

PENTRON Clinical

Material Safety Data Sheet

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

Revision Date: 31st May 2011

SECTION 1

Product & Company identification

1.1 Product name

ARTISTE[®] Nano Composite

1.2 Uses/Application:

Dental restorative 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.
None	N/A	N/A	N/A	N/A	N/A

3.2 Other non-hazardous ingredients

Amorphous Silica (SiO₂) and pigments (synthetic Iron oxides).

SECTION 4**First aid measures**

- 4.1 Treatment for eye contact: Rinse with water and consult 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: CO₂, water, dry chemicals.
- 5.2 Forbidden extinguishing media: Unknown.
- 5.3 Special fire fighting measures: None particular.
- 5.4 Unusual fire and explosion hazards: Heat can cause polymerization with rapid release of energy.
- 5.5 Special protection equipment: Wear a self contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

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: Wipe up with absorbent material and collect in closed containers for disposal.

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. Avoid exposure to excessive heat.
- 7.2 Precautions in case of Fire and Explosion: Extinguish all ignition sources.
- 7.3 Storage Conditions: Store at ambient temperature, in a cool, dry place away from heat and light.
- 7.4 Suggested container(s): Original sealed containers provided by manufacturer.
- 7.5 Indication for Combined Storage: Avoid contact with strong oxidizing/reducing agents and peroxides.
- 7.6 Environmental precautions: Do not allow product to reach sewers and rivers.
- 7.7 Other Precautions: Use according to directions.

SECTION 8	
Exposure controls/personal protection	
<i>8.1 Exposure Limits:</i>	SiO₂ TWA: 6 mg/m ³ ; (US OSHA); 3 mg/m ³ -breathable fraction (EU) Synthetic Iron oxides TWA: 4 mg/m ³ (respirable dust); 10 mg/m ³ (inhalable dust)
<i>8.2 Exposure control measures</i>	
<i>8.2.1 Precautionary Measures:</i> (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 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:	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 to use a lab coat.
<i>Measures listed in this paragraph are to be considered as indications and NOT prescriptions (89/656/EEC)</i>	
<i>8.2.2 Environment exposure control measures</i> Not Applicable.	

SECTION 9	
Physical and Chemical Properties	
<i>9.1 General information</i>	
<u>Appearance:</u> Pigmented viscous paste.	<u>Odour:</u> Slight ester-like odour.
<i>9.2 Information related to health, safety and environment</i>	
<u>pH:</u> Not available	<u>Relative density:</u> Not determined
<u>Boiling point:</u> Not determined (N/D)	<u>Specific gravity:</u> 1,8 - 1,9 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
<i>9.3 Other information (according to communitarian directive 94/9/EC):</i>	
<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: Heat, light, and presence of free radical initiators.

10.2 Materials to avoid (incompatibility): Strong oxidizing/reducing agents and peroxides.

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 non-hazardous polymerization inhibitors.

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: Unknown.

Toxic-kinetic effects: Unknown.

Effects on metabolism: Unknown.

Toxicological data for ingredients:

Silicon dioxide	LD ₅₀ (oral rat)	> 10000 mg/Kg
	LD ₅₀ (dermal rabbit)	> 5000 mg/Kg

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:

None.

SECTION 13**Disposal considerations**

Unpolymerized (uncured) material may be hazardous waste. 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.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

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