Material Safety Data Sheet

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

Revision Date: 20th April 2008

SECTION 1

Product & Company identification

1.1 Product name

CLEANIC without Fluoride

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

Dental prophy paste.

1.3 Company (Name, address and info phone number)

KERRHAWE S.A.

Via Strecce n°4

6934 Bioggio (Switzerland)

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 <u>Hazard classification</u> (according to communitarian directives 67/548/EEC & 99/45/EC) None.

2.2 Other hazard

See TLV of Titanium Dioxide (section 8.1).

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	CAS N.	EINECS N.
INGREDIENTS		SYMBOLS	PHRASES		
None	None	None	None	None	None

3.2 Other non-hazardous ingredients

Titanium Dioxide..

SECTION 4

First aid measures

- 4.1 Treatment for eye contact: Rinse opened eye for several minutes under running water.
- 4.2 Treatment for skin contact: Wash with water.
- 4.3 Treatment for inhalation (breathing): None.
- 4.4 Treatment for ingestion (swallowing): For ingestion of large amounts of material, dilute with water.

SECTION 5

Fire-fighting Measures

- 5.1 Suitable extinguishing media: Water jet.
- 5.2 Forbidden extinguishing media: Unknown.
- 5.3 Special fire fighting measures: Not applicable.
- 5.4 Unusual fire and explosion hazards: Combustion and explosion does not occur.
- 5.5 Special protection equipment: None.

SECTION 6

Accidental Release Measures

- 6.1 Personal Precautions: None.
- <u>6.2 Environmental Precautions:</u> None.
- <u>6.3 Reclaiming Methods:</u> Pick up mechanically and wash with water surface on which the material is spilled.

SECTION 7

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

- 7.1 Handling Precautions: None required.
- 7.2 Precautions in case of Fire and Explosion: The product is not flammable.
- 7.3 Storage Conditions: Store at ambient temperature, in original closed containers.
- <u>7.4 Suggested container(s)</u>: The original containers provided by manufacturer.
- 7.5 Indication for Combined Storage: None.
- 7.6 Environmental precautions: None.
- 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: 3,1 ppm (10mg/m ³): Titanium Dioxide		
8.2 Exposure control measures			
8.2.1 Precautionary Measure.	s:		
	n directives 89/686/EEC & article 4 of 98/24/EC)		
	Local Exhaust Ventilation: None required.		
Ventilation:	Special Ventilation: None.		
	Mechanical (General) Ventilation: None.		
	Other Ventilation: None.		
Respiratory Protection:	None.		
Hands Protection:	None.		
Eyes Protection:	Not necessary.		
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 consider as indications and NOT as prescriptions (89/656/EEC)		
8.2.2 Environment exposure control measures			
Not Applicable.			

SECTION 9			
Physical and Chemical Properties			
9.1 General information			
Appearance: Light blue paste Odour: Mint odour			
9.2 Information related to health, safety and c	environment		
<u>pH</u> : Not applicable (N/A)	Relative density: Not available		
Boiling point: Not applicable	Specific gravity: 1,25 g/ml		
Flash point: Not applicable	Solubility: Insoluble		
<u>Flammability</u> : Not flammable.	Partition coefficient n-octanol/water: N/A		
Lower Explosivity Limit (L.E.L.): N/A	<u>Viscosity</u> : Not determined		
Upper Explosivity Limit (U.E.L.): N/A	<u>Vapour density (air = 1)</u> : N/A		
Oxidizing properties: None	Evaporation rate (n-butane = 1): Not applicable		
Vapour pressure: Not applicable	Melting point: N/A		
9.3 Other information (according to communitarian directive 94/9/EC):			
Miscibility: Not applicable.	Conducibility: N/D		
Solubility in Lipids: Not available	Gases Group: N/A		

SECTION 10

Stability and Reactivity

Stability: Stable.

10.1 Conditions to avoid: Not applicable.

10.2 Materials to avoid (incompatibility): Unknown.

10.3 Hazardous decomposition products: Unknown.

Other precautions:

<u>Hazardous Polymerization Products</u>: 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 a mild irritation for mechanical friction.

Effects and hazards of skin contact. Mild abrasive for continuous contact.

Effects and hazards of Inhalation (Breathing): Inhalation of the material is an improbable event.

Effects and hazards of Ingestion (Swallowing): Large amounts of material may cause a mild irritation to the

throat.

Effects for prolonged Exposure: Unknown.

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
	LC50 (Illiaiation fat/4ills)	/ 0,0 mg/1

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.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.

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

CAUTION: PRODUCT FOR PROFESSIONAL USE

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