KERR

Material Safety Data Sheet

in accordance with Community Regulation 2006/1907/EC (R.E.A.Ch.)

Revision Date: 28th May 2009

SECTION 1

Product & Company identification

1.1 Product name

PERMLASTIC BASE (Regular, Light & Heavy Bodies)

1.2 <u>Uses/Application</u>:

Dental impression material.

1.3 Company (Name, address and info phone number)

KERR ITALIA s.r.l.

Via Passanti, 332 84018 Scafati (SA) - Italy 00-800-41-050-505

1.4 Emergency phone (according to communitarian directive 99/45/EC, article 17)

+39.081.8508.325 (08.00-17.00, European time, GMT+1)

E-mail address: safety@kerrhawe.com

SECTION 2

Hazard identification

2.1 <u>Hazard classification</u> (according to communitarian directives 67/548/EEC & 99/45/EC)

Toxic for Reproduction (Cat. 1-2); Toxic to aquatic organisms.

2.2 Other hazard

None.

SECTION 3

Composition/Information on Ingredients

(according to communitarian directives 67/548/EEC, 99/45/EC & 2001/58/EC)

3.1 Hazardous ingredients

HAZARDOUS	%	HAZARD	RISK	CAS N.	EINECS N.
INGREDIENTS		SYMBOLS	PHRASES		
Polysulfide polymer	60-75	None	52-53	68611-50-7	Polymer
Butyl Benzyl Phthalate (BBP)	5-10	T; N	61-62-50/53	85-68-7	201-622-7
Octamethylcyclotetrasiloxane	1	Xn	62-53	556-67-2	209-136-7

3.2 Other non-hazardous ingredients

None.

SECTION 4

First aid measures

- 4.1 Treatment for eye contact: Flush with large amounts of water.
- 4.2 Treatment for skin contact: Normal hygienic practices.
- 4.3 Treatment for inhalation (breathing): None particular.
- <u>4.4 Treatment for ingestion (swallowing):</u> Induce vomiting. Consult a physician.

SECTION 5

Fire-fighting Measures

- 5.1 Suitable extinguishing media: Not applicable.
- 5.2 Forbidden extinguishing media: Not determined.
- 5.3 Special fire fighting measures: None.
- 5.4 Unusual fire and explosion hazards: Unknown.
- 5.5 Special protection equipment: Sealed overall.

SECTION 6

Accidental Release Measures

- 6.1 Personal Precautions: Follow recommended precautions listed in other sections.
- 6.2 Environmental Precautions: Material should not be allowed to drain into sewers.
- <u>6.3 Reclaiming Methods:</u> Absorb spill with paper towels and transfer into suitable containers.

SECTION 7

Handling and Storage (according to article 5 of communitarian directive 98/24/EC)

- 7.1 Handling Precautions: Excessive heat may cause the aging of the product.
- 7.2 Precautions in case of Fire and Explosion: Extinguish all ignition sources.
- 7.3 Storage Conditions: Store at ambient temperature in a dry place
- 7.4 Suggested container(s): Original sealed containers provided by manufacturer.
- 7.5 Indication for Combined Storage: Avoid powerful reducing agents.
- 7.6 Environmental precautions: Do not allow product to reach sewers and rivers.
- <u>7.7 Other Precautions</u>: Keep out of the reach of children. Do not ingest. Avoid contamination of food. Use according to directions.

SECTION 8			
Exposure controls/personal protection			
8.1 Exposure Limits:	For BBP: <u>TWA/TLV</u> : 3 mg/m ³ (Germany, Austria, Denmark & Sweden);		
	STEL: 5 mg/m ³ (Austria & Sweden); 15 mg/m ³ (Great Britain)		
8.2 Exposure control measur	8.2 Exposure control measures		
8.2.1 Precautionary Measures: (according to communitarian directives 89/686/EEC & article 4 of 98/24/EC)			
Ventilation:	Local Exhaust Ventilation: Good general ventilation should be sufficient to keep vapour concentration under listed limits. Special Ventilation: None. Mechanical (General) Ventilation: Should be sufficient. Other Ventilation: None.		
Respiratory Protection:	When vapour concentration exceeds exposure limits, use self-contained breathing apparatus.		
Hands Protection:	Impervious rubber or nitrile gloves.		
Eyes Protection:	Safety glasses.		
Skin Protection:	Handle in accordance with good personal hygiene and safety practices.		
Other Protective Equipments	: It would be better use a lab coat.		
Measures listed in this paragraph are to be considered as indications and NOT prescriptions (89/656/EEC)			
8.2.2 Environment exposure control measures			
Not Applicable.			

SECTION 9		
Physical and Chemical Properties		
9.1 General information		
Appearance: White paste	Odour: Sulphur odour	
9.2 Infromation related to health, safety and e	environment	
<u>pH</u> : Not determined	Relative density: Not available	
Boiling point: Not applicable (N/A)	Specific gravity: > 1 g/ml	
Flash point: N/A	Solubility: Insoluble in water	
<u>Flammability</u> : Not flammable.	Partition coefficient n-octanol/water: N/D	
Lower Explosivity Limit (L.E.L.): N/A	<u>Viscosity</u> : Similar to water	
Upper Explosivity Limit (U.E.L.): N/A	<u>Vapour density (air = 1)</u> : N/A	
Oxidizing properties: None	Evaporation rate (n-butane = 1): N/A	
Vapour pressure: N/A	Melting point: N/A	
9.3 Other information (according to communitarian directives 94/9/EC):		
Miscibility: N/A.	Conducibility: N/A	
Solubility in Lipids: N/A	Gases Group: N/A	

SECTION 10

Stability and Reactivity

Stability: Stable.

10.1 Conditions to avoid: Excessive heat may cause the aging of the product.

10.2 Materials to avoid (incompatibility): Avoid powerful reducing agents.

10.3 Hazardous decomposition products: Sulphur gases may form.

Other precautions:

<u>Hazardous Polymerization Products</u>: Will not occur

Safety significance in case of change in physical appearance: None known

Stabilizers: No stabilizers are present in this product.

SECTION 11

Toxicological Information

CMR effects (Carcinogenicity, Mutagenicity and toxicity for reproduction):

Possible.

Effects and hazards of eye contact: May cause irritation.

Effects and hazards of skin contact: May cause mild irritation.

Effects and hazards of Inhalation (Breathing): May cause low or mild irritation.

Effects and hazards of Ingestion (Swallowing): Although ingestion is an unlike event, ingestion of uncured

material may pose health hazard for reproduction (see

Section 2.1).

Effects for prolonged Exposure: Same health hazards listed in Effects of ingestion (current section).

Toxic-kinetic effects: Unknown.

Effects on metabolism: Unknown.

<u>Toxicological data for ingredients:</u>

Polysulphide Polymer	LD ₅₀ (oral rat):	> 5000 mg/Kg
BBP	LD ₅₀ (oral rat):	20400 mg/Kg
	LD ₅₀ (skin rabbit):	> 10000 mg/Kg
	LC ₅₀ (inhalation rat/4 hours):	> 6,7 mg/l
		"

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SECTION 12

Ecological Information

This product has not known ecological hazardous effects.

12.1 Eco-toxicity: Not available

12.2 Mobility: Not available

12.3 Persistence and degradability: Not available

12.4 Bioaccumulative potential: Data available for BBP only: 12 BCF, based on parent compound analysis;

Log Pow: 4.58.

12.5 Results of PBT (Persistent Bio-Toxicity) assessment: Not available

12.6 Other adverse effects: Not available

Aquatic toxicity data for single ingredient:

Polysulphide Polymer	LC ₅₀ (pimephales promelas):	320 mg/l (96 hours)
	LC ₅₀ (cyprinodont variegatus):	> 1000 mg/l (96 hours)
	EC ₅₀ (daphnia magna):	32 mg/l (48 hours)
	LC ₅₀ (mysidopsis bahia):	59 mg/l (96 hours)
	EC ₅₀ (alga, selenastrum capricornutum): 17 mg/l (72 hours)	
BBP	LC ₅₀ (fishes, trout):	1,1 mg/l (96 hours)
	LC ₅₀ (fathead minnow):	1,5 mg/l (96 hours)
	LC ₅₀ (daphnia, water flea):	1,7 mg/l (48 hours)
	LC ₅₀ (alga):	1,5 mg/l (72 hours)

SECTION 13

Disposal considerations

Dispose of in accordance of local regulations.

SECTION 14

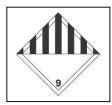
Transport information

14.1 Sea transportation (IMDG)

UN number: 3077 Class: 9 Packing group: III EMS-No: F-A, S-F

Stowage/segregation: Category A; Limited Quantity: 5 Kg

Proper shipping name: Environmentally hazardous substance, solid, n.o.s.



14.2 Air transportation (ICAO/IATA)

UN number: 3077 Class: 9 Packing group: III Labels: 9

Maximum quantities: No limits (for both Passenger Aircraft and Cargo Aircraft only)

Limited Quantity: 30 Kg G Proper shipping name: Environmentally

hazardous substance, solid, n.o.s.



14.3 Transportation by Road/Railway (RID/ADR)

<u>UN number</u>: 3077 <u>Class</u>: 9 <u>Packing group</u>: III <u>Labels</u>: 9

Limited Quantity: LQ27 (6 Kg/30 Kg for combined, 6 Kg/20 Kg for bandaged trays).

External package type: carton (4G) both for simple and combined packages; <u>Proper shipping name</u>: Environmentally hazardous substance, solid, n.o.s.

SECTION 15 (Classification according to communitarian directives 67/548/EEC & 99/45/EC)

Regulatory information

Hazard labelling not required.

This product is an exempted medical device (directive 1999/45/EC, article 1, paragraph 5g).

SECTION 16

Other information

16.1 Risk phrases of all ingredients

- May cause harm to the unborn child.
- Possible risk of impaired fertility.
- 50/53 Very toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment.
- Harmful to aquatic organisms
- May cause long-term adverse effects in the aquatic environment.

16.1.1 Safety phrases of all ingredients

- 23 Do not breathe vapour
- This material and its container must be disposed of as hazardous waste
- Avoid release to the environment. Refer to special instructions / safety data sheets.

16.2 Sources of key data used to compile the Safety Data Sheet:

European Chemicals Bureau (ECB – www.ecb.jrc.it)

European chemical Substances Information System (ESIS - www.ecb.jrc.it/esis)

A.C.G.I.H. (www.acgih.org)

N.I.OS.H. (www.cdc.gov/niosh/)

O.S.H.A. (www.osha.gov/)

U.E. (www.europa.eu/index it.htm)

I.A.R.C. (www.iarc.fr/)

N.T.P. (www.ntp.niehs.nih.gov)

European Community Directives:

67/548/EEC:	Classification, packaging and labelling of dangerous substances.
99/45/EC:	Directive concerning the approximation of the laws, regulations and administrative
	provisions of the Member States relating to the classification, packaging and labelling of
	dangerous preparations.
2001/58/EC:	Second amendment of directive 91/155/EEC for the definition of a detailed arrangement
	of specific information relating to dangerous preparations (art. 14 of 99/45/EC) and
	substances (art. 27 of 67/548/EEC).
89/656/EEC:	Directive on the minimum health and safety requirements for the use by workers of
	personal protective equipment at the workplace (third individual directive within the
	meaning of Article 16 (1) of Directive 89/391/EEC).
89/686/EEC:	Approximation of the laws of the Member States relating to personal protective
	equipment.
94/9/EC:	Approximation of the laws of the Member States concerning equipment and protective
	systems intended for use in potentially explosive atmospheres
98/24/EC:	Protection of the health and safety of workers from the risks related to chemical agents at
	work.

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Document modification history:

15th September 2008 First version in compliance of Community Regulation 2006/1907/EC

(R.E.A.Ch.)

28th May 2009 <u>Second revision</u>: Change in transport hazard classification (Section 14).

CAUTION: PRODUCT FOR PROFESSIONAL USE

The information on this Safety Sheet is based on presently available data and to our best knowledge for the correct handling of the product under normal conditions. Any use of this product in any way not indicated on this Sheet or the use of this product together with any other process/procedure will be exclusively under the user's responsibility. This document does not constitute explicit or implicit warranty of product quality or fitness for a particular purpose.