

PENTRON Clinical

Material Safety Data Sheet

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

Revision Date: 10th April 2011

SECTION 1

Product & Company identification

1.1 Product name

BUILD-IT[®] Light Cure

1.2 Uses/Application:

Core Build-up dental material

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

SECTION 2

Hazard identification

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

None.

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.
Sodium Fluoride	< 1	T; Xi	25-32-36/38	7681-49-4	231-667-8

3.2 Other non-hazardous ingredients

Photoinitiators and stabilizers.

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 the skin thoroughly with soap and water.
- 4.3 Treatment for inhalation (breathing): Remove to fresh air. Get medical attention.
- 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: Handle away from sources of ignition. Adopt precautions listed in section 8.
- 7.2 Precautions in case of Fire and Explosion: Not determined.
- 7.3 Storage Conditions: Refrigeration is required. Store at 2 – 8°C, away from direct sunlight, initiators, oxidizing, and/or reducing agents.
- 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	
8.1 Exposure Limits:	<u>TWA/TLV</u> : 2,5 mg/m ³ (as Fluorine)
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 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 may be used.
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 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> : White paste.	<u>Odour</u> : Fruity ester-like 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> : 1,7 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
9.3 Other information (according to communitarian directive 94/9/EC):	
<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 does not contain stabilizers.

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: May cause irritation.

Effects and hazards of Inhalation (Breathing): Prolonged or excessive inhalation may cause respiratory tract irritation.

Effects and hazards of Ingestion (Swallowing): Large amounts of uncured material may be harmful if swallowed.

Effects for prolonged Exposure: Prolonged or repeated exposure to uncured material may cause irritation or skin rash especially in sensitive individuals.

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: 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:

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

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

- 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.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.