1
· Product identifier	
· Trade name: Palaseal	
• Relevant identified uses of the substance or mixture and uses advised against	
No further relevant information available.	
 Application of the substance / the mixture Auxiliary for manufacture of dental prothesis 	
Details of the supplier of the safety data sheet Manufacturer/Supplier: Heraeus Kulzer GmbH Grüner Weg 11, D-63450 Hanau Tel.: 0800 4372522	2
 Information department: Marc Henn Tel. +1 (574) 2995444 / Fax: +1 (574) 2912542 e-mail: marc.henn@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	-
Flam. Liq. 2 H225 Highly flammable liquid and vapor. Skin Irrit. 2 H315 Causes skin irritation. Eye Dam. 1 H318 Causes serious eye damage. Skin Sens. 1 H317 May cause an allergic skin reaction.	
Repr. 2 H361 Suspected of damaging fertility or the unborn child.	
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 GHS02 GHS05 GHS07 GHS08 	
· Signal word Danger	
 Hazard-determining components of labeling: Tris(2-hydroxyethyl)-isocyanurat-triacrylat methyl methacrylate diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide Bisphenol A Diglycidylether Diacrylat (BADGE-DA) Hazard statements Highly flammable liquid and vapor. Causes skin irritation. Causes serious eye damage. 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.	
IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.	1
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(Contd. of page 1) If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center/doctor. Store locked up. Dispose of contents/container in accordance with local/regional/national/international regulations. · Classification system NFPA ratings for USA (scale 0-4) Health = 2Fire = 3Reactivity = 2· HMIS-Ratings (Scale 0-4) HEALTH *2 Health = *2FIRE 3



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:	
80-62-6 methyl methacrylate	25-50%
40220-08-4 Tris(2-hydroxyethyl)-isocyanurat-triacrylat	25-50%
55818-57-0 Bisphenol A Diglycidylether Diacrylat (BADGE-DA)	5-10%
52408-84-1 Oligotriacrylat	5-10%
75980-60-8 diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide	0-5%
Additional information For the wording of the listed risk phrases refer to section 16.	

4 First-aid measures

Description of first aid measures

- · After inhalation Supply fresh air; consult doctor in case of complaints.
- After skin contact immediately rinse with water.
- · 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.
- 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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5 Fire-fighting measures

· Extinguishing media

- Suitable extinguishing agents CO2, sand, extinguishing powder. Do not use water. For safety reasons unsuitable extinguishing agents
 - Water.
 - Water with full jet.
- · 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). Do not flush with water or aqueous cleansing agents
- 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 Please observe the additional instructions in the product's instructions for use. Keep receptacles tightly sealed.
- 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.

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

PEL () 410 mg/m³, 100 ppm

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(Contd. of page 3) REL () 410 mg/m³, 100 ppm Short-term value: 410 mg/m³. 100 ppm TLV () Long-term value: 205 mg/m³, 50 ppm SEŇ · 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: If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization. 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 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 trough time has to be found out by the manufacturer of the protective gloves and has to be observed. For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable: Wear protective gloves based on polyvinyl alcohole. For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable: Butyl rubber, BR Fluorocarbon rubber (Viton) Nitrile rubber, NBR Chloroprene rubber, CR · Eye protection: Protective goggles are recommended. Body protection: Light weight protective clothing 9 Physical and chemical properties · Information on basic physical and chemical properties General Information Appearance: Form: Fluid Color: Yellow · Odor: Characteristic

Change in condition
 Melting point/Melting range: undetermined
 Boiling point/Boiling range: 100 °C (212 °F)

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· Flash point:	13 °C (55 °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: Upper: 	2.1 Vol % 12.5 Vol %
· Vapor pressure at 20 °C (68	° F): 47 hPa (35 mm Hg)
· Density at 20 °C (68 °F):	1.060 g/cm³ (8.846 lbs/gal)
Solubility in / Miscibility with Water:	n Not miscible or difficult to mix
 Viscosity: dynamic at 20 °C (68 °F): 	11 mPas
Solvent content: VOC USA	1020.0 g/l / 8.51 lb/gl
Solids content: Other information	32.6 % 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.

	ion on toxi toxicity:	cological effects	
		es that are relevant for classification:	
80-62-6 r	nethyl met	hacrylate	
Oral	LD50	>5000 mg/kg (rat)	
Dermal	LD50	>5000 mg/kg (rab)	
Inhalative	LC50/4 h	29.8 mg/l (rat)	
40220-08	-4 Tris(2-h	ydroxyethyl)-isocyanurat-triacrylat	
Oral	LD50	>5000 mg/kg (rat)	
4687-94-	9 Bis-Glyc	dylacrylat	
Oral	LD50	>2000 mg/kg (rat)	
Dermal	LD50	>2000 mg/kg (rabbit)	
52408-84	-1 Oligotri	acrylat	
Oral	LD50	>2000 mg/kg (rat)	

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· Primary irritant effect:

- on the skin: Irritant to skin and mucous membranes.
- on the eye: Strong irritant with the danger of severe eye injury. Sensitization: Sensitization possible through skin contact.

Additional toxicological information:

The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version: Irritant

· Carcinogenic categories

· IARC (International Agency for Research on Cancer)

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:

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.

13 Disposal considerations

- Waste treatment methods
 - Recommendation

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· Uncleaned packagings:

Recommendation: Disposal must be made according to official regulations.

14 Transport information		
· UN-Number · DOT, ADR, IMDG, IATA	UN1247	
· UN proper shipping name · ADR	1247 METHYL METHACRYLATE MONOMER STABILIZED, solution	
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	(Contd. of pag
· IMDG, IATA	METHYL METHACRYLATE MONOME STABILIZED, solution
· Transport hazard class(es)	
·DOT	
*	
· Class · Label	3 Flammable liquids 3
· ADR	
()	
· Class · Label	3 (F1) Flammable liquids 3
· IMDG, IATA	
*	
· Class	3 Flammable liquids
· Label	3
 Packing group DOT, ADR, IMDG, IATA 	11
 Environmental hazards: Marine pollutant: 	No
· Special precautions for user	Warning: Flammable liquids
· Danger code (Kemler): · EMS Number:	339 F-E,S-D
 Transport in bulk according to Annex MARPOL73/78 and the IBC Code 	<i>Il of</i> Not applicable.
· Transport/Additional information:	-
· UN "Model Regulation":	UN1247, Methyl methacrylate monomer, stabilize solution, 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.

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

· Cancerogenity categories

TLV (Threshold Limit Value established by ACGIH)

80-62-6 methyl methacrylate

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(Contd. of page 7) · GHS label elements The product is classified and labeled according to the Globally Harmonized System (GHS). Hazard pictograms GHS02 GHS05 GHS07 GHS08 · Signal word Danger · Hazard-determining components of labeling: Tris(2-hydroxyethyl)-isocyanurat-triacrylat methyl methacrylate diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide Bisphenol A Diglycidylether Diacrylat (BADGE-DA) · Hazard statements Highly flammable liquid and vapor. Causes skin irritation. Causes serious eye damage. 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. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center/doctor. Store locked up. Dispose of contents/container in accordance with local/regional/national/international regulations. · 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. Date of preparation / last revision 08/14/2015 / -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 ELINCS: European List of Notilied Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) NFPA: National Fire Protection Association (USA) HMIS: Hazardous Materials Identification System (USA) VOC: Volatile Organic Compounds (USA, EU) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent DDT: Designator Licencenvolution and Taxin PBT: Persistent, Bioaccumulative and Toxic VPvB: very Persistent and very Bioaccumulative VPvB: very Persistent and very Bioaccumulative Flam. Liq. 2: Flammable liquids, Hazard Category 2 Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2 Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1 Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

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Trade name: Palaseal

Repr. 2: Reproductive toxicity, Hazard Category 2 STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3 • * **Data compared to the previous version altered.**

USA