PENTRON

# SAFETY DATA SHEET

Correct Bite Impression Materials Base and Catalyst

## **Section 1. Identification**

**GHS** product identifier

: Correct Bite Impression Materials Base and Catalyst

Other means of identification

: Quick Bite and Plus Bite SF

**Product type** 

: Paste.

Relevant identified uses of the substance or mixture and uses advised against

**Product use** : Dental product: Denture impression material.

Area of application : Professional applications.

**Manufacturer** : Pentron Clinical

> 1717 West Collins Avenue Orange, CA 92867-5422

Telephone no.: 1-203-265-7397, Toll Free: 1-800-551-0283

e-mail address of person responsible for this SDS

: edwin.varela@kavokerrgroup.com

**Emergency telephone** number (with hours of

operation)

: CHEMTREC® (24 hours) U.S. : 1-800-424-9300 International: +1-703-527-3887

## Section 2. Hazards identification

OSHA/HCS status

: This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Health effects are based on the uncured material.

Classification of the substance or mixture : EYE IRRITATION - Category 2A

TOXIC TO REPRODUCTION (Fertility) - Category 2

Percentage of the mixture consisting of ingredient(s) of unknown toxicity: 81.6%

**GHS label elements** 

**Hazard pictograms** 





Signal word : Warning

**Hazard statements** : Causes serious eye irritation. Suspected of damaging fertility.

**Precautionary statements** 

**Prevention** 

: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. Wear eye

or face protection. Wash hands thoroughly after handling.

Date of issue/Date of revision : 04/30/2015 Date of previous issue : 11/28/2014 Version : 2 1/11

## Section 2. Hazards identification

Response : IF exposed or concerned: Get medical attention. IF IN EYES: Rinse cautiously with

water for several minutes. Remove contact lenses, if present and easy to do. Continue

rinsing. If eye irritation persists: Get medical attention.

Storage : Store locked up.

Disposal : Dispose of contents and container in accordance with all local, regional, national and

international regulations.

Supplemental label

elements

: Avoid contact with skin and clothing. Wash thoroughly after handling.

**Hazards not otherwise** 

classified

: Prolonged or repeated contact may dry skin and cause irritation.

# Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Other means of identification

: Quick Bite and Plus Bite SF

#### **CAS** number/other identifiers

**CAS number** : Not applicable.

Product code : Q31E, Q31EB, Q34IA, Q34IC

| Ingredient name   | Other names                                 | %              | CAS number           |
|---|---|----------------|----------------------|
| Methyl hydrogen dimethyl polysiloxanes octamethylcyclotetrasiloxane | Not available. octamethylcyclotetrasiloxane | 10-30<br>0.1-1 | Proprietary 556-67-2 |

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health and hence require reporting in this section.

## Section 4. First aid measures

#### **Description of necessary first aid measures**

**Eye contact**: No special measures are required. In case of contact with eyes, rinse immediately with

plenty of water. Get medical attention if symptoms occur.

Inhalation : No special measures required. If inhaled, remove to fresh air. Get medical attention if

symptoms occur.

**Skin contact**: No special measures required. In case of contact, immediately flush skin with plenty of

water. Get medical attention if symptoms occur.

Ingestion : Wash out mouth with water. If material has been swallowed and the exposed person is

conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Get medical attention if adverse health effects persist or

are severe.

#### Most important symptoms/effects, acute and delayed

#### Potential acute health effects

**Eye contact** : Causes serious eye irritation.

**Inhalation**: No known significant effects or critical hazards.

**Skin contact**: Defatting to the skin. May cause skin dryness and irritation.

**Ingestion**: No known significant effects or critical hazards.

Date of issue/Date of revision : 04/30/2015 Date of previous issue : 11/28/2014 Version : 2 2/11

## Section 4. First aid measures

#### Over-exposure signs/symptoms

**Eye contact**: Adverse symptoms may include the following:

pain or irritation watering

redness

**Inhalation** : Adverse symptoms may include the following:

reduced fetal weight increase in fetal deaths skeletal malformations

**Skin contact**: Adverse symptoms may include the following:

irritation dryness cracking

reduced fetal weight increase in fetal deaths skeletal malformations

**Ingestion** : Adverse symptoms may include the following:

reduced fetal weight increase in fetal deaths skeletal malformations

#### Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician

: Treat symptomatically. Contact poison treatment specialist immediately if large

quantities have been ingested or inhaled.

**Specific treatments** 

: No specific treatment.

**Protection of first-aiders** 

: In case of major fire and large quantities: No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing

aid to give mouth-to-mouth resuscitation.

#### See toxicological information (Section 11)

## Section 5. Fire-fighting measures

#### Extinguishing media

Suitable extinguishing

media

: Use an extinguishing agent suitable for the surrounding fire.

**Unsuitable extinguishing** 

media

: Do not use water jet.

Specific hazards arising from the chemical

: In a fire or if heated, a pressure increase will occur and the container may burst.

Hazardous thermal decomposition products

: Decomposition products may include the following materials:

carbon dioxide carbon monoxide sulfur oxides metal oxide/oxides

Special protective actions for fire-fighters

: In case of major fire and large quantities: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken

involving any personal risk or without suitable training.

Date of issue/Date of revision : 04/30/2015 Date of previous issue : 11/28/2014 Version : 2 3/11

## Section 5. Fire-fighting measures

**Special protective** equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

## Section 6. Accidental release measures

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

For non-emergency personnel

: Low release. For professional use only. Handling of product in very small amounts or in situations where release is highly unlikely

For emergency responders: Low release. See also the information in "For non-emergency personnel".

**Environmental precautions** 

: Low release. Avoid dispersal of spilled material and runoff and contact with soil. waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

#### Methods and materials for containment and cleaning up

**Small spill** 

: Small Quantity. For professional use only. Absorb with an inert material and place in an appropriate waste disposal container.

Large spill

: Small Quantity. For professional use only. Absorb with an inert material and place in an appropriate waste disposal container.

# Section 7. Handling and storage

#### Precautions for safe handling

**Protective measures** 

No special measures are required for small quantities under normal and intended conditions of product use. For professional use only. Put on appropriate personal protective equipment (see Section 8). Handle with care and dispose in a safe manner.

Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating. drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

Conditions for safe storage, including any incompatibilities

: Store between the following temperatures: 20 to 25°C (68 to 77°F). Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

# Section 8. Exposure controls/personal protection

#### Control parameters

Occupational exposure limits

None.

Appropriate engineering controls

: No special measures are required for small quantities under normal and intended conditions of product use.

**Environmental exposure** controls

: No special measures are required for small quantities under normal and intended conditions of product use.

Date of issue/Date of revision : 04/30/2015 : 11/28/2014 Version : 2 Date of previous issue 4/11

## Section 8. Exposure controls/personal protection

#### Individual protection measures

**Hygiene measures** : No special measures are required for small quantities under normal and intended

conditions of product use.

**Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk

assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.

**Skin protection** 

**Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be

> worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the

protection time of the gloves cannot be accurately estimated.

**Body protection** : No special measures are required for small quantities under normal and intended

conditions of product use.

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected

based on the task being performed and the risks involved and should be approved by a

specialist before handling this product.

**Respiratory protection** : No special measures are required for small quantities under normal and intended

conditions of product use.

## Section 9. Physical and chemical properties

**Appearance** 

**Physical state** : Liquid. [Paste.]

Color : Various Odor : Odorless. **Odor threshold** : Not available. Hq : Not available. : Not available. **Melting point Boiling point** : Not available.

: Closed cup: 252°C (485.6°F) [DIN 51755] Flash point

**Evaporation rate** : Not available. Flammability (solid, gas) : Not applicable. Lower and upper explosive : Not available.

(flammable) limits

: Not available.

Vapor pressure Vapor density : Not available. **Relative density** : Not available.

**Solubility** : Insoluble in the following materials: cold water and hot water.

Solubility in water : Not available. Partition coefficient: n-: Not available.

octanol/water

**Auto-ignition temperature** : Not available. **Decomposition temperature** : Not available. SADT : Not available.

Date of issue/Date of revision : 04/30/2015 Date of previous issue : 11/28/2014 Version : 2 5/11

**United States** 

## Section 9. Physical and chemical properties

Viscosity : Not available.

## Section 10. Stability and reactivity

**Reactivity** : No specific test data related to reactivity available for this product or its ingredients.

**Chemical stability**: The product is stable.

Possibility of hazardous reactions

: Under normal conditions of storage and use, hazardous reactions will not occur.

Under normal conditions of storage and use, hazardous polymerization will not occur.

**Conditions to avoid** : Store away from direct sunlight.

**Incompatible materials** : Reactive or incompatible with the following materials: oxidizing materials and reducing

materials. Initiators

Hazardous decomposition products

: Under normal conditions of storage and use, hazardous decomposition products should

not be produced.

# Section 11. Toxicological information

#### Information on toxicological effects

#### **Acute toxicity**

| Product/ingredient name                | Result  | Species | Dose                                | Exposure          |
|--|---|---------|-------------------------------------|-------------------|
| Methyl hydrogen dimethyl polysiloxanes | LD50 Dermal                                       | Rabbit  | >2000 mg/kg                         | -                 |
|  | LD50 Oral   | Rat     | >2000 mg/kg                         | -                 |
| octamethylcyclotetrasiloxane           | LC50 Inhalation Vapor<br>LD50 Dermal<br>LD50 Oral |         | 36 g/m³<br>1770 mg/kg<br>1540 mg/kg | 4 hours<br>-<br>- |

**Conclusion/Summary** 

: Based on the criteria of the protocol, this product is considered non-cytotoxic per ISO

10993-5.

Based on analysis and test results, this product is considered as biocompatible per EN ISO 7405:2008 and EN ISO 10993-1:2009.

#### **Irritation/Corrosion**

| Product/ingredient name                | Result                   | Species | Score | Exposure     | Observation |
|--|--------------------------|---------|-------|--------------|-------------|
| Methyl hydrogen dimethyl polysiloxanes | Skin - Mild irritant     | Rabbit  | -     | -            | -           |
|  | Eyes - Moderate irritant | Rabbit  | -     | -            | -           |
| octamethylcyclotetrasiloxane           | Eyes - Mild irritant     | Rabbit  | _     | 24 hours 500 | -           |
|  |                          |         |       | milligrams   |             |
|  | Skin - Mild irritant     | Rabbit  | _     | 24 hours 500 | -           |
|  |                          |         |       | milligrams   |             |

#### **Sensitization**

Not available.

#### **Mutagenicity**

Date of issue/Date of revision : 04/30/2015 Date of previous issue : 11/28/2014 Version : 2 6/11

# Section 11. Toxicological information

Not available.

#### Carcinogenicity

Not available.

#### Reproductive toxicity

Not available.

#### **Teratogenicity**

Not available.

#### Specific target organ toxicity (single exposure)

Not available.

#### Specific target organ toxicity (repeated exposure)

Not available.

#### **Aspiration hazard**

Not available.

## Information on the likely

routes of exposure

: Routes of entry anticipated: Oral, Dermal, Inhalation.

#### Potential acute health effects

**Eye contact** : Causes serious eye irritation.

**Inhalation** : No known significant effects or critical hazards.

**Skin contact**: Defatting to the skin. May cause skin dryness and irritation.

Ingestion : No known significant effects or critical hazards.

#### Symptoms related to the physical, chemical and toxicological characteristics

**Eye contact**: Adverse symptoms may include the following:

pain or irritation watering redness

**Inhalation** : Adverse symptoms may include the following:

reduced fetal weight increase in fetal deaths skeletal malformations

**Skin contact**: Adverse symptoms may include the following:

irritation dryness cracking

reduced fetal weight increase in fetal deaths skeletal malformations

**Ingestion** : Adverse symptoms may include the following:

reduced fetal weight increase in fetal deaths skeletal malformations

# <u>Delayed and immediate effects and also chronic effects from short and long term exposure</u> <u>Short term exposure</u>

Date of issue/Date of revision : 04/30/2015 Date of previous issue : 11/28/2014 Version : 2 7/11

# Section 11. Toxicological information

**Potential immediate** 

effects

: Not available.

Potential delayed effects

: Not available.

**Long term exposure** 

**Potential immediate** 

: Not available.

effects

Potential delayed effects : Not available.

Potential chronic health effects

Not available.

General: Prolonged or repeated contact can defat the skin and lead to irritation, cracking and/or

dermatitis.

Carcinogenicity : No known significant effects or critical hazards.
 Mutagenicity : No known significant effects or critical hazards.
 Teratogenicity : No known significant effects or critical hazards.
 Developmental effects : No known significant effects or critical hazards.

Fertility effects : Suspected of damaging fertility.

#### **Numerical measures of toxicity**

#### **Acute toxicity estimates**

| Route | ATE value     |
|-------|---------------|
| Oral  | 18843.9 mg/kg |

# Section 12. Ecological information

#### **Toxicity**

| Product/ingredient name | Result  | Species   | Exposure           |
|-------------------------|---|---|--------------------|
| 1                       | Chronic NOEC 1.7 to 15 µg/l Fresh water Chronic NOEC 4.4 µg/l Fresh water | Daphnia - Daphnia magna<br>Fish - Oncorhynchus mykiss - Egg | 21 days<br>93 days |

#### Persistence and degradability

| Product/ingredient name      | Test | Result        | Dose | Inoculum |
|------------------------------|------|---------------|------|----------|
| octamethylcyclotetrasiloxane | -    | 0 % - 42 days | -    | -        |

#### **Bioaccumulative potential**

| Product/ingredient name      | LogPow | BCF   | Potential |
|------------------------------|--------|-------|-----------|
| octamethylcyclotetrasiloxane | 6.488  | 13400 | high      |

#### **Mobility in soil**

Soil/water partition coefficient (Koc)

: Not available.

Date of issue/Date of revision : 04/30/2015 Date of previous issue : 11/28/2014 Version : 2 8/11

## Section 12. Ecological information

Other adverse effects : No known significant effects or critical hazards.

## Section 13. Disposal considerations

**Disposal methods** 

: The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

## Section 14. Transport information

|                            | DOT Classification | IMDG           | IATA           |
|----------------------------|--------------------|----------------|----------------|
| UN number                  | Not regulated.     | Not regulated. | Not regulated. |
| UN proper shipping name    | -                  | -              | -              |
| Transport hazard class(es) | -                  | -              | -              |
| Packing group              | -                  | -              | -              |
| Environmental hazards      | No.                | No.            | No.            |
| Additional information     | -                  | -              | -              |

Special precautions for user : Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

: Not available.

## Section 15. Regulatory information

U.S. Federal regulations

: TSCA 8(a) PAIR: octamethylcyclotetrasiloxane; 1,1,3,3-tetramethyl-1,3-divinyldisiloxane;

2,4,6,8-tetramethyl-2,4,6,8-tetravinylcyclotetrasiloxane

Clean Water Act (CWA) 307: 3,6-bis(diethylamino)-9-[2-(methoxycarbonyl)phenyl]

United States inventory (TSCA 8b): All components are listed or exempted.

xanthylium tetrachlorozincate

Clean Air Act Section 112

(b) Hazardous Air **Pollutants (HAPs)**  : Not listed

Clean Air Act Section 602

: Not listed

Class I Substances Clean Air Act Section 602

: Not listed

**Class II Substances** 

Date of issue/Date of revision : 04/30/2015 : 11/28/2014 9/11 Date of previous issue Version : 2

**United States** 

## Section 15. Regulatory information

**DEA List I Chemicals** 

: Not listed

(Precursor Chemicals)

DEA List II Chemicals

: Not listed

(Essential Chemicals)

**SARA 302/304** 

**Composition/information on ingredients** 

No products were found.

SARA 304 RQ : Not applicable.

**SARA 311/312** 

Classification : Immediate (acute) health hazard
Delayed (chronic) health hazard

**Composition/information on ingredients** 

| Name  | %              |             | Sudden<br>release of<br>pressure |     | •    | Delayed<br>(chronic)<br>health<br>hazard |
|---|----------------|-------------|----------------------------------|-----|------|--|
| Methyl hydrogen dimethyl polysiloxanes octamethylcyclotetrasiloxane | 10-30<br>0.1-1 | No.<br>Yes. |                                  | No. | Yes. | No.<br>Yes.                              |

#### **SARA 313**

Not applicable.

### State regulations

Massachusetts : The following components are listed: STARCH DUST; SOAPSTONE; AMORPHOUS

SILICA

New York : None of the components are listed.

New Jersey : The following components are listed: SOAPSTONE

Pennsylvania: The following components are listed: STARCH; SOAPSTONE DUST; SILICA

California Prop. 65

None of the components are listed.

## Section 16. Other information

#### **Hazardous Material Information System (U.S.A.)**



Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks Although HMIS® ratings are not required on SDSs under 29 CFR 1910. 1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered mark of the National Paint & Coatings Association (NPCA). HMIS® materials may be purchased exclusively from J. J. Keller (800) 327-6868.

The customer is responsible for determining the PPE code for this material.

**National Fire Protection Association (U.S.A.)** 

Date of issue/Date of revision : 04/30/2015 Date of previous issue : 11/28/2014 Version : 2 10/11

## Section 16. Other information



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Copyright ©2001, National Fire Protection Association, Quincy, MA 02269. This warning system is intended to be interpreted and applied only by properly trained individuals to identify fire, health and reactivity hazards of chemicals. The user is referred to certain limited number of chemicals with recommended classifications in NFPA 49 and NFPA 325, which would be used as a guideline only. Whether the chemicals are classified by NFPA or not, anyone using the 704 systems to classify chemicals does so at their own risk.

#### **History**

Date of issue/Date of

revision

Date of previous issue : 11/28/2014

Version : 2

**Key to abbreviations** : ATE = Acute Toxicity Estimate

: 04/30/2015

BCF = Bioconcentration Factor

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

IATA = International Air Transport Association

IBC = Intermediate Bulk Container

IMDG = International Maritime Dangerous Goods

LogPow = logarithm of the octanol/water partition coefficient

MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships,

1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)

UN = United Nations

References : HCS (U.S.A.)- Hazard Communication Standard

International transport regulations

✓ Indicates information that has changed from previously issued version.

#### **Notice to reader**

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot quarantee that these are the only hazards that exist.

Date of issue/Date of revision : 04/30/2015 Date of previous issue : 11/28/2014 Version : 2 11/11