

# PENTRON Clinical

## Material Safety Data Sheet

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

Revision Date: 27<sup>th</sup> May 2011

### SECTION 1

#### Product & Company identification

1.1 Product name

**CEMENT-IT<sup>®</sup> Catalyst**

1.2 Uses/Application:

Dual cure resin cement for cementation of metal, ceramic or indirect composite crowns, bridges, inlays/onlays, and posts.

1.3 Company (Name, address and info phone number)

**PENTRON CLINICAL**

1717 West Collins Avenue

Orange, CA 92867

Free phone number: +1-800-5377-123

1.4 Emergency phone (according to communitarian directive 99/45/EC, article 17)

+39-081-8508325 (08.00-17.00, European time, GMT+1)

E-mail address: [safety@kerrhawe.com](mailto: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 in large amounts.

### 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.
Benzoyl Peroxide (BPO)	0,5-1,5	E; Xi	3-7-36-43	94-36-0	202-327-6

3.2 Other non-hazardous ingredients

Stabilizers and inhibitors. Pigments only in shaded Bases.

**SECTION 4****First aid measures**

- 4.1 Treatment for eye contact: Rinse with plenty of water and contact an ophthalmologist.
- 4.2 Treatment for skin contact: Wash with plenty of 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): Seek medical advice immediately.

**SECTION 5****Fire-fighting Measures**

- 5.1 Suitable extinguishing media: CO<sub>2</sub>, water, dry chemical.
- 5.2 Forbidden extinguishing media: Unknown.
- 5.3 Special fire fighting measures: Wear a 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 vapours.

**SECTION 6****Accidental Release Measures**

- 6.1 Personal Precautions: Follow recommended precautions listed in other sections.
- 6.2 Environmental Precautions: Material should not be allowed to drain into sewers.
- 6.3 Reclaiming Methods: Absorb with inert material, collect in closed containers and dispose of in accordance with local regulations.

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

- 7.1 Handling Precautions: Avoid exposure to excessive heat.
- 7.2 Precautions in case of Fire and Explosion: None particular. Extinguish all ignition sources.
- 7.3 Storage Conditions: Store in a cool, dry place away from heat, light/sunlight and ignition sources. Refrigeration is required (2-8°C).
- 7.4 Suggested container(s): Original sealed 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: Do not allow product to reach sewers and rivers.
- 7.7 Other Precautions: Use according to directions. Over time, spontaneous polymerization may occur.

<b>SECTION 8</b>	
<b>Exposure controls/personal protection</b>	
8.1 Exposure Limits:	PEL/TLV (BPO): 0,5ppm (5 mg/m <sup>3</sup> )
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> : Good general ventilation should be sufficient to control airborne levels of vapours released by uncured material. <u>Special Ventilation</u> : None. <u>Mechanical (General) Ventilation</u> : Good general ventilation recommended. <u>Other Ventilation</u> : Not applicable.
Respiratory Protection:	Avoid prolonged or excessive breathing of vapours of uncured material
Hands Protection:	Impervious rubber gloves recommended when contacting uncured material
Eyes Protection:	Not required if used as directed. May be used 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 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.	

<b>SECTION 9</b>	
<b>Physical and Chemical Properties</b>	
9.1 General information	
<u>Appearance</u> : Pigmented paste.	<u>Odour</u> : Fruity ester-like odor.
9.2 Information related to health, safety and environment	
<u>pH</u> : Not available	<u>Relative density</u> : Not determined
<u>Boiling point</u> : Not determined (N/D)	<u>Specific gravity</u> : ~ 1,7 g/ml
<u>Flash point</u> : Not determined	<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> : Not determined
<u>Upper Explosivity Limit (U.E.L.)</u> : N/A	<u>Vapour density (air = 1)</u> : Not determined
<u>Oxidizing properties</u> : None	<u>Evaporation rate (n-butane = 1)</u> : Not determined
<u>Vapour pressure</u> : Not determined	<u>Melting point</u> : Not determined
9.3 Other information (according to communitarian directives 94/9/EC & 1882/2003/EC):	
<u>Miscibility</u> : Not determined	<u>Conducibility</u> : Not determined
<u>Solubility in Lipids</u> : Not determined	<u>Gases Group</u> : N/A

**SECTION 10****Stability and Reactivity**

Stability: Stable if stored as directed.

10.1 Conditions to avoid: Excessive heat.

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

10.3 Hazardous decomposition products: Carbon oxides.

Other precautions:

Hazardous Polymerization Products: May occur

Safety significance in case of change in physical appearance: None

Stabilizers: The product is stabilized with not hazardous stabilizers.

**SECTION 11****Toxicological Information**

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

None.

Effects and hazards of eye contact: May cause irritation.

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 in large amounts.

Effects for prolonged Exposure: May cause sensitisation by skin contact.

Toxic-kinetic effects: Unknown.

Effects on metabolism: Unknown.

Toxicological data for ingredients:

<b>BPO</b>	LD <sub>50</sub> (oral rat)	> 5000 mg/Kg
	LC <sub>50</sub> (inhalation rat/4hrs)	> 24,3 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:

<b>BPO</b>	LC <sub>50</sub> (Fishes, acute toxicity)	2,0 mg/l (96 hours)
	EC <sub>50</sub> ( <i>Daphnia</i> )	2,91 mg/l (48 hours)
	EC <sub>50</sub> (Bacteria, breathing inhibition of active muds)	35 mg/l

**SECTION 13****Disposal considerations**

Unpolymerized (uncured) material may be hazardous waste. Dispose of in accordance with 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

- 3 Extreme risk of explosion by shock, friction, fire or other sources of ignition.  
 7 May cause fire.  
 36 Irritating to eyes.  
 43 May cause sensitisation by skin contact.

16.1.1 Safety phrases of all ingredients

- 2 Keep out of the reach of children  
 3/7 Keep container tightly closed in a cool place.  
 14 Keep away from peroxides and amines.  
 36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

16.2 Sources of key data used to compile the Safety Data Sheet:

European Chemicals Bureau (ECB – [www.ecb.jrc.it](http://www.ecb.jrc.it))

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

A.C.G.I.H. ([www.acgih.org](http://www.acgih.org))

N.I.O.S.H. ([www.cdc.gov/niosh/](http://www.cdc.gov/niosh/))

O.S.H.A. ([www.osha.gov/](http://www.osha.gov/))

U.E. ([www.europa.eu/index\\_it.htm](http://www.europa.eu/index_it.htm))

I.A.R.C. ([www.iarc.fr/](http://www.iarc.fr/))

N.T.P. ([www.ntp.niehs.nih.gov](http://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.**