

## Material Safety Data Sheet

(Regulation REACH n°1907/2006 and le regulation CLP N°1272/2008)

### 1. Identification of mixture and the company

#### 1.1 Commercial name

|                 |                            |
|-----------------|----------------------------|
| Name            | Still Bite                 |
| Type of product | Bite registration material |
| Reference       | SB-100 & SB-200            |

#### 1.2 Relevant use of product:

Vinyl polysiloxane occlusion registration material

#### 1.3 Information concerning safety data sheet manufacturer:

|               |                                                                                                      |
|---------------|------------------------------------------------------------------------------------------------------|
| Name:         | G-PHARMA                                                                                             |
| Localisation: | 35, avenue du Gros Chêne - ZI des Bellevues<br>BP 10279 Herblay<br>95617 Cergy-Pontoise Cedex France |
| Email:        | elsodent@elsodent.com                                                                                |
| Phone:        | + 33 (0)1 30 37 75 75                                                                                |

#### 1.4 Emergency telephone number

Number ORFILA: + 33 (0)1 45 42 59 59

### 2. Hazards Identification

The mixture meets the criteria for classification of Regulation 1272/2008 / EC amending Directives 67/548 / EEC and 1999/45 / EC and regulation 1907/2006 / EC (CLP). The mixture requires security sheet according to the requested requirements.

#### 2.1 Classification of the mixture

##### 2.1.1 Classification according to regulation (EC) N° 1272/2008 (CLP) :

The mixture is not classified as hazardous.

##### 2.1.2 Classification according to the directive N° 67/548/CEE:

The mixture is not classified as hazardous.

##### 2.1.3 Additional information

The full text of the classes and categories of danger: hazards H and R phrases are mentioned in Section 16.

#### 2.2 Label elements

Labeling according to Regulation (EC) No 1272/2008 (CLP) and its exemptions from Article 17 (relating to labeling and packaging requirements) provided for products with a capacity of less than 125 ml (Annex I of Regulations section 1.5.2.1)

|                                         |                |
|-----------------------------------------|----------------|
| <u>Pictogram</u>                        | Not Applicable |
| <u>Signal Word</u> :                    | Not Applicable |
| <u>Hazard statement</u>                 | Not Applicable |
| <u>Precautionary statements</u>         | Not Applicable |
| <u>Additional hazards information</u> : | Not Applicable |

**2.3 Other hazards** The mixtures do not contain PBT or vPvP.

### 3. Composition / Information on ingredients

#### 3.1 Product

|                                                      |                |
|------------------------------------------------------|----------------|
| EC designation:                                      | Not Applicable |
| Classification according to the directive 93/42/EEC: | Class I        |

#### 3.2 Mixture

Mixture of polyvinyl pastes and inorganic fillers.

### 4. First aid measures

#### 4.1 Description of first aid measures

|               |                                                       |
|---------------|-------------------------------------------------------|
| Inhalation:   | Not applicable under normal conditions of use.        |
| Ingestion:    | Consult a physician in case of persistent discomfort. |
| Skin contact: | Wash with water and soap.                             |

Contact with the eyes: Wash with plenty of water. Seek medical advice.  
Other measures: Remove contaminated clothing.

**4.2 Most important symptoms and effects, both acute and delayed** Not available.

**4.3 Indication of any immediate medical attention and special treatment needed:** Not available

## 5. Firefighting measures

### 5.1 Extinguishing media:

Suitable Extinguishing media: Water spray, Carbon dioxide (CO<sub>2</sub>)  
Special protective equipment: Not special measures  
Auto-ignition temperature: Not applicable

**5.2 Special hazards arising from the substance or mixture:** Not applicable

**5.3 Tips for firefighters** None

## 5 Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures:

Avoid contact with skin and eyes. Wash with soap and water in case of contact.

### 6.2 Environmental precautions:

Dispose of the product according to national, federal, state or local laws (by incineration).  
Dispose of the container in the same way as the product itself.

### 6.3 Methods and material for containment and cleaning up:

Not applicable

### 6.4 References to other sections

See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

## 6 Handling and Storage

### 7.1 Precautions for safe handling

No special precautions necessary.

### 7.2 Conditions for safe storage, including any incompatibilities

No special precautions necessary.

### 7.3 Specific end use(s):

Dental professional use only.

Use only plastic or steel utensils for mixing. The product vulcanises by polyaddition

The product vulcanises by polyaddition reaction and could be inhibited by contact with the following products:

- Heavy metal salts,
- amines,
- sulphur and derivatives,
- epoxy resin catalysts.

## 7 Exposure controls / personal protection

### 8.1 Control parameters

Respiratory protection: Not required in normal conditions of use.  
Personal protective equipment: Mask, protective gloves and protection clothe.  
Eye protection: Safety glasses.

Usual hygienic measures for dental practice. Wash hands before breaks and at the end of work. Avoid contact with the eyes and skin. Keep away from foodstuffs, beverages and feed. Wash with soap and water in case on contact.

**8.2 Explosion parameters** Not applicable

## 8 Physical & Chemical properties

### 9.1 Information regarding the physicals and chemicals properties

|                       |                 |                        |                             |
|-----------------------|-----------------|------------------------|-----------------------------|
| Appearance:           | paste           | Melting point:         | Not established             |
| Inflammability:       | Not established | Vapour pressure (20°): | Not established             |
| Auto flammability:    | Not applicable  | Specific gravity:      | Not established             |
| Odour:                | odourless       | Solubility in water:   | Insoluble                   |
| Explosive properties: | Not applicable  | Flash point:           | Not established             |
| Boiling point:        | Not established | Density:               | 1,6 - 1,7 g/cm <sup>3</sup> |
| Oxidizing properties: | Not applicable  | Solubility in water:   | Not established             |

**9.2 Other information**            None

## 9 Stability & reactivity

|                                                 |                                         |
|-------------------------------------------------|-----------------------------------------|
| <b>10.1 Reactivity:</b>                         | Not applicable                          |
| <b>10.2 Chemical stability:</b>                 | Stable under normal conditions          |
| <b>10.3 Possibility of hazardous reactions:</b> | None known under the conditions of use. |
| <b>10.4 Conditions to avoid:</b>                | Unknown                                 |
| <b>10.5 Incompatible materials:</b>             | Unknown                                 |
| <b>10.6 Hazardous decomposition products:</b>   | None known under conditions of use.     |
| <b>10.7 uncontrolled polymerization:</b>        | Not applicable.                         |

## 10 Toxicological information

### 11.1 Information on toxicological effects

|                                        |                                         |
|----------------------------------------|-----------------------------------------|
| <u>Acute toxicity for health:</u>      | LD50 2000mg/kg Rat                      |
| <u>Chronical toxicity:</u>             | None known under the conditions of use. |
| <u>Signs and symptoms of exposure:</u> | Non-irritating.                         |

**11.2 Other information:**            Not applicable

## 11 Ecological information

### 12.1 Toxicity

No ecological toxicity or impact on the environment has been identified for this product in the quantities present in the normal packaging. It is inert once polymerized. Not a polluting agent according to the CLP classification. Do not allow the product to enter sewers, surface and ground water.

|                                                 |                |
|-------------------------------------------------|----------------|
| <b>12.2 Persistence and degradability:</b>      | Not applicable |
| <b>12.3 Bioaccumulative potential:</b>          | Not applicable |
| <b>12.4 Mobility in soil:</b>                   | Not applicable |
| <b>12.5 Results of PBT and vPvB assessment:</b> | Not applicable |
| <b>12.6 Other adverse effects:</b>              | Not applicable |

## 12 Disposal measures

### 13.1 Waste treatment methods

|                   |                                                                                                      |
|-------------------|------------------------------------------------------------------------------------------------------|
| Large quantities: | Disposal must be made according to local, state and federal regulations. Do not pour down the drain. |
| Small quantities: | Dispose normally after polymerization.                                                               |

**13.2 Uncleaned packaging:** Disposal must be in accordance to all federal, national and local

## 13 Transport information

This information regarding the transportation follows the international transportation requirements. No restriction for the road, boat or plane transportation.  
Avoid high temperatures during transportation.

## 14 Regulation

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:

Class I medical device according to the Directive 93/42/EEC

**15.2 Chemical safety assessment:**            Not applicable

## 15 Other information

### Symbol of potential danger:

Xi : Irritating  
STOT SE 3: Specific target organ toxicity - single exposure hazard category 3

**R phrases**

R 52: Harmful to aquatic organisms

**H phrases**

H412: May be harmful to aquatic organisms in the long term.

**P phrases:**

P280: Wear protective gloves

P305 + P351 + P338: In case of contact with eyes, rinse cautiously with water for several minutes, remove contact lenses if present and easily removable. Continue rinsing.

P302 + P352: In case of skin contact, wash with plenty of soap and water.

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