

KERR

Material Safety Data Sheet

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

Revision Date: 12th December 2008

SECTION 1

Product & Company identification

1.1 Product name

IMPRESSION COMPOUND (Green & Red)

1.2 Uses/Application:

Dental impression material.

1.3 Company (Name, address and info phone number)

KERR ITALIA s.r.l.

Via Passanti, 332

84018 Scafati (SA) - Italy

+39-081-850-8311

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

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.
Colophony Rosin	3-12	Xi	43	8050-09-7	232-475-7

3.2 Other non-hazardous ingredients

Talc, pigments.

SECTION 4**First aid measures**

- 4.1 Treatment for eye contact: Flush with large amounts of water for at least 15 minutes.
- 4.2 Treatment for skin contact: Wash with water and soap.
- 4.3 Treatment for inhalation (breathing): May be irritating to respiratory tract. In case of need, seek medical attention.
- 4.4 Treatment for ingestion (swallowing): Ingestion of large quantities may obstruct digestive tract. In case of need, consult a physician.

SECTION 5**Fire-fighting Measures**

- 5.1 Suitable extinguishing media: Not applicable.
- 5.2 Forbidden extinguishing media: Not determined.
- 5.3 Special fire fighting measures: None.
- 5.4 Unusual fire and explosion hazards: Unknown.
- 5.5 Special protection equipment: Sealed overall and respiratory mask with a filter against organic vapours.

SECTION 6**Accidental Release Measures**

- 6.1 Personal Precautions: Follow recommended precautions listed in other sections.
- 6.2 Environmental Precautions: The product is considered not dangerous for environment, however, uncontrolled release of the product in the environment should be avoided..
- 6.3 Reclaiming Methods: Collect and pick-up the material with hands protected by gloves. Transfer it in suitable containers for disposal.

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

- 7.1 Handling Precautions: When the material is warmed to be softened, avoid breathing of its vapours. Handle material with protective gloves.
- 7.2 Precautions in case of Fire and Explosion: None particular.
- 7.3 Storage Conditions: Store at ambient temperature.
- 7.4 Suggested container(s): Original sealed containers provided by manufacturer.
- 7.5 Indication for Combined Storage: None.
- 7.6 Environmental precautions: The product is considered not dangerous for environment.
- 7.7 Other Precautions: Use according to directions.

SECTION 8	
Exposure controls/personal protection	
8.1 Exposure Limits:	Talc: TWA: 1 mg/m ³ ; Colophony: TWA: lower (ppm) possible
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> General. <u>Special Ventilation:</u> None. <u>Mechanical (General) Ventilation:</u> Should be sufficient. <u>Other Ventilation:</u> None.
Respiratory Protection:	None required in normal conditions. In case of high concentration of vapours, use a respiratory mask with filter suitable for organic vapours.
Hands Protection:	Impervious vinyl gloves. Skin should be protected, especially in sensitive individuals.
Eyes Protection:	May be used safety glasses.
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>	
8.2.2 Environment exposure control measures Not Applicable.	

SECTION 9	
Physical and Chemical Properties	
9.1 General information	
<u>Appearance:</u> Green or red waxy solid	<u>Odour:</u> Slight paraffinic odour
9.2 Information related to health, safety and environment	
<u>pH:</u> Not determined (N/D)	<u>Relative density:</u> Not available
<u>Boiling point:</u> Not applicable (N/A)	<u>Specific gravity:</u> > 1,0 g/ml
<u>Flash point:</u> N/A	<u>Solubility:</u> Insoluble
<u>Flammability:</u> Not flammable.	<u>Partition coefficient n-octanol/water:</u> N/D
<u>Lower Explosivity Limit (L.E.L.):</u> N/A	<u>Viscosity:</u> N/A
<u>Upper Explosivity Limit (U.E.L.):</u> N/A	<u>Vapour density (air = 1):</u> N/A
<u>Oxidizing properties:</u> N/A	<u>Evaporation rate (n-butane = 1):</u> N/A
<u>Vapour pressure:</u> N/A	<u>Melting point:</u> 50-56°C (Softening point)
9.3 Other information (according to communitarian directives 94/9/EC):	
<u>Miscibility:</u> N/A.	<u>Conducibility:</u> N/A
<u>Solubility in Lipids:</u> N/A	<u>Gases Group:</u> N/A

SECTION 10**Stability and Reactivity**

Stability: Stable.

10.1 Conditions to avoid: Temperatures higher than softening point may cause irritating vapours formation.

10.2 Materials to avoid (incompatibility): Unknown.

10.3 Hazardous decomposition products: None known.

Other precautions:

Hazardous Polymerization Products: Will not occur

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

Stabilizers: No stabilizers are present in this product.

SECTION 11**Toxicological Information**

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

No.

Effects and hazards of eye contact: May cause slight irritation especially in sensitive individuals.

Effects and hazards of skin contact: May cause irritation, the product is a sensitizing agent in sensitive individuals.

Effects and hazards of Inhalation (Breathing): It is an unlikely event at ambient and usage temperature. Nevertheless, once warmed prior of use, vapours may cause irritation to the throat and to respiratory tract.

Effects and hazards of Ingestion (Swallowing): Product may quickly harden and cause obstruction.

Effects for prolonged Exposure: Sensitization by skin contact, especially for prolonged and repeated use.

Toxic-kinetic effects: Unknown.

Effects on metabolism: Unknown.

Toxicological data for ingredients:

None

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 single ingredient:

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.

16.1.1 Safety phrases of all ingredients

- 2 Keep out of the reach of children
 24 Avoid contact with skin.
 37 Wear suitable gloves.

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.