# **PENTRON Clinical**

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

Revision Date: 31<sup>st</sup> May 2011

## SECTION 1 Product & Company identification

- 1.1 Product name MOJO Try-In Gels
- 1.2 <u>Uses/Application</u>: Try gel for Dental luting 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 <u>Emergency phone</u> (according to communitarian directive 99/45/EC, article 17) +39-081-8508325 (08.00-17.00, European time, GMT+1) E-mail address: <u>safety@kerrhawe.com</u>

#### SECTION 2 Hazard identification

- 2.1 <u>Hazard classification</u> (according to communitarian directives 67/548/EEC & 99/45/EC) None.
- 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<br>INGREDIENTS | %   | HAZARD<br>SYMBOLS | RISK PHRASES | CAS N. | EINECS<br>N. |
|--------------------------|-----|-------------------|--------------|--------|--------------|
| None                     | N/A | N/A               | N/A          | N/A    | N/A          |

#### 3.2 Other non-hazardous ingredients

Titanium Dioxide (TiO<sub>2</sub>) and Amorphous silica (SiO<sub>2</sub>).

#### SECTION 4 First aid measures

4.1 Treatment for eye contact: Rinse with plenty of water and consult an ophthalmologist.

4.2 Treatment for skin contact: Wash with soap and water. Consult a physician if irritation occurs.

4.3 Treatment for inhalation (breathing): Remove to fresh air.

4.4 Treatment for ingestion (swallowing): Seek medical attention immediately.

### SECTION 5 Fire-fighting Measures

5.1 Suitable extinguishing media: Chemical foam, CO<sub>2</sub>, dry chemical.

5.2 Forbidden extinguishing media: Unknown.

5.3 Special fire fighting measures: None particular.

5.4 Unusual fire and explosion hazards: None.

5.5 Special protection equipment: Wear protective equipment.

#### 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 with inert material and collect in closed container for disposal.

# **SECTION 7**

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

7.1 Handling Precautions: Adopt precautions listed in section 8.

7.2 Precautions in case of Fire and Explosion: None particular.

7.3 Storage Conditions: Store at ambient temperature, in a cool, dry place, away from light.

<u>7.4 Suggested container(s)</u>: The original containers provided by manufacturer.

<u>7.5 Indication for Combined Storage</u>: Avoid contact with strong oxidizing and reducing 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<br>Exposure controls/personal protection |   |  |
|--|---|--|
| 8.1 Exposure Limits:                               | <b>SiO<sub>2</sub></b> <u>TWA</u> : 6 mg/m <sup>3</sup> ;(US OSHA); 3 mg/m <sup>3</sup> -breathable fraction (EU) |  |
| 1  | <b>TiO<sub>2</sub></b> <u>PEL/TLV</u> : 3,1ppm (10 mg/m <sup>3</sup> )  |  |
| 8.2 Exposure control measures                      | <u>1</u>  |  |
| 8.2.1 Precautionary Measure                        |   |  |
| (according to communita                            | rrian directives 89/686/EEC & article 4 of 98/24/EC)  |  |
|  | Local Exhaust Ventilation: None required.   |  |
| Ventilation:                                       | Special Ventilation: None required.   |  |
|  | Mechanical (General) Ventilation: Should be sufficient.   |  |
|  | Other Ventilation: None required.   |  |
| Respiratory Protection:                            | Not required.   |  |
| Hands Protection:                                  | Protective gloves are recommended to avoid skin contact.  |  |
| Eyes Protection:                                   | Safety glasses.   |  |
| Skin Protection:                                   | n Protection: Handle in accordance with good personal hygiene and safety practices.                               |  |
|  | These practices include avoiding unnecessary exposure to uncured material.  |  |
| Other Protective Equipments:                       | ipments: It would be better to use a lab coat.  |  |
| Measures listed in this paragra                    | uph are to be considered as indications and NOT prescriptions (89/656/EEC)  |  |
| 8.2.2 Environment exposure control measures        |   |  |
| Not Applicable.                                    |   |  |

| SECTION 9<br>Physical and Chemical Properties                         |   |  |
|---|---|--|
| 9.1 General information   |   |  |
| Appearance: Gel-like shaded paste.                                    | <u>Odour</u> : Slight.                                  |  |
| 9.2 Information related to health, safety and environment             |   |  |
| <u>pH</u> : Not applicable (N/A)                                      | <u>Relative density</u> : Not available                 |  |
| Boiling point: Not applicable   | Specific gravity: ~ 1,3 g/ml                            |  |
| Flash point: Not applicable   | Solubility: Soluble in water                            |  |
| Flammability: Not applicable.   | Partition coefficient n-octanol/water: N/A              |  |
| Lower Explosivity Limit (L.E.L.): N/A                                 | <u>Viscosity</u> : Not applicable                       |  |
| Upper Explosivity Limit (U.E.L.): N/A                                 | <u>Vapor density (air = 1)</u> : N/A                    |  |
| Oxidizing properties: None  | <u>Evaporation rate (n-butane = 1)</u> : Not applicable |  |
| Vapour pressure: Not applicable                                       | Melting point: Not determined                           |  |
| 9.3 Other information (according to communitarian directive 94/9/EC): |   |  |
| Miscibility: N/D.   | Conducibility: N/D                                      |  |
| Solubility in Lipids: Not available                                   | <u>Gases Group</u> : N/A                                |  |

#### SECTION 10 Stability and Reactivity

Stability: Stable.

10.1 Conditions to avoid: Excessive heat.

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

10.3 Hazardous decomposition products: Unknown.

Other precautions:

Hazardous Polymerization Products: Will not occur

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 be irritating.

Effects and hazards of skin contact: May be irritating. Repeated contact may cause allergic dermatitis.

Effects and hazards of Inhalation (Breathing): Prolonged exposure may cause drowsiness.

Effects and hazards of Ingestion (Swallowing): May be irritating.

Effects for prolonged Exposure: Not applicable.

Toxic-kinetic effects: Unknown.

Effects on metabolism: Unknown.

#### Toxicological data for ingredients:

| Silicon dioxide  | LD <sub>50</sub> (oral rat)      | > 10000 mg/Kg |  |
|------------------|----------------------------------|---------------|--|
|                  | LD <sub>50</sub> (dermal rabbit) | > 5000 mg/Kg  |  |
| Titanium Dioxide | $LD_{50}$ (oral rat)             | > 20000 mg/Kg |  |
|                  | $LD_{50}$ (skin rabbit)          | > 10000 mg/Kg |  |
|                  | $LC_{50}$ (inhalation rat/4hrs)  | > 6,8 mg/l    |  |
|                  |                                  |               |  |

#### SECTION 12 Ecological Information

This product has not known ecological hazardous effects.

<u>12.1 Eco-toxicity</u>: 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:

| Titanium DioxideLC50 (Leuciscus Idus) |   | > 1000 mg/l (48 hours)  |  |
|---------------------------------------|---|-------------------------|--|
|                                       | EC <sub>50</sub> (Daphnia magna, crustacea) | > 3  mg/l (30  days)    |  |
|                                       | EC <sub>50</sub> (Pseudomonas fluorescens)  | > 10000 mg/l (24 hours) |  |

# SECTION 13

# **Disposal considerations**

None. Dispose of in accordance of local regulations.

#### SECTION 14 Transport information

<u>14.1 Sea transportation (IMDG)</u> The product is not regulated.

<u>14.2 Air transportation (ICAO/IATA)</u> The product is not regulated.

#### <u>14.3 Transportation by Road/Railway (RID/ADR)</u> 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**

<u>16.1 Risk phrases of all ingredients</u> 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 – <u>www.ecb.jrc.it</u>) European chemical Substances Information System (ESIS - <u>www.ecb.jrc.it/esis</u>) A.C.G.I.H. (<u>www.acgih.org</u>) N.I.OS.H. (<u>www.acgov/niosh/</u>) O.S.H.A. (<u>www.osha.gov/</u>) U.E. (<u>www.europa.eu/index\_it.htm</u>) I.A.R.C. (<u>www.iarc.fr/</u>) N.T.P. (<u>www.ntp.niehs.nih.gov</u>)

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<br>of specific information relating to dangerous preparations (art. 14 of 99/45/EC) and<br>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.   |

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## 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.