

# KERR

## Material Safety Data Sheet

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

Revision Date: 08<sup>th</sup> April 2008

### SECTION 1

#### Product & Company identification

1.1 Product name

**MAXCEM ELITE (Base & Catalyst)**

1.2 Uses/Application:

Resin based dental cement.

1.3 Company (Name, address and info phone number)

**Kerr Corporation**

1717 West Collins Avenue

92867 Orange – CALIFORNIA (U.S.A.)

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](mailto:safety@kerrhawe.com)

### SECTION 2

#### Hazard identification

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

Sensitizing.

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 INGREDIENTS	%	HAZARD SYMBOLS	RISK PHRASES	CAS N.	EINECS N.
HydroxyEthylMethAcrylate (HEMA)	2-5	Xi	36/38-43	868-77-9	212-782-2
4 Methoxyphenol (MEHQ)	< 1	Xn; Xi	22-36-43	150-76-5	205-769-8
Cumene HydroPerOxide (CHPO)	< 1	O; T; N	7-23-21/22-48/20/22-34-51-53	80-15-9	201-254-7

3.2 Other non-hazardous ingredients

Uncured Methacrylate Ester Monomers, Titanium Dioxide (TiO<sub>2</sub>) and pigments.

**SECTION 4****First aid measures**

- 4.1 Treatment for eye contact: Flush with water for 15 minutes including under eyelids.
- 4.2 Treatment for skin contact: Wash thoroughly with soap and water.
- 4.3 Treatment for inhalation (breathing): Remove to fresh air-get medical attention if discomfort persists.
- 4.4 Treatment for ingestion (swallowing): Rinse mouth out with water—do not introduce vomiting. Seek medical attention.

**SECTION 5****Fire-fighting Measures**

- 5.1 Suitable extinguishing media: Chemical foam, CO<sub>2</sub>, dry chemical.
- 5.2 Forbidden extinguishing media: Unknown.
- 5.3 Special fire fighting measures: None. Wear self-contained breathing apparatus.
- 5.4 Unusual fire and explosion hazards: Heat can cause polymerization with rapid release of energy.
- 5.5 Special protection equipment: Sealed overall against liquids and gases.

**SECTION 6****Accidental Release Measures**

- 6.1 Personal Precautions: Adopt the same precautions of section 8.
- 6.2 Environmental Precautions: Keep spilled material out of sewers.
- 6.3 Reclaiming Methods: Absorb spills with inert material.

**SECTION 7****Handling and Storage** (according to article 5 of communitarian directive 98/24/EC)

- 7.1 Handling Precautions: Keep away from sources of ignition. Adopt precautions listed in section 8.
- 7.2 Precautions in case of Fire and Explosion: None particular.
- 7.3 Storage Conditions: Store in a cool, dry place away from heat, light and ignition sources.
- 7.4 Suggested container(s): The original containers provided by manufacturer.
- 7.5 Indication for Combined Storage: Avoid the contact with reducing and oxidizing agents, peroxides and amines.
- 7.6 Environmental precautions: Avoid contamination of sewers with product.
- 7.7 Other Precautions: Use according to directions and good personal hygiene and safety practices.

**SECTION 8****Exposure controls/personal protection**

8.1 Exposure Limits:	TWA/TLV (MEHQ): 1 ppm (5 mg/m <sup>3</sup> )
8.2 Exposure control measures	
8.2.1 Precautionary Measures: (according to communitarian directives 89/686/EEC & article 4 of 98/24/EC)	
Ventilation:	<u>Local Exhaust Ventilation</u> : Good general ventilation should be sufficient to control airborne levels of vapours released by uncured material. <u>Special Ventilation</u> : None required. <u>Mechanical (General) Ventilation</u> : Good general ventilation recommended. <u>Other Ventilation</u> : None required.
Respiratory Protection:	Avoid prolonged or excessive breathing of vapours of uncured material.
Hands Protection:	Impervious rubber gloves recommended when contacting uncured material.
Eyes Protection:	Safety glasses.
Skin Protection:	Handle in accordance with good personal hygiene and safety practices. These practices include avoiding unnecessary exposure to uncured material.
Other Protective Equipments:	It would be better use a lab coat.
<i>Measures listed in this paragraph are to be consider as indications and NOT as prescriptions (89/656/EEC)</i>	
8.2.2 Environment exposure control measures	
Not Applicable.	

**SECTION 9****Physical and Chemical Properties**

9.1 General information	
<u>Appearance</u> : Colored paste.	<u>Odour</u> : Slight Peppermint odour.
9.2 Information related to health, safety and environment	
<u>pH</u> : Not applicable (N/A)	<u>Relative density</u> : Not available
<u>Boiling point</u> : Not applicable	<u>Specific gravity</u> : 2,5 g/ml
<u>Flash point</u> : Not applicable	<u>Solubility</u> : Insoluble
<u>Flammability</u> : Not applicable.	<u>Partition coefficient n-octanol/water</u> : N/A
<u>Lower Explosivity Limit (L.E.L.)</u> : N/A	<u>Viscosity</u> : Not applicable
<u>Upper Explosivity Limit (U.E.L.)</u> : N/A	<u>Vapor density (air = 1)</u> : N/A
<u>Oxidizing properties</u> : None	<u>Evaporation rate (n-butane = 1)</u> : Not applicable
<u>Vapour pressure</u> : Not applicable	<u>Melting point</u> : Not determined
9.3 Other information (according to communitarian directive 94/9/EC):	
<u>Miscibility</u> : N/D.	<u>Conducibility</u> : N/D
<u>Solubility in Lipids</u> : Not available	<u>Gases Group</u> : N/A

**SECTION 10****Stability and Reactivity**

Stability: Stable if stored as directed.

10.1 Conditions to avoid: Heat, light, aging and contamination.

10.2 Materials to avoid (incompatibility): Reducing and oxidizing agents, peroxides and amines.

10.3 Hazardous decomposition products: Oxides of Carbon.

Other precautions:

Hazardous Polymerization Products: Not determined

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

Stabilizers: Product is stabilized with MEHQ (see section 3.1)

**SECTION 11****Toxicological Information**

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

None.

Effects and hazards of eye contact: May cause irritation and damage if not removed promptly.

Effects and hazards of skin contact: Prolonged or repeated exposure to uncured material may cause irritation or skin rash especially in sensitive individuals.

Effects and hazards of Inhalation (Breathing): Prolonged or excessive inhalation may cause respiratory tract irritation.

Effects and hazards of Ingestion (Swallowing): Uncured material may be harmful or fatal if swallowed.

Effects for prolonged Exposure: Not applicable.

Toxic-kinetic effects: Unknown.

Effects on metabolism: Unknown.

Toxicological data for ingredients:

<b>HEMA</b>	LD <sub>50</sub> (oral rat)	> 5000 mg/Kg
	LD <sub>50</sub> (skin rabbit)	> 3000 mg/Kg
	LC <sub>50</sub> (inhalation rat/3 weeks)	> 0,5 mg/Kg
<b>MEHQ</b>	LD <sub>50</sub> (oral rat)	1600 mg/Kg
	LD <sub>50</sub> (intraperitoneal mouse)	250 mg/Kg
	LD <sub>50</sub> (skin rabbit)	6 g/12D-I (Std Draize)

**KERR**Material Safety Data Sheet for: **MAXCEM ELITE**

<b>CHPO</b>	LD <sub>50</sub> (oral rat)	382 mg/Kg
	LD <sub>50</sub> (skin rat)	500 mg/Kg
	LC <sub>50</sub> (inhalation mouse/4 hours)	200 ppm
<b>Titanium Dioxide</b>	LD <sub>50</sub> (oral rat)	> 20000 mg/Kg
	LD <sub>50</sub> (skin rabbit)	> 10000 mg/Kg
	LC <sub>50</sub> (inhalation rat/4hrs)	> 6,8 mg/l

**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: Not available

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

12.6 Other adverse effects: Not available

Aquatic toxicity data for ingredients:

<b>HEMA</b> Easily biodegradable: 84% (OCSE 301D, closed bottle test, 28 days)	LC <sub>50</sub> (Fish, Oryzias Latipes)	> 100 mg/l (OCSE 203, 96h)
	LC <sub>50</sub> (Fish, Oryzias Latipes)	> 100 mg/l (OCSE 204, 14 days)
	NOEC (Daphnia magna)	24,1 mg/l (OCSE 202/2, 21 days)
	EC <sub>50</sub> (Daphnia magna)	380 mg/l (OCSE 202/1, 48h)
	EC <sub>50</sub> (Selenastrum Copricornutum)	345 mg/l (OCSE 201, 72h)
	EC <sub>50</sub> (Pseudomonas fluorescens)	> 3000 mg/l (DEV LB, 16h)
<b>MEHQ</b>	LC <sub>50</sub> (Oryzias Latipes)	> 100 mg/l (OCSE 203, 96h)
	LD <sub>50</sub> (intraperitoneal mouse)	250 mg/Kg
	LD <sub>50</sub> (skin rabbit)	6 g/12D-I (Std Draize)
<b>Titanium Dioxide</b>	LC <sub>50</sub> (Leuciscus Idus)	> 1000 mg/l (48 hours)
	EC <sub>50</sub> (Daphnia magna, crustacea)	> 3 mg/l (30days)
	EC <sub>50</sub> (Pseudomonas fluorescens)	> 10000 mg/l (24 hours)

**SECTION 13****Disposal considerations**

Dispose of in accordance of local regulations.

**SECTION 14****Transport information**14.1 Sea transportation (IMDG)

The product is not regulated.

14.2 Air transportation (ICAO/IATA)

The product is not regulated.

14.3 Transportation by Road/Railway (RID/ADR)

The product is not regulated.

**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

- |          |  |
|----------|--|
| 7        | May cause fire.  |
| 21/22    | Harmful in contact with the skin and if swallowed.   |
| 23       | Toxic by inhalation.   |
| 34       | Causes burns.  |
| 36/38    | Irritating to eyes and skin.   |
| 43       | May cause sensitisation by skin.   |
| 48/20/22 | Harmful: danger of serious damage to health by prolonged exposure through inhalation and if swallowed. |
| 51/53    | Toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment.            |

16.1.1 Safety phrases of all ingredients

- |    |   |
|----|---|
| 15 | Keep away from heat.  |
| 37 | Wear suitable gloves.   |
| 46 | If swallowed, seek medical advice immediately and show this container or label. |
| 49 | Keep only in the original container.  |

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

European Chemicals Bureau (ECB – [www.ecb.jrc.it](http://www.ecb.jrc.it))

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

A.C.G.I.H. ([www.acgih.org](http://www.acgih.org))

N.I.O.S.H. ([www.cdc.gov/niosh/](http://www.cdc.gov/niosh/))

O.S.H.A. ([www.osha.gov/](http://www.osha.gov/))

U.E. ([www.europa.eu/index\\_it.htm](http://www.europa.eu/index_it.htm))

I.A.R.C. ([www.iarc.fr/](http://www.iarc.fr/))

N.T.P. ([www.ntp.niehs.nih.gov](http://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.

Document modification history: First version in compliance of Community Regulation 2006/1907/EC (R.E.A.C.H.)

**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.

# KERR

## Material Safety Data Sheet

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

Revision Date: 19<sup>th</sup> September 2008

### SECTION 1

#### Product & Company identification

1.1 Product name

**TEMP BOND N.E. ACCELERATOR (Tubes & dual syringes)**

1.2 Uses/Application:

Dental Temporary Cement

1.3 Company (Name, address and info phone number)

**KERR ITALIA S.r.l.**

Via Passanti, 332

84018 Scafati (SA) - Italy

Free Phone: 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](mailto:safety@kerrhawe.com)

### SECTION 2

#### Hazard identification

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

None

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 INGREDIENTS	%	HAZARD SYMBOLS	RISK PHRASES	CAS N.	EINECS N.
(R)-p-mentha-1,8-diene	<1	Xi; N	10-38-43-50/53	5989-27-5	227-813-5
Zinc Acetate dihydrate	0-1,5	Xn; Xi	22-36	5970-45-6	-

3.2 Other non-hazardous ingredients

Rosin, oligomers (NLP).



**SECTION 4****First aid measures**

4.1 Treatment for eye contact: Flush with water for at least 15 minutes.

4.2 Treatment for skin contact: Wash with soap and water.

4.3 Treatment for inhalation (breathing): Remove to fresh air.

4.4 Treatment for ingestion (swallowing): Consult a physician.

**SECTION 5****Fire-fighting Measures**

5.1 Suitable extinguishing media: Carbon dioxide, foam, dry chemical.

5.2 Forbidden extinguishing media: None.

5.3 Special fire fighting measures: None.

5.4 Unusual fire and explosion hazards: None.

5.5 Special protection equipment: Mask with self breathing apparatus.

**SECTION 6****Accidental Release Measures**

6.1 Personal Precautions: Adopt precautions listed in following sections (VII and VIII).

6.2 Environmental Precautions: None particular.

6.3 Reclaiming Methods: Absorb spill with towels and transfer to suitable containers.

**SECTION 7****Handling and Storage** (according to article 5 of communitarian directive 98/24/EC)

7.1 Handling Precautions: Use protective clothes listed in Section VIII. Wash after handling.

7.2 Precautions in case of Fire and Explosion: None in particular.

7.3 Storage Conditions: Store in a cool and dry place.

7.4 Suggested container(s): The original containers provided by manufacturer.

7.5 Indication for Combined Storage: Not available.

7.6 Environmental precautions: Not applicable.

7.7 Other Precautions: Use according to directions and good personal hygiene and safety practices. Do not invert caps on tubes as this will cause hardening of material in the tubes. (Refers to tubed variety only).

**SECTION 8****Exposure controls/personal protection**

8.1 Exposure Limits:	TWA: Not Applicable; TLV: Not Applicable
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**8.2 Exposure control measures****8.2.1 Precautionary Measures:***(according to communitarian directives 89/686/EEC & article 4 of 98/24/EC)*

Ventilation:	<u>Local Exhaust Ventilation</u> : Recommended. <u>Special Ventilation</u> : None. <u>Mechanical (General) Ventilation</u> : None. <u>Other Ventilation</u> : None.
Respiratory Protection:	Avoid breathing of vapours. If concentration exceeds the limits, wear a suitable mask with approved filter for organic vapours.
Hands Protection:	Gloves (neoprene or vinyl type) may be used to avoid skin contact.
Eyes Protection:	Safety glasses or goggles optional.
Skin Protection:	Handle in accordance with good personal hygiene and safety practices. These practices include avoiding unnecessary exposure.
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**

<u>Appearance</u> : Amber paste.	<u>Odour</u> : Faint odour.
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**9.2 Information related to health, safety and environment**

<u>pH</u> : Not applicable (N/A)	<u>Relative density</u> : Not available
<u>Boiling point</u> : Not established	<u>Specific gravity</u> : > 1 g/ml
<u>Flash point</u> : Not applicable	<u>Solubility</u> : Insoluble
<u>Flammability</u> : Not flammable.	<u>Partition coefficient n-octanol/water</u> : N/A
<u>Lower Explosivity Limit (L.E.L.)</u> : N/A	<u>Viscosity</u> : Not determined
<u>Upper Explosivity Limit (U.E.L.)</u> : N/A	<u>Vapor density (air = 1)</u> : N/A
<u>Oxidizing properties</u> : None	<u>Evaporation rate (n-butane = 1)</u> : Not available
<u>Vapour pressure</u> : Not determined (N/D)	<u>Melting point</u> : N/A

**9.3 Other information (according to communitarian directive 94/9/EC):**

<u>Miscibility</u> : N/D.	<u>Conducibility</u> : N/D
<u>Solubility in Lipids</u> : Not available	<u>Gases Group</u> : N/A

**SECTION 10****Stability and Reactivity**

Stability: Stable.

10.1 Conditions to avoid: Excessive heat.

10.2 Materials to avoid (incompatibility): Not applicable.

10.3 Hazardous decomposition products: Not applicable.

Other precautions:

Hazardous Polymerization Products: Not applicable

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

Stabilizers: Product is not required to be stabilized.

**SECTION 11****Toxicological Information**

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

None.

Effects and hazards of eye contact: May cause damages to the eyes if not removed promptly.

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

Effects and hazards of Inhalation (Breathing): May cause irritation to the throat and respiratory tract.

Effects and hazards of Ingestion (Swallowing): May be harmful if swallowed in large quantities.

Effects for prolonged Exposure: Repeated contact may cause allergic dermatitis in sensitive individuals.

Toxic-kinetic effects: Unknown.

Effects on metabolism: Unknown.

Toxicological data for ingredients:

<b>(R)-p-mentha-1,8-diene</b>	LD <sub>50</sub> (oral rat)	> 4800 mg/Kg
	LD <sub>50</sub> (skin rabbit)	> 5000 mg/Kg
<b>n-Octanoic Acid</b> (Acute toxicity)	LD <sub>50</sub> (oral rat)	10080 mg/Kg
	LD <sub>50</sub> (intravenous mouse)	600 mg/Kg
	LD <sub>50</sub> (skin rabbit)	> 5000 mg/Kg
<b>(Dermal irritation, RTECS)</b>	LD <sub>50</sub> (skin rabbit)	500 mg/Kg (24 hours)

**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: Not available

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

12.6 Other adverse effects: Not available

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Aquatic toxicity data for ingredients:

None

**SECTION 13****Disposal considerations**

Dispose of in accordance of local regulations.

**SECTION 14****Transport information**

14.1 Sea transportation (IMDG)

The product is not regulated.

14.2 Air transportation (ICAO/IATA)

The product is not regulated.

14.3 Transportation by Road/Railway (RID/ADR)

The product is not regulated.

**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

43 May cause sensitisation by skin contact.

10 Flammable

**KERR**      Material Safety Data Sheet for: **TEMP BOND N.E. Accelerator (tubes & dual syringes)**

- 38      Irritating to skin.  
22      Harmful if swallowed.  
36      Irritating to eyes.  
50/53   Very toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment.

**16.1.1 Safety phrases of all ingredients**

- 24/25   Avoid contact with skin and eyes.  
37/39   Wear suitable gloves and eye/face protection.

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

European Chemicals Bureau (ECB – [www.ecb.jrc.it](http://www.ecb.jrc.it))  
European chemical Substances Information System (ESIS - [www.ecb.jrc.it/esis](http://www.ecb.jrc.it/esis))  
A.C.G.I.H. ([www.acgih.org](http://www.acgih.org))  
N.I.O.S.H. ([www.cdc.gov/niosh/](http://www.cdc.gov/niosh/))  
O.S.H.A. ([www.osha.gov/](http://www.osha.gov/))  
U.E. ([www.europa.eu/index\\_it.htm](http://www.europa.eu/index_it.htm))  
I.A.R.C. ([www.iarc.fr/](http://www.iarc.fr/))  
N.T.P. ([www.ntp.niehs.nih.gov](http://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.

**Document modification history:** First version in compliance of Community Regulation 2006/1907/EC (R.E.A.Ch.)

**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.

# KERR

## Material Safety Data Sheet

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

Revision Date: 19<sup>th</sup> September 2008

### SECTION 1

#### Product & Company identification

1.1 Product name

**TEMP BOND BASE N.E. (tubes and dual syringes)**

1.2 Uses/Application:

Dental temporary cement.

1.3 Company (Name, address and info phone number)

**KERR ITALIA S.r.l.**

Via Passanti, 332

84018 Scafati (SA) - Italy

Free Phone: 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](mailto:safety@kerrhawe.com)

### SECTION 2

#### Hazard identification

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

Dangerous for environment.

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 INGREDIENTS	%	HAZARD SYMBOLS	RISK PHRASES	CAS N.	EINECS N.
Zinc Oxide (ZnO)	85-90	N	50/53	1314-13-2	215-222-5

3.2 Other non-hazardous ingredients

None.

**SECTION 4****First aid measures**

4.1 Treatment for eye contact: Flush with water for at least 15 minutes.

4.2 Treatment for skin contact: Wash with soap and water.

4.3 Treatment for inhalation (breathing): None.

4.4 Treatment for ingestion (swallowing): Consult a physician.

**SECTION 5****Fire-fighting Measures**

5.1 Suitable extinguishing media: Carbon dioxide, foam, dry chemical.

5.2 Forbidden extinguishing media: Not applicable.

5.3 Special fire fighting measures: Not applicable.

5.4 Unusual fire and explosion hazards: Not applicable.

5.5 Special protection equipment: Not applicable.

**SECTION 6****Accidental Release Measures**

6.1 Personal Precautions: Adopt precautions listed in following sections (VII and VIII).

6.2 Environmental Precautions: Do not allow product reaching rivers or sewers and avoid soil contamination. Avoid dust formation which could be spread by wind.

6.3 Reclaiming Methods: 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: Adopt precautions listed in following sections (VII and VIII).

7.2 Precautions in case of Fire and Explosion: Not applicable.

7.3 Storage Conditions: Store at ambient temperature.

7.4 Suggested container(s): The original containers provided by manufacturer.

7.5 Indication for Combined Storage: Not available.

7.6 Environmental precautions: Store in a dry place far from sewers and water.

7.7 Other Precautions: Use according to directions and good personal hygiene and safety practices. Do not invert caps on tubes as this will cause hardening of material in the tubes. (Refers to tubed variety only).



**SECTION 8****Exposure controls/personal protection**

8.1 Exposure Limits:	ZnO: TWA: 0,6 ppm (2 mg/m <sup>3</sup> ); TLV: 3 ppm (10 mg/m <sup>3</sup> ); Corn Starch TWA: 10 mg/m <sup>3</sup>
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**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: Not necessary. Special Ventilation: None. Mechanical (General) Ventilation: None. Other Ventilation: None.
Respiratory Protection:	None required.
Hands Protection:	Use of disposable vinyl gloves is optional.
Eyes Protection:	Safety glasses or goggles optional.
Skin Protection:	Handle in accordance with good personal hygiene and safety practices.
Other Protective Equipments:	Not applicable (use of a lab coat is optional).

*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: Odourless.
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**9.2 Information related to health, safety and environment**

pH: Not applicable (N/A)	Relative density: Not available
Boiling point: Not applicable	Specific gravity: > 1 g/ml
Flash point: Not applicable	Solubility: Insoluble
Flammability: Not flammable.	Partition coefficient n-octanol/water: N/A
Lower Explosivity Limit (L.E.L.): N/A	Viscosity: Not applicable
Upper Explosivity Limit (U.E.L.): N/A	Vapor density (air = 1): N/A
Oxidizing properties: None	Evaporation rate (n-butane = 1): Not applicable
Vapour pressure: > 1	Melting point: Not applicable

**9.3 Other information (according to communitarian directive 94/9/EC):**

Miscibility: N/D.	Conducibility: N/D
Solubility in Lipids: Not available	Gases Group: N/A



**SECTION 10****Stability and Reactivity**

Stability: Stable.

10.1 Conditions to avoid: Avoid contact with strong acids.

10.2 Materials to avoid (incompatibility): Strong acids (Nitric acid).

10.3 Hazardous decomposition products: When in contact with Nitric acid, may generate Nitrous oxide.

Other precautions:

Hazardous Polymerization Products: Will not occur

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

Stabilizers: Product is not required to be stabilized.

**SECTION 11****Toxicological Information**

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

None.

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

Effects and hazards of skin contact: Prolonged exposure may cause a mild irritation.

Effects and hazards of Inhalation (Breathing): It is an unlikely event.

Effects and hazards of Ingestion (Swallowing): May cause gastric pain.

Effects for prolonged Exposure: Not determined.

Toxic-kinetic effects: Unknown.

Effects on metabolism: Unknown.

Toxicological data for ingredients:

<b>ZnO</b>		
(Acute toxicity):	LD <sub>50</sub> (oral mouse)	7950 mg/Kg
	LD <sub>50</sub> (skin rat)	> 2000 mg/Kg
	LD <sub>Lo</sub> (oral human)	500 mg/Kg
	LC <sub>50</sub> (inhalation rat/4hrs)	> 5700 mg/m <sup>3</sup> (4 hrs)

**SECTION 12****Ecological Information**

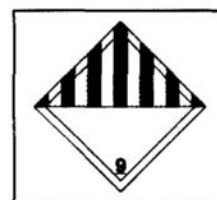
Refer to data regarding Zinc Oxide.

12.1 Eco-toxicity: Not available12.2 Mobility: Not available12.3 Persistence and degradability: Not available12.4 Bioaccumulative potential: Not available12.5 Results of PBT (Persistent Bio-Toxicity) assessment: Not available12.6 Other adverse effects: Not availableAquatic toxicity data for ingredients:**ZnO**

(Acute toxicity):	EC <sub>50</sub> (Daphnia magna)	> 1000 mg/l (48 hrs)
	LC <sub>50</sub> (Oncorhynchus mykiss)	1,1 mg/l (96 hrs)
	LC <sub>50</sub> (Lepomis macrochirus)	> 320 mg/l (96 hrs)
	LC <sub>50</sub> (Pimephales promelas)	2246 mg/l (96 hrs)
	EC <sub>50</sub> (Selenastrum capricornutum)	0,17 mg/l (72 hr; Lisec 1997)

**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-FStowage/segregation: Category A;      Limited Quantity: 5KgProper shipping name: Environmentally hazardous substance, solid, n.o.s.14.2 Air transportation (ICAO/IATA)UN number: 3077;      Class: 9;      Packing group: III;      Label: 9Maximum quantities: No limits (both for Passenger Aircraft and Cargo Aircraft only)Limited Quantity: 30Kg (G);Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Zinc Oxide)14.3 Transportation by Road/Railway (RID/ADR)UN number: 3077;      Class: 9;      Packing group: III (12°C);      Hazard identification n°: 90      Label: 9Proper shipping name: Environmentally hazardous substance, solid, n.o.s.Limited Quantity: LQ27 (6Kg/30Kg for combined, 6Kg/20Kg for bandaged trays).

**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

50/53 Very toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment.

16.1.1 Safety phrases of all ingredients

60 This material and its container must be disposed of as hazardous waste

61 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](http://www.ecb.jrc.it))

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

A.C.G.I.H. ([www.acgih.org](http://www.acgih.org))

N.I.O.S.H. ([www.cdc.gov/niosh/](http://www.cdc.gov/niosh/))

O.S.H.A. ([www.osha.gov/](http://www.osha.gov/))

U.E. ([www.europa.eu/index\\_it.htm](http://www.europa.eu/index_it.htm))

I.A.R.C. ([www.iarc.fr/](http://www.iarc.fr/))

N.T.P. ([www.ntp.niehs.nih.gov](http://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.

Document modification history: First version in compliance of Community Regulation 2006/1907/EC (R.E.A.Ch.)

**KERR**

**Material Safety Data Sheet for: TEMP BOND BASE N.E. (tubes and dual syringes)**

**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.**