

SAFETY DATA SHEETS

This SDS packet was issued with item:

076468656

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

076468557 076468565 076468573 076468581 076468615 076468623 076468631 076468649 076468698 076468706

076468714 076468722 076468730 076468771 076468789 076468797 076468805 076473029

1. Chemical Product and Contact Information

Product Name: Correct Plus[®] Vinyl Polysiloxane Impression Material

Material Safety Sheet Number: 00052

Date of Issue: 05/26/00

Revision Date: 03/30/10

Company Identification: Pentron Clinical
 1717 West Collins Ave.
 Orange, CA 92867
 Phone: 800-551-0283
 203-265-7397

Emergency Information Chemtrec: 800-424-9300

Chemtrec International: 202-483-7616

2. Composition/Information on Ingredients

Chemical characteristics: Polyvinylidimethylsiloxane.
Description: Polyvinylsiloxane resin mixture with inorganic fillers, pigments, platinum catalyst and SiH capped polysiloxane, with or without flavoring agents.

Hazardous components:

| Element | CAS # | Exposure Limit mg/m ³ | |
|----------------------------|------------|----------------------------------|-----------|
| | | OSHA PEL | ACGIH TLV |
| Polyvinylidimethylsiloxane | 68083-18-1 | N/E | N/E |
| Inorganic Fillers | Mixture | N/A | N/A |
| Pigments | Various | N/A | N/A |
| Platinum Catalyst | N/A | N/A | N/A |
| SiH capped polysiloxane | 68037-59-2 | N/E | N/E |
| Flavoring Agents | Unknown | N/A | N/A |

3. Hazard Identification

Risk identification:
Special risks for human beings and environment: None known.
Classification: Unknown.

4. First Aid Measures

General information:
After skin contact: Wash with plenty of water and soap. Consult a physician if irritation occurs.
After eye contact: Immediately flush eyes with eyelids retracted with plenty of water for 15 minutes. Consult an ophthalmologist if needed.
After swallowing: Seek medical advice immediately.

5. Fire Fighting Measures

Extinguishing media: Sand, chemical foam, carbon dioxide or dry chemical. During a fire, irritating and/or toxic gases and aerosols may be present from the decomposition/combustion products.
Protective equipment: Firefighters should wear full protective clothing, including a self-contained breathing apparatus.

6. Accidental Release Measures

Personal precautions: Protective gloves and goggles.
Environmental precautions: Absorb with inert material. Collect in closed containers and dispose of as recommended. Avoid skin contact, wear protective equipment.
Methods for cleaning up: Dispose in accordance to Federal, State, and local regulations.
Additional information: Unknown.

7. Handling and Storage

Handling: Not applicable.
Handling procedures: Not applicable.
Recommendation for fire and explosion protection: Not applicable.
Storage: Store at ambient temperature. Store away from direct sunlight, initiators, oxidizing, and/or reducing agents.
Requirements at storerooms and containers: Over time, spontaneous polymerization may occur.
Additional storage conditions: Not applicable.
Storage classification: Not applicable.
VBF- classification: Not applicable.

8. Exposure Controls/Personal Protection

Additional information:

| | |
|--|--|
| Personal protective equipment: | Protective gloves (Rubber, PVS, Nitrile), goggles, and a rubber apron. |
| General measure of protection and hygiene: | Normal hygienic measures. |
| Respiration: | Unknown |
| Hands: | Protective gloves. |
| Eyes: | OSHA approved goggles. |

9. Physical and Chemical Properties

| | | |
|-------------|--------|-----------------------------|
| Appearance: | Form: | Gel or Putty-like. |
| | Color: | Shaded. |
| | Odor: | Odorless, or berry-scented. |

Information on change in the physical state

| | |
|---------------------------------------|---------------------------------------|
| Melting point/melting range: | Not applicable. |
| Boiling point/boiling range: | Not applicable. |
| Flash point: | 485°F (252°C) Closed cup - DIN 51755. |
| Autoignition temperature: | Unknown. |
| Danger of explosion: | Unlikely. |
| Density: | Various. |
| Vapor pressure: | Not applicable. |
| Viscosity: | Not applicable. |
| pH: | Not applicable. |
| Solubility in/miscibility with water: | Insoluble. |
| Content of solvents: | None. |
| Percent Volatile: | < 2%. |
| Water: | None. |
| Content of solids: | Various. |

10. Stability and Reactivity

| | |
|--|-----------------|
| Chemical Stability: | Stable. |
| Incompatibility with other substances: | Not applicable. |
| Hazardous decomposition products: | Not applicable. |

11. Toxicological Information

| | |
|--------------------------|---|
| Carcinogenicity: | None of the components of this material are listed by IARC, NTP, OSHA, or ACGIH as carcinogens. |
| TLV: | None. |
| Primary Routes of entry: | Inhalation, skin, and eyes. |

12. Ecological Information

| | |
|---------------------------------------|----------|
| General information: | Unknown. |
| Classification of water endangerment: | Unknown. |

13. Disposal Considerations

| | |
|-------------------------|--|
| Disposal consideration: | Dispose of in accordance with Federal, State, and local regulations. |
|-------------------------|--|

14. Transport Information

Not classified as dangerous goods.

15. Regulatory Information

| | |
|---|----------|
| Classification according to EEC guidelines: | Unknown. |
| National Prescriptions: | Unknown. |
| Classification according to VbF: | Unknown. |

16. Other Information


The information and recommendations set forth herein (hereinafter "information") are presented in good faith and believed to be correct as of the date hereof. Pentron Clinical however, makes no representations as to the completeness or accuracy of this information and supplies it on the condition that the persons receiving same will make their own determination as to its suitability for their purposes prior to use. In no event will Pentron Clinical be responsible for damages of any nature whatsoever resulting from the use of or reliance upon information.

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Section 1. Identification

| | |
|---|--|
| GHS product identifier | Correct Plus VPS® Putty Impression Material Base |
| Other means of identification | : VPS Putty, Plus Putty and Berry Putty. Product Code: Q03, Q34H, Q34HCA |
| Product type | : Gel. Putty. |
| <u>Relevant identified uses of the substance or mixture and uses advised against</u> | |
| 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 | : TOXIC TO REPRODUCTION (Fertility) - Category 2 Percentage of the mixture consisting of ingredient(s) of unknown toxicity: 100% |
| <u>GHS label elements</u> | |
| Hazard pictograms | :  |
| Signal word | : Warning |
| Hazard statements | : Suspected of damaging fertility. |
| <u>Precautionary statements</u> | |
| Prevention | : Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. |
| Response | : IF exposed or concerned: Get medical attention. |
| Storage | : Store locked up. |
| Disposal | : Dispose of contents and container in accordance with all local, regional, national and international regulations. |

Date of issue/Date of revision : 12/03/2014 **Date of previous issue** : No previous validation **Version** : 1 1/11

Section 2. Hazards identification

- 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** : Not available.

CAS number/other identifiers

- CAS number** : Not applicable.
- Product code** : Not available.

| Ingredient name | Other names | % | CAS number |
|--|------------------------------|-------|------------|
| crystalite | crystalite | 30-60 | 14464-46-1 |
| Siloxanes and Silicones, di-Me, Me hydrogen, hydrogen-terminated | Not available. | 1-5 | 69013-23-6 |
| octamethylcyclotetrasiloxane | octamethylcyclotetrasiloxane | 0.1-1 | 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** : No known significant effects or critical hazards.
- 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.

Over-exposure signs/symptoms

- Eye contact** : No specific data.
- Inhalation** : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations

Section 4. First aid measures

- 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
halogenated compounds
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.

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).

Section 6. Accidental release measures

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

| Ingredient name | Exposure limits |
|-----------------|---|
| cristobalite | <p>OSHA PEL Z3 (United States, 2/2013). TWA: 250 MPPCF / 2 x (%SiO₂+5) 8 hours. Form: Respirable TWA: 10 MG/M3 / 2 x (%SiO₂+2) 8 hours. Form: Respirable TWA: 30 MG/M3 / 2 x (%SiO₂+2) 8 hours. Form: Total dust</p> <p>OSHA PEL 1989 (United States, 3/1989). TWA: 0.05 mg/m³, (as quartz) 8 hours. Form: Respirable dust</p> <p>ACGIH TLV (United States, 6/2013). TWA: 0.025 mg/m³ 8 hours. Form: Respirable fraction</p> <p>NIOSH REL (United States, 10/2013). TWA: 0.05 mg/m³ 10 hours. Form: respirable dust</p> |

- 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.

Individual protection measures

Section 8. Exposure controls/personal protection

- 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: safety glasses with side-shields.
- 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** : Gel. Putty.
- Color** : Various
- Odor** : Odorless. Berry.
- Odor threshold** : Not available.
- pH** : Not available.
- Melting point** : Not available.
- Boiling point** : Not available.
- Flash point** : Closed cup: 252°C (485.6°F) [DIN 51755]
- Evaporation rate** : Not available.
- Flammability (solid, gas)** : Not available.
- Lower and upper explosive (flammable) limits** : Not available.
- Vapor pressure** : Not available.
- 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-octanol/water** : Not available.
- Auto-ignition temperature** : Not available.
- Decomposition temperature** : Not available.
- SADT** : Not available.
- 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** : Hazardous reactions or instability may occur under certain conditions of storage or use.
Hazardous polymerization may occur under certain conditions of storage or use.
- Conditions to avoid** : Keep away from heat and direct sunlight.
- Incompatible materials** : Reactive or incompatible with the following materials: oxidizing materials and reducing materials.
Incompatible with peroxides. free radical 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 |
|--|-----------------------|---------|---------------------|----------|
| Siloxanes and Silicones, di-Me, Me hydrogen, hydrogen-terminated | LD50 Dermal | Rabbit | >2000 mg/kg | - |
| octamethylcyclotetrasiloxane | LD50 Oral | Rat | >2000 mg/kg | - |
| | LC50 Inhalation Vapor | Rat | 36 g/m ³ | 4 hours |
| | LD50 Dermal | Rat | 1770 mg/kg | - |
| | LD50 Oral | Rat | 1540 mg/kg | - |

- Conclusion/Summary** : Based on analysis and test results, this product is considered as biocompatible per EN ISO 7405:2008 and EN ISO 10993-1:2009. Based on the criteria of the protocol, this product is considered non-cytotoxic per ISO 10993-5.

Irritation/Corrosion

| Product/ingredient name | Result | Species | Score | Exposure | Observation |
|------------------------------|----------------------|---------|-------|-------------------------|-------------|
| octamethylcyclotetrasiloxane | Eyes - Mild irritant | Rabbit | - | 24 hours 500 milligrams | - |
| | Skin - Mild irritant | Rabbit | - | 24 hours 500 milligrams | - |

Sensitization

Not available.

Mutagenicity

Not available.

Carcinogenicity

Not available.

Classification

| Product/ingredient name | OSHA | IARC | NTP |
|-------------------------|------|------|---------------------------------|
| cristobalite | - | 1 | Known to be a human carcinogen. |

Reproductive toxicity

Section 11. Toxicological information

Not available.

Teratogenicity

Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

| Name | Category | Route of exposure | Target organs |
|--------------|------------|-------------------|---------------|
| cristobalite | Category 2 | Not determined | lungs |

Aspiration hazard

Not available.

Information on the likely routes of exposure : Routes of entry anticipated: Oral, Dermal, Inhalation.

Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
- 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** : No specific data.
- 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

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

- Potential immediate effects** : Not available.
- Potential delayed effects** : Not available.

Long term exposure

- Potential immediate effects** : Not available.
- Potential delayed effects** : Not available.

Potential chronic health effects

Section 11. Toxicological information

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

Not available.

Section 12. Ecological information

Toxicity

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

Persistence and degradability

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

Bioaccumulative potential

| Product/ingredient name | LogP _{ow} | BCF | Potential |
|------------------------------|--------------------|-------|-----------|
| octamethylcyclotetrasiloxane | 6.488 | 13400 | high |

Mobility in soil

- Soil/water partition coefficient (K_{oc})** : Not available.

- 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
United States inventory (TSCA 8b): All components are listed or exempted.
Clean Water Act (CWA) 311: Formaldehyde

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

| Name | % | EHS | SARA 302 TPQ | | SARA 304 RQ | |
|--------------|---------|------|--------------|-----------|-------------|-----------|
| | | | (lbs) | (gallons) | (lbs) | (gallons) |
| Formaldehyde | <0.0004 | Yes. | 500 | 73.9 | 100 | 14.8 |

SARA 304 RQ : 27777777.8 lbs / 12611111.1 kg

SARA 311/312

Section 15. Regulatory information

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

Composition/information on ingredients

| Name | % | Fire hazard | Sudden release of pressure | Reactive | Immediate (acute) health hazard | Delayed (chronic) health hazard |
|--|-------|-------------|----------------------------|----------|---------------------------------|---------------------------------|
| crystalite | 30-60 | No. | No. | No. | No. | Yes. |
| Siloxanes and Silicones, di-Me, Me hydrogen, hydrogen-terminated | 1-5 | No. | No. | No. | Yes. | No. |
| octamethylcyclotetrasiloxane | 0.1-1 | Yes. | No. | No. | No. | Yes. |

SARA 313

Not applicable.

State regulations

Massachusetts

: The following components are listed: MAGNESITE DUST; SOAPSTONE; SILICA, CRYSTALLINE, QUARTZ; CRISTOBALITE DUST

New York

: None of the components are listed.

New Jersey

: The following components are listed: MAGNESITE; CARBONIC ACID, MAGNESIUM SALT (1:1); SOAPSTONE; SILICA, QUARTZ; QUARTZ (SiO₂); SILICA, CRISTOBALITE; CRISTOBALITE (SiO₂); MINERAL OIL (UNTREATED and MILDLY TREATED)

Pennsylvania

: The following components are listed: SOAPSTONE DUST; QUARTZ (SiO₂); CRISTOBALITE (SiO₂); SILICA AMORPHOUS DIATOMACEOUS EARTH (UNCALCINED)

California Prop. 65

WARNING: This product contains a chemical known to the State of California to cause cancer.

| Ingredient name | Cancer | Reproductive | No significant risk level | Maximum acceptable dosage level |
|-----------------------------------|--------|--------------|---------------------------|---------------------------------|
| crystalite | Yes. | No. | No. | No. |
| crystalline silica non-respirable | Yes. | No. | No. | No. |
| crystalline silica respirable | Yes. | No. | No. | No. |
| Formaldehyde | Yes. | No. | Yes. | No. |

Section 16. Other information

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

| | | |
|------------------|---|---|
| Health | * | 2 |
| Flammability | | 1 |
| Physical hazards | | 0 |
| | | |

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.)

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 : 12/03/2014

Date of previous issue : No previous validation

Version : 1

Prepared by : IHS

Key to abbreviations :

- ATE = Acute Toxicity Estimate
- 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 guarantee that these are the only hazards that exist.

Section 1. Identification

| | |
|---|--|
| GHS product identifier | : Correct Plus VPS® Putty Impression Material Catalyst |
| Other means of identification | : VPS Putty, Plus Putty and Berry Putty. Product Code: Q03, Q34H, Q34HCA |
| Product type | : Gel. Putty. |
| <u>Relevant identified uses of the substance or mixture and uses advised against</u> | |
| 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 | : TOXIC TO REPRODUCTION (Fertility) - Category 2 Percentage of the mixture consisting of ingredient(s) of unknown toxicity: 100% |
| <u>GHS label elements</u> | |
| Hazard pictograms | :  |
| Signal word | : Warning |
| Hazard statements | : Suspected of damaging fertility. |
| <u>Precautionary statements</u> | |
| Prevention | : Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. |
| Response | : IF exposed or concerned: Get medical attention. |
| Storage | : Store locked up. |
| Disposal | : Dispose of contents and container in accordance with all local, regional, national and international regulations. |

Date of issue/Date of revision : 12/03/2014 **Date of previous issue** : No previous validation **Version** : 1 1/11

Section 2. Hazards identification

Hazards not otherwise classified : None known.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Other means of identification : Not available.

CAS number/other identifiers

CAS number : Not applicable.

Product code : Not available.

| Ingredient name | Other names | % | CAS number |
|------------------------------|------------------------------|-------|------------|
| crystalite | crystalite | 30-60 | 14464-46-1 |
| octamethylcyclotetrasiloxane | octamethylcyclotetrasiloxane | 0.1-1 | 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 : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact : No specific data.

Inhalation : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations

Skin contact : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations

Section 4. First aid measures

- 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
halogenated compounds
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.

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

| Ingredient name | Exposure limits |
|-----------------|---|
| crystalobalite | <p>OSHA PEL Z3 (United States, 2/2013). TWA: 250 MPPCF / 2 x (%SiO₂+5) 8 hours. Form: Respirable</p> <p>TWA: 10 MG/M³ / 2 x (%SiO₂+2) 8 hours. Form: Respirable</p> <p>TWA: 30 MG/M³ / 2 x (%SiO₂+2) 8 hours. Form: Total dust</p> <p>OSHA PEL 1989 (United States, 3/1989). TWA: 0.05 mg/m³, (as quartz) 8 hours. Form: Respirable dust</p> <p>ACGIH TLV (United States, 6/2013). TWA: 0.025 mg/m³ 8 hours. Form: Respirable fraction</p> <p>NIOSH REL (United States, 10/2013). TWA: 0.05 mg/m³ 10 hours. Form: respirable dust</p> |

- 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.

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: safety glasses with side-shields.

Skin protection

Section 8. Exposure controls/personal 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** : Gel. Putty.
- Color** : Various
- Odor** : Odorless. Berry.
- Odor threshold** : Not available.
- pH** : Not available.
- Melting point** : Not available.
- Boiling point** : Not available.
- Flash point** : Closed cup: 252°C (485.6°F)
- Evaporation rate** : Not available.
- Flammability (solid, gas)** : Not available.
- Lower and upper explosive (flammable) limits** : Not available.
- Vapor pressure** : Not available.
- 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-octanol/water** : Not available.
- Auto-ignition temperature** : Not available.
- Decomposition temperature** : Not available.
- SADT** : Not available.
- 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** : Hazardous reactions or instability may occur under certain conditions of storage or use.
Hazardous polymerization may occur under certain conditions of storage or use.

Section 10. Stability and reactivity

Conditions to avoid : Keep away from heat and direct sunlight.

Incompatible materials : Reactive or incompatible with the following materials: oxidizing materials and reducing materials.
Incompatible with peroxides. free radical 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 |
|------------------------------|-----------------------|---------|---------------------|----------|
| octamethylcyclotetrasiloxane | LC50 Inhalation Vapor | Rat | 36 g/m ³ | 4 hours |
| | LD50 Dermal | Rat | 1770 mg/kg | - |
| | LD50 Oral | Rat | 1540 mg/kg | - |

Conclusion/Summary : Based on analysis and test results, this product is considered as biocompatible per EN ISO 7405:2008 and EN ISO 10993-1:2009. Based on the criteria of the protocol, this product is considered non-cytotoxic per ISO 10993-5.

Irritation/Corrosion

| Product/ingredient name | Result | Species | Score | Exposure | Observation |
|------------------------------|----------------------|---------|-------|-------------------------|-------------|
| octamethylcyclotetrasiloxane | Eyes - Mild irritant | Rabbit | - | 24 hours 500 milligrams | - |
| | Skin - Mild irritant | Rabbit | - | 24 hours 500 milligrams | - |

Sensitization

Not available.

Mutagenicity

Not available.

Carcinogenicity

Not available.

Classification

| Product/ingredient name | OSHA | IARC | NTP |
|-------------------------|------|------|---------------------------------|
| crystalite | - | 1 | Known to be a human carcinogen. |

Reproductive toxicity

Not available.

Teratogenicity

Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

| Name | Category | Route of exposure | Target organs |
|------------|------------|-------------------|---------------|
| crystalite | Category 2 | Not determined | lungs |

Aspiration hazard

Section 11. Toxicological information

Not available.

Information on the likely routes of exposure : Routes of entry anticipated: Oral, Dermal, Inhalation.

Potential acute health effects

Eye contact : No known significant effects or critical hazards.
Inhalation : No known significant effects or critical hazards.
Skin contact : No known significant effects or critical hazards.
Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No specific data.
Inhalation : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations
Skin contact : Adverse symptoms may include the following:
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

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects : Not available.
Potential delayed effects : Not available.

Long term exposure

Potential immediate effects : Not available.
Potential delayed effects : Not available.

Potential chronic health effects

Not available.

General : No known significant effects or critical hazards.
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

Not available.

Section 12. Ecological information

Toxicity

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

Persistence and degradability

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

Bioaccumulative potential

| Product/ingredient name | LogP _{ow} | BCF | Potential |
|------------------------------|--------------------|-------|-----------|
| octamethylcyclotetrasiloxane | 6.488 | 13400 | high |

Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

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.

Section 14. Transport information

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

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : Delayed (chronic) health hazard

Composition/information on ingredients

| Name | % | Fire hazard | Sudden release of pressure | Reactive | Immediate (acute) health hazard | Delayed (chronic) health hazard |
|------------------------------|-------|-------------|----------------------------|----------|---------------------------------|---------------------------------|
| crystalite | 30-60 | No. | No. | No. | No. | Yes. |
| octamethylcyclotetrasiloxane | 0.1-1 | Yes. | No. | No. | No. | Yes. |

SARA 313

Not applicable.

State regulations

Massachusetts : The following components are listed: MAGNESITE DUST; SOAPSTONE; SILICA, CRYSTALLINE, QUARTZ; CRISTOBALITE DUST

New York : None of the components are listed.

New Jersey : The following components are listed: MAGNESITE; CARBONIC ACID, MAGNESIUM SALT (1:1); SOAPSTONE; SILICA, QUARTZ; QUARTZ (SiO₂); SILICA, CRISTOBALITE; CRISTOBALITE (SiO₂); MINERAL OIL (UNTREATED and MILDLY TREATED)

Pennsylvania : The following components are listed: SOAPSTONE DUST; QUARTZ (SiO₂); CRISTOBALITE (SiO₂); SILICA AMORPHOUS DIATOMACEOUS EARTH (UNCALCINED)

California Prop. 65

WARNING: This product contains a chemical known to the State of California to cause cancer.

Section 15. Regulatory information

| Ingredient name | Cancer | Reproductive | No significant risk level | Maximum acceptable dosage level |
|-----------------------------------|--------|--------------|---------------------------|---------------------------------|
| crystalite | Yes. | No. | No. | No. |
| crystalline silica non-respirable | Yes. | No. | No. | No. |
| crystalline silica respirable | Yes. | No. | No. | No. |

Section 16. Other information

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

| | | |
|------------------|---|---|
| Health | * | 0 |
| Flammability | | 1 |
| Physical hazards | | 0 |
| | | |

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.)



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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 | : 12/03/2014 |
| Date of previous issue | : No previous validation |
| Version | : 1 |
| Prepared by | : IHS |
| Key to abbreviations | : ATE = Acute Toxicity Estimate 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 |

Section 16. Other information

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 guarantee that these are the only hazards that exist.