

KERR

Material Safety Data Sheet

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

Revision Date: 12th September 2008

SECTION 1

Product & Company identification

1.1 Product name

NX3 LIGHT CURE

1.2 Uses/Application:

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 Hazard classification (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 Hazardous ingredients

HAZARDOUS INGREDIENTS	%	HAZARD SYMBOLS	RISK PHRASES	CAS N.	EINECS N.
HydroxyEthylMethAcrylate (HEMA)	0,8-1,5	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

3.2 Other non-hazardous ingredients

Uncured Methacrylate Ester Monomers, Titanium Dioxide (TiO₂) 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 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.
- 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	
<i>8.1 Exposure Limits:</i>	<u>TWA/TLV</u> (MEHQ): 1ppm (5 mg/m ³)
<i>8.2 Exposure control measures</i>	
<i>8.2.1 Precautionary Measures:</i> (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 to use a lab coat.
<i>Measures listed in this paragraph are to be considered as indications and NOT prescriptions (89/656/EEC)</i>	
<i>8.2.2 Environment exposure control measures</i> Not Applicable.	

SECTION 9 Physical and Chemical Properties	
<i>9.1 General information</i>	
<u>Appearance:</u> Pigmented paste.	<u>Odour:</u> Slight Peppermint odour.
<i>9.2 Information related to health, safety and environment</i>	
<u>pH:</u> Not applicable (N/A)	<u>Relative density:</u> Not available
<u>Boiling point:</u> Not applicable	<u>Specific gravity:</u> 2,0 – 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
<i>9.3 Other information (according to communitarian directive 94/9/EC):</i>	
<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: 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.

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 if swallowed.

Effects for prolonged Exposure: Not applicable.

Toxic-kinetic effects: 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
MEHQ	LD ₅₀ (oral rat)	1600 mg/Kg
	LD ₅₀ (intraperitoneal mouse)	250 mg/Kg
	LD ₅₀ (skin rabbit)	6 g/12D-I (Std Draize)

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 Easily biodegradable: 84% (OCSE 301D, closed bottle test, 28 days)	LC ₅₀ (Fish, Oryzias Latipes)	> 100 mg/l (OCSE 203, 96h)
	LC ₅₀ (Fish, Oryzias Latipes)	> 100 mg/l (OCSE 204, 14 days)
	NOEC (Daphnia magna)	24,1 mg/l (OCSE 202/2, 21 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.
 36/38 Irritating to eyes and skin.
 22 Harmful if swallowed.

16.1.1 Safety phrases of all ingredients

- 2 Keep out of the reach of children.
 24/25 Avoid contact with skin and eyes.
 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
 28 After contact with skin, wash immediately with plenty of water.
 46 If swallowed, seek medical advice immediately and show this container or label.

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.O.S.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.

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: 27th May 2009

SECTION 1

Product & Company identification

1.1 Product name

LIFE BASE

1.2 Uses/Application:

Dental cavity liner and pulp capping agent.

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

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)	12-17	N	50/53	1314-13-2	215-222-5

3.2 Other non-hazardous ingredients

Calcium Hydroxide (**Ca(OH)₂**), Calcium Oxide (CaO) and Zinc Stearate.

SECTION 4**First aid measures**

- 4.1 Treatment for eye contact: Flush with water for 15-30 minutes. If irritation persists, consult a physician.
- 4.2 Treatment for skin contact: Wash with soap and water.
- 4.3 Treatment for inhalation (breathing): Inhalation of the material, due to its physical form and the modality of use, should be an unlikely event.
- 4.4 Treatment for ingestion (swallowing): If large quantities are ingested, administer large quantities of water or milk if available. Do not induce vomiting. Do not administer anything to unconscious persons. 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: Wash thoroughly after handling.
- 7.2 Precautions in case of Fire and Explosion: Not applicable.
- 7.3 Storage Conditions: Store at ambient temperature. High moisture level may cause material hardening
- 7.4 Suggested container(s): The original containers provided by manufacturer.
- 7.5 Indication for Combined Storage: Avoid contact with strong acids.
- 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**

<i>8.1 Exposure Limits:</i>	ZnO: <u>TWA/TLV:</u> 0,6 ppm (2 mg/m ³); <u>PEL:</u> 3 ppm (10 mg/m ³); CaO: <u>TWA/TLV:</u> 2 mg/m ³ ; Ca(OH)₂: <u>TWA/TLV:</u> 2 mg/m ³ ; Zinc Stearate: <u>TWA/TLV:</u> 10 mg/m ³
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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> Not necessary. <u>Special Ventilation:</u> None. <u>Mechanical (General) Ventilation:</u> None. <u>Other Ventilation:</u> 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*

<u>Appearance:</u> White paste.	<u>Odour:</u> Odourless.
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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 applicable	<u>Specific gravity:</u> N/A
<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 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> N/A
<u>Vapour pressure:</u> N/A	<u>Melting point:</u> N/A

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

<u>Miscibility:</u> N/A.	<u>Conducibility:</u> Not available
<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: Avoid contact with strong acids. High moisture level may cause material hardening.

10.2 Materials to avoid (incompatibility): Strong acids.

10.3 Hazardous decomposition products: Unknown.

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 be irritating by mechanical friction.

Effects and hazards of skin contact: May dry skin.

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

Effects and hazards of Ingestion (Swallowing): May cause irritation to the oral-pharyngeal and digestive tracts. May result in an obstruction.

Effects for prolonged Exposure: Not determined.

Toxic-kinetic effects: Unknown.

Effects on metabolism: Unknown.

Toxicological data for ingredients:

ZnO (Acute toxicity):	LD ₅₀ (oral mouse)	7950 mg/Kg
	LD ₅₀ (skin rat)	> 2000 mg/Kg
	LD _{L0} (oral human)	500 mg/Kg
	LC ₅₀ (inhalation rat/4hrs)	> 5700 mg/m ³ (4 hrs)
Calcium Hydroxide	LD ₅₀ (oral mouse)	7300 mg/Kg

SECTION 12**Ecological Information**

Refer to data regarding Zinc Oxide.

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:

ZnO (Acute toxicity):	EC ₅₀ (Daphnia magna)	> 1000 mg/l (48 hrs)
	LC ₅₀ (Oncorhynchus mykiss)	1,1 mg/l (96 hrs)
	LC ₅₀ (Lepomis macrochirus)	> 320 mg/l (96 hrs)
	LC ₅₀ (Pimephales promelas)	2246 mg/l (96 hrs)
	EC ₅₀ (Selenastrum capricornutum)	0,17 mg/l (72 hr; Lisecc 1997)
Zinc Stearate	LC ₅₀ (Daphnia, 48 hours)	1,7 mg/l

SECTION 13**Disposal considerations**

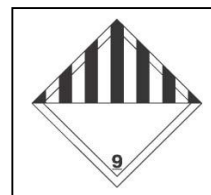
Dispose of in accordance of local regulations.

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; Label: 9

Maximum 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.

14.3 Transportation by Road/Railway (RID/ADR)

UN number: 3077; Class: 9; Packing group: III (12°C); Hazard identification n°: 90 Label: 9

Proper 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)

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

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

N.I.O.S.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.

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: 28th May 2009

SECTION 1

Product & Company identification

1.1 Product name

LIFE CATALYST

1.2 Uses/Application:

Dental cavity liner and pulp capping agent.

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

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.
None	None	None	None	None	None

3.2 Other non-hazardous ingredients

The product contains Methyl Salicylate (See also Sections 11 and 16),

Titanium Dioxide (**TiO₂**) and Barium Sulphate, **BaSO₄**.

SECTION 4**First aid measures**

- 4.1 Treatment for eye contact: Flush eye with water for at least 15 minutes. If irritation persists, consult a physician.
- 4.2 Treatment for skin contact: Wash with soap and water.
- 4.3 Treatment for inhalation (breathing): Inhalation of material, due to its physical form and the intended use, should be an unlikely event.
- 4.4 Treatment for ingestion (swallowing): Consult a physician.

SECTION 5**Fire-fighting Measures**

- 5.1 Suitable extinguishing media: Not applicable.
- 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: None particular.
- 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: Use protective clothes listed in Section 8. Wash after handling.
- 7.2 Precautions in case of Fire and Explosion: None in particular.
- 7.3 Storage Conditions: Store at ambient temperature, in a dry a cool place.
- 7.4 Suggested container(s): The original containers provided by manufacturer.
- 7.5 Indication for Combined Storage: Avoid contact with oxidizing agents.
- 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.

SECTION 8 Exposure controls/personal protection	
<i>8.1 Exposure Limits:</i>	<u>TWA/TLV</u> TiO₂ : 3,1ppm (10mg/m ³); BaSO₄ : 10 (Italy), 0,5 (Denmark), 4 (U.K.)
<i>8.2 Exposure control measures</i>	
<i>8.2.1 Precautionary Measures:</i> (according to communitarian directives 89/686/EEC & article 4 of 98/24/EC)	
Ventilation:	<u>Local Exhaust Ventilation</u> : Not needed. <u>Special Ventilation</u> : None. <u>Mechanical (General) Ventilation</u> : None. <u>Other Ventilation</u> : None.
Respiratory Protection:	None.
Hands Protection:	It's sufficient to use disposable vinyl gloves.
Eyes Protection:	Safety glasses or goggles optional.
Skin Protection:	Handle in accordance with good personal hygiene and safety practices.
Other Protective Equipments:	It would be better use a lab coat.
<i>Measures listed in this paragraph are to be considered as indications and NOT prescriptions (89/656/EEC)</i>	
<i>8.2.2 Environment exposure control measures</i> Not Applicable.	

SECTION 9 Physical and Chemical Properties	
<i>9.1 General information</i>	
<u>Appearance</u> : Slight beige paste.	<u>Odour</u> : Typical odour.
<i>9.2 Information related to health, safety and environment</i>	
<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
<i>9.3 Other information (according to communitarian directive 94/9/EC):</i>	
<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: Unknown.

10.2 Materials to avoid (incompatibility): Strong oxidizing agents.

10.3 Hazardous decomposition products: Unknown.

Other precautions:

Hazardous Polymerization Products: Unknown

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):

The product contains Methyl Salicylate, which has shown evidence of teratogenicity in animals. See also Section 16.

Effects and hazards of eye contact: May cause irritation by mechanical friction.

Effects and hazards of skin contact: May dry skin.

Effects and hazards of Inhalation (Breathing): None.

Effects and hazards of Ingestion (Swallowing): May cause irritation to the oral-pharyngeal and digestive tracts. Ingestion of material may result in an obstruction.

Effects for prolonged Exposure: None.

Toxic-kinetic effects: Unknown.

Effects on metabolism: Unknown.

Toxicological data for ingredients:

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:

Titanium Dioxide	LC ₀ (Leuciscus Idus)	> 1000 mg/l (48 hours)
	EC ₀ (Daphnia magna, crustacea)	> 3 mg/l (30days)
	EC ₀ (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

None.

16.1.1 Safety phrases of all ingredients

None

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.O.S.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)

Evidence of methyl Salicylate teratogenicity in animals:

-Dangerous Properties of Industrial Materials, Ed. Sax & Lewis, 7th Ed.

-Dushyant Gulati et al., Environmental Health Perspectives Supplements Volume 105, Number S1, February 1997.

-George P. Daston et al., Functional Teratogens of the Rat Kidney, Toxicological Sciences, Volume 11, Number 1 - Pp. 381-400, 1988.

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.