

KERRHAWE

Material Safety Data Sheet

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

Revision Date: 20th February 2008

SECTION 1

Product & Company identification

1.1 Product name

CLEANIC with Fluoride, single dose (monodose)

1.2 Uses/Application:

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

Toxic.

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.
Sodium Fluoride	< 0,25	T; Xi	25-32-36/38	7681-49-4	231-667-8

3.2 Other non-hazardous ingredients

Titanium Dioxide.

SECTION 4**First aid measures**

- 4.1 Treatment for eye contact: Flush with 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: The product is not flammable.
- 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.
- 6.2 Environmental Precautions: None.
- 6.3 Reclaiming Methods: Absorb spill with paper towels.

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.
- 7.4 Suggested container(s): The original containers provided by manufacturer.
- 7.5 Indication for Combined Storage: Avoid contact with acids.
- 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:	TLV-TWA: 2,5 mg/m ³ (as Fluorine); 3,1 ppm (10mg/m ³ , Titanium Dioxide)
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> None required. <u>Special Ventilation:</u> None. <u>Mechanical (General) Ventilation:</u> None. <u>Other Ventilation:</u> 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.
<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> Light blue paste	<u>Odour:</u> Mint 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> 1,25 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>Vapour 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> N/A
9.3 Other information (according to communitarian directive 94/9/EC):	
<u>Miscibility:</u> Not applicable.	<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: The product contains fluoride salts which, in contact with acids, produce very toxic gases of fluorine.

10.2 Materials to avoid (incompatibility): Acids.

10.3 Hazardous decomposition products: Fluorine.

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 a mild irritation for mechanical friction.

Effects and hazards of skin contact: May cause irritation.

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:

Sodium Fluoride	LD ₅₀ (oral rat)	52 mg/Kg
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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: BCF of Sodium Fluoride: 2,3

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

12.6 Other adverse effects: Not available

Aquatic toxicity data for ingredients:

Sodium Fluoride	NOEC (Cyprinodon variegates)	500 mg/l (96hrs)
	LC ₅₀ (Oncorhynchus mykiss):	200 mg/l (96hrs)
	EC ₅₀ (Daphnia magna):	98 mg/l (48hrs)

SECTION 13**Disposal considerations**

Dispose of in accordance of local regulations.

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

UN number: 2811 Class: 6.1 Packing group: III EMS-No: F-A, S-A
Stowage/segregation: (Category A); Limited Quantity: 5Kg
Proper shipping name: Toxic solid, organic, n.o.s. (Organic solid preparation containing Sodium Fluoride)

14.2 Air transportation (ICAO/IATA)

UN number: 2811 Class: 6.1 Packing group: III Label: 6.1 (Toxic solid, organic, n.o.s.)
Proper shipping name: Toxic solid, organic, n.o.s.
Limited Quantity (Passenger and Cargo Aircraft): 10 Kg/30 Kg
Maximum quantities: 100 Kg (Passenger Aircraft); 200 Kg (Cargo Aircraft only)

14.3 Transportation by Road/Railway (RID/ADR)

UN number: 2811; Class: 6.1; Packing group: III (25°C); Hazard identif. n°: 60; Label: 6.1
Proper shipping name: Toxic solid, organic, n.o.s. (Organic, solid preparation containing Sodium Fluoride)
External package type: carton (4G) both for simple and combined packages;
Limited Quantity: LQ9 (6Kg/30Kg for combined, 3Kg/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

- 25 Toxic if swallowed.
- 32 Contact with acids liberates very toxic gas
- 36/38 Irritating to eyes and skin.

16.1.1 Safety phrases of all ingredients

- 2 Keep out of the reach of children
- 13 Keep away from food, drink and animal foodstuffs
- 14 Keep away from acids
- 23 Do not breathe vapour
- 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.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.