KERR

Material Safety Data Sheet

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

Revision Date: 09th September 2008

SECTION 1

Product & Company identification

1.1 Product name

NX3 DUAL CURE (Base & Catalyst)

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

Dental luting material.

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

SECTION 2

Hazard identification

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

2.2 Other hazard

Uncured material may be harmful if swallowed.

SECTION 3

Composition/Information on Ingredients

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

3.1 <u>Hazardous ingredients</u>

HAZARDOUS	%	HAZARD	RISK PHRASES	CAS N.	EINECS
INGREDIENTS		SYMBOLS			N.
HydroxyEthylMethAcrylate	*	Xi	36/38-43	868-77-9	212-782-2
(HEMA)					
2-PyridylThioUrea (PTU)**	< 1	Xn	20/21/22	14294-11-2	-
Cumene HydroPerOxide			7-23-21/22-		
(CHPO)***	< 1	O; T; N	48/20/22-34-51/53	80-15-9	201-254-7

^{* 0.5-2.5%} in Base, 2-5.5% in Catalyst;

3.2 Other non-hazardous ingredients

Uncured Methacrylate Ester Monomers, Titanium Dioxide (TiO₂) and pigments.

^{**} Contained only in Base;

^{**} Contained only in Catalyst.

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.
- <u>4.4 Treatment for ingestion (swallowing)</u>: Rinse mouth out with water—do not induce vomiting. Seek medical attention.

SECTION 5

Fire-fighting Measures

- 5.1 Suitable extinguishing media: Chemical foam, CO₂, 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.
- <u>5.5 Special protection equipment:</u> Sealed overall against liquids and gases.

SECTION 6

Accidental Release Measures

- 6.1 Personal Precautions: Adopt 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 and ignition sources.
- 7.4 Suggested container(s): The original containers provided by manufacturer.
- <u>7.5 Indication for Combined Storage</u>: 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: Not available		
8.2 Exposure control measures			
8.2.1 Precautionary Meas	ures:		
(according to communita	arian directives 89/686/EEC & article 4 of 98/24/EC)		
Ventilation:	Local Exhaust Ventilation: Good general ventilation should be sufficient to control airborne levels of vapours released by uncured material.		
	Special Ventilation: None required.		
	Mechanical (General) Ventilation: Good general ventilation recommended.		
	Other Ventilation: 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 to 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: Pigmented paste.	Odour: Slight Peppermint odour.	
9.2 Information related to health, safety and envir	ronment	
<u>pH</u> : Not applicable (N/A)	Relative density: Not available	
Boiling point: Not applicable	Specific gravity: 2,0 – 2,5 g/ml	
Flash point: Not applicable	Solubility: Insoluble	
Flammability: Not applicable.	Partition coefficient n-octanol/water: N/A	
Lower Explosivity Limit (L.E.L.): N/A	<u>Viscosity</u> : Not applicable	
<u>Upper Explosivity Limit (U.E.L.)</u> : N/A	Vapor density (air = 1): N/A	
Oxidizing properties: None	Evaporation rate (n-butane = 1): Not applicable	
Vapour pressure: Not applicable	Melting point: Not determined	
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	

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SECTION 10

Stability and Reactivity

Stability: Stable if stored as directed.

10.1 Conditions to avoid: Heat, aging, thermal stress and contamination.

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

10.3 Hazardous decomposition products: Carbon Oxides.

Other precautions:

Hazardous Polymerization Products: Not determined

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

Stabilizers: The product is stabilized with non-hazardous polymerization inhibitors.

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.

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

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

Effects for prolonged Exposure: Not applicable.

<u>Toxic-kinetic effects</u>: Unknown.

Effects on metabolism: Unknown.

Toxicological data for ingredients:

HEMA	LD ₅₀ (oral rat)	> 5000 mg/Kg
	LD ₅₀ (skin rabbit)	> 3000 mg/Kg
	LC ₅₀ (inhalation rat/3 weeks)	> 0,5 mg/Kg
СНРО	LD ₅₀ (oral rat)	382 mg/Kg
	LD ₅₀ (skin rat)	500 mg/Kg
	LC ₅₀ (inhalation mouse/4 hours)	200 ppm

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Titanium Dioxide	LD ₅₀ (oral rat)	> 20000 mg/Kg
	LD ₅₀ (skin rabbit)	> 10000 mg/Kg
	LC ₅₀ (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:

HEMA	LC ₅₀ (Fish, Oryzias Latipes)	> 100 mg/l (OCSE 203, 96h)	
Easily biodegradable: 84%	LC ₅₀ (Fish, Oryzias Latipes)	> 100 mg/l (OCSE 204, 14 days)	
(OCSE 301D, closed bottle	NOEC (Daphnia magna)	24,1 mg/l (OCSE 202/2, 21 days)	
test, 28 days)			
	EC ₅₀ (Daphnia magna)	380 mg/l (OCSE 202/1, 48h)	
	EC ₅₀ (Selenastrum Copricornutum)	345 mg/l (OCSE 201, 72h)	
	EC ₅₀ (Pseudomonas fluorescens)	> 3000 mg/l (DEV LB, 16h)	
Titanium Dioxide	LC ₅₀ (Leuciscus Idus)	> 1000 mg/l (48 hours)	
	EC ₅₀ (Daphnia magna, crustacea)	> 3 mg/l (30days)	
	EC ₅₀ (Pseudomonas fluorescens)	> 10000 mg/l (24 hours)	

SECTION 13

Disposal considerations

Unpolymerized (uncured) material may be hazardous waste. 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.

7 May cause fire.

20/21/22 Harmful by inhalation, in contact with the skin and if swallowed.

Toxic by inhalation.

Causes burns.

36/38 Irritating to eyes and skin.

48/20/22 Harmful: danger of serious damage to health by prolonged exposure through inhalation and if

swallowed.

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.
- 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)

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).	

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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.

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

CAUTION: PRODUCT FOR PROFESSIONAL USE

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