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 Art.-Nr., product name: **7001 PERMAFLEX®**



1. Identification of the substance / preparation and of the company / undertaking

- 1.1 Identification of the substance or preparation:
- 1.1.1 Commercial Product Name: PERMAFLEX®
- 1.2 Application of substance/preparation: commercial
Relining material for dental use
- 1.3 Company / undertaking identification:
- Manufacturer / distributor: Kohdent Roland Kohler Medizintechnik GmbH & Co. KG
 Street / POB-No.: Bodenseeallee 14-16
 State / postal code / city: D-78333 Stockach
 Telephone: +49 7771 / 64999-0 Telefax: +49 7771 / 64999-50
 E-Mail: info@kohler-medizintechnik.de
- 1.4 Emergency telephone: +49 7771 / 64999-0
 This number is busy only to office hours
 (Mo.- Do 7.00 – 17.30, Fr. 7.00 – 12.30)

2. Hazards identification

- 2.1 Classification: The product is not dangerous preparation in the sense of the guideline 1999/45/EG.
- 2.2 Critical hazards to man and environment: While appropriate handling and considering the usual industrial hygiene admits no special hazards.

3. Composition / information on ingredients

- 3.1 Chemical characterisation (preparation): Contains Polydimethylsiloxan and fillers and small part of organic peroxide.
- 3.2 Hazards ingredient: None
- Description: Dibenzoylperoxid
 CAS-No.: 94-36-0
 EG-No.: 202-327-06
 Index-No.: 617-008-00-0
 Concentration: < 1 %
 Hazard symbol: E Xi
 R-Phrases: 2-36-43
 Additional information: The wording of the Hazard symbol and the R-Phrases is specified in chapter 16.

4. First aid measures

- 4.1 General information: With accident or indisposition take to medical advice (if possible, label or SDB present).
- 4.2 After inhalation: provide fresh air
- 4.3 After contact with the skin: Products with cloth or paper mechanically remove. Wash off with much water

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- and soap. With visible skin change or complaints take to medical advice (if possible, label or SDB present).
- 4.4 After contact with the eyes: Eyes with opened eyelid gap immediately 15 minutes with flowing water rinse out. Optician consult.
- 4.5 After swallowing: Rinse mouth out immediately and plentifully water in small portions after-drink. No vomiting cause. Take to medical advice with illness.
- 4.6 Self protection of the first-aid: To self protection pay attention (hand guard, foil masks („Life keys “).

5. Fire fighting measures

- 5.1 Suitable extinguishing media: Water mist, dry powder, foam, carbon dioxide
- 5.2 Extinguishing media which must not be used for safety reasons: Jet of water
- 5.3 Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases: Incineration gases do not inhale
- 5.4 Special protective equipment for fire fighting: Use self-contained breathing apparatus

6. Accidental release measures:

- 6.1 Personal precautions: If material were set free, on slip hazard to make attentive. By buried material do not run.
- 6.2 Environmental precautions: Do not leave waste water and into the ground in waters, to arrive. Local official regulations consider.
- 6.3 Methods for cleaning up: Take up mechanically or with liquid-binding material (sand, sawdust); To disposal see point 13

7. Handling and storage:

- 7.1 Handling:
 Handling procedures: The precautionary measures usual while handling chemicals are to be considered. With the use do not eat, drink or smoke.
 Recommendation for fire and explosion protection: General rules of the preventive fire protection consider.
- 7.2 Storage:
 technical measures and storage conditions:
 Requirements at Store drying separately in closely closed original bundles coolly and from food.

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storerooms and containers: Provide to good room ventilation.
 Requirements for storage with other products: With strong oxidizing agents do not together-store.
 Additional storage conditions: Protect against direct sun exposure. Keep in the refrigerator with 2°C - 12°C (32-50°F).
 7.3 Specified use: silicone material for relining of dental plate; to the use by trained technical personnel

8. Exposure controls / personal protection

8.1 Exposition limit values No assigned materials with workstation-furnished, to supervising limit values.

Air limit value after TRGS 900: CAS-Nr. 94-36-0
 Dibenzoylperoxid
 5 mg/m³ related to the respirable group
 Top limit: crossing faktor 1; time 15 min, midpoint; 4 times pro layer; interval 1 h.
 categorie I – material with those the local effect is limit value-determining or breath-way-sensitizing materials.
 DFG: Practically no or only very weak fringe effect.

8.2 Limitation and control of the exposition

8.2.1 Limitation and control of the exposition at the place of work:
 General protection and hygiene measures: General hygiene measures while handling chemical materials consider. Do not eat with the work and drink.
 Personal protective equipment:
 Respiration: Not necessarily
 Hands: Recommended, e.g. Protective gloves from nitrile rubber.
 Eyes: Eye protector for the avoidance of mechanical injuries at the eye recommended.

8.2.2 Personal: Work clothes wearing
 Delimitation and monitoring of the environmental exposition: In waters and into the ground to arrive do not leave.

9. Physical and chemical properties

9.1 Appearance
 Form: Paste
 Colour: Flash coloured
 Odour: Odourless

9.2 Important information to the health and environmental protection as well as for security Method (67/548/EWG)
 Flashpoint: = > 100 °C / 212 °F DIN 51755

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	Ignition temperature:	= > 200 °C / 392 °F	DIN 51794
	Oxidizing properties:	n.a.	
	Explosive properties:	n.a.	
	Vapour pressure:	= < 1 hPa bei 20 °C / 68 °F	DIN 51757
	Density:	= ca. 1,1 g/cm ³ bei 20 °C / 68 °F	
	Solubility in water:	= virtually insoluble	
	pH-value	n.a.	
	Distribution coefficient octanol / water:	n.a.	
	Viscosity (dynamic):	No tested	Brookfield
9.3	Further information::		
	Thermal decomposition:	= > 250 °C / 482°F	

10 Stability and reactivity

10.1	Incompatibility with other substances:	The product can polymerize approx temperatures 60 °C, 140 °F from there in closed containers in the refrigerator with 2°C - 12°C (32-50°F).
10.2	Avoiding materials	Can react with inflammatory as well as fire-promoting materials.
10.3	Hazardous decomposition products:	In presence of air small quantities formaldehyde can be formed at temperatures starting from approx. 150 degrees / 302 °F by oxidative dismantling

11 Toxicological information

11.1	General information	To handle after past knowledge while appropriate handling and considering the usual industrial hygiene without health dangers. After the conditions of our present knowledge neither mutagen, carcinogenically still teratogen.
11.2	Toxicological Test Acute toxicity: Acute orale toxicity:	For the product no toxicological data are present. For products of similar composition a LD ₅₀ (oral, rat) was found of over 5 000 mg/kg

12. Ecological information

12.1	Ökotoxizität: Behavior in sewage plants (bacteria toxicity: Breathing/increase inhibition)	To expect after present experience no unfavourable effects in sewage plants.
12.2	Mobilität:	Forms on the water surface a thin oil film. By suspended particles one absorbs. Separation by sedimentation.
12.3	Persistence and degradableness	
	Biological attack/ further information:	Biologically not degradable. Polydimethylsiloxane are degradable by abiotische procedures to certain extent.
12.4	Bio accumulation potential:	Bio accumulation improbably
12.5	Other harmful effects:	none admits

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12.6 Further ökologische behavior: In the case of appropriate handling and use no environmental problems are to be expected.

13 Disposal consideration

13.1 Disposal/waste (product): Recommendation: Correct removal by burning in a special refuse combustion plant. Local official regulations are to be considered.
 EAK/AW-Waste-key: 07 02 17 (wastes from HZVA von plastic, synthetic rubber and artificial fibers; silicone type wastes, others than in 07 0216 specified)
 13.2 Uncleaned packaging: Recommendation: Packing is completely to empty (drip-free, putty clean). Packing is under attention that valid in each case local/national regulations prefers supplying to a re-use and/or an utilization.

14 Transport Information

14.1 Land transport ADR/RID and GGVS/GGVE (Germany): Not classified as hazardous goods.
 GGVS/GGVE class: Not classified as hazardous goods.
 ADR/RID class:
 Warning sign – hazard no.:
 Identification product:
 Notice:
 Shipping symbol:
 LQ
 14.2 Binnenschifftransport ADN/ADNR: Not classified as hazardous goods.
 Note:
 14.3 Sea transport IMDG/GGVSee: Not classified as hazardous goods.
 IMDG/GGVSee-class:
 EmS-No.
 Marine pollutant:
 Proper shipping Name
 Technical name:
 LTD. QTY:
 14.4 Air transport ICAO-TI and IATA-DGR: Not classified as hazardous goods.
 ICAO/IATA-class:
 Proper shipping name:
 Technical name:
 Notice:
 Air post: permitted

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15 Regulatory information:

- 15.1 Classification according to EEC-guidelines: According to the regulations for hazardous goods and the corresponding EC-Guidelines the product is not to be labelled.
- 15.2 National Prescription (Germany)
 Water hazard class: WGK 1 = weakly water-endangering (classification in accordance with appendix 4 VwVwS of 17.05.1999 in the current version).

16 Other information

- 16.1 Wording of the R-sentences under section 3: R-Phrases and hazard symbol:
 R-Phrases:
 R2 By impact, friction, fire or other ignition sources explosive
 R36 Irritant of eyes
 R43 Sensitization by skin contact possible
 Hazards symbols:
 E explosive
 Xi irritant
- 16.2 Further Information:
 Explanation of the abbreviations: n.a. = not applicable n.u. = not subject to:
- 16.3 Data original:

Guideline 1999/45/EG for the classification, packing and marking of dangerous preparations.
 Guideline 67/548/EWG for the classification, packing and marking of dangerous materials, appendix I.

Characteristic data in terms of safety of chemical materials, exomed publishing house, collection of sheets with auxiliary supplies.

DFG German research council: MAK and asking values - list 2007

Manual of the refuse disposal, ecomed publishing house, collection of sheets with auxiliary supplies General administrative regulation for the change of the administrative regulation of water-endangering materials - VwVwS from 27 July of 2005.

Safety data sheets and further data of suppliers/manufacturers.

Data the given the product describe excluding the safety requirements of the Product/the products and support themselves on the today's conditions of our knowledge. They do not represent a warranty of characteristics of the descriptive product/the descriptive products in the sense of the legal guarantee regulations.