



Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Date Issued: 28 January 2015

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier:

Trade Name (as labeled):
Part/Item Number:

Elements™ Bite Registration Materials
PD-190, PD-188, PD-187, PD-186, PD-185, PD-190-4,
PD-188-4, PD-187-4, PD-186-4, PD-185-4

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

Recommended Use: Impression models
Restrictions on Use: For professional use only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name: Pac-Dent Inc.
Manufacturer/Supplier Address: 670 Endeavor Circle
Brea, CA, USA
Manufacturer/Supplier Telephone Number: 1-909-839-0888

1.4 Emergency Telephone Number:

Emergency Contact Telephone Number: 800-535-5053 (INFOTRAC)

2. HAZARD(s) IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS SDS Classification: Not hazardous

EU Classification (1999/45/EC as amended): Not a dangerous preparation

2.2 Labeling Elements: None Required

2.3 Other Hazards: None

3. COMPOSITION AND INFORMATION ON INGREDIENTS

3.2 Mixture

Hazardous Components	C.A.S. #	WT %
Poly(dimethylsiloxane), vinyl terminated	68083-19-2	30-60
Crystalline Silica, Quartz *	13983-17-0	40-60

* The crystalline silica in this product is inextricably bound in a manner that no exposure occurs during normal use and handling. Therefore this product is not classified as a carcinogen.

4. FIRST-AID MEASURES

4.1 Description of First Aid Measures:

Routes of Exposure First Aid Instructions

Eye	Wipe off excess. Flush eyes with large quantities of water for several minutes, holding the eyelids apart. Get medical attention if irritation persists.
Skin	Wipe excess off skin. Wash skin with soap and water.
Inhalation	None needed under normal use conditions
Ingestion	Rinse mouth with water. If large amounts are swallowed, get medical attention.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed:

May cause mild eye irritation

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:

None required under normal conditions of use.

Note to Physicians (Treatment, Testing, and Monitoring): Treatment of overexposure should be directed at the control of symptoms and clinical conditions.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media

Use media appropriate for surrounding fire.

5.2 Special Hazards Arising from the Substance or Mixture:

None Known

5.3 Advice for Fire-Fighters:

Fire Fighting Procedures: Cool fire exposed containers and structures with water.

Precautions for Fire Fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

For large spills, wear eye protection. Small spills do not require special precautions.

6.2 Environmental Precautions:

Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

Scoop or scrape up and place in appropriate containers for disposal. May cause a slip hazard. Wash spill area with soap and water.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handling:

Avoid contact with the eyes. Use in accordance with package instructions.

7.2 Conditions for Safe Storage, Including Any Incompatibilities:

Store away from extreme heat.

7.3 Specific End Use (s): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Crystalline Silica, Quartz	United States	0.025 TWA ACGIH TLV (respirable) <u>10 mg/m³</u> TWA US OSHA PEL (respirable dust) % SiO ₂ +2
	Germany	None Established
	United Kingdom	0.1 mg/m ³ TWA UL OEL
	France	0.1 mg/m ³ TWA INRS VME
	Spain	0.1 mg/m ³ TWA VLA-ED (respirable fraction)
	Italy	None Established
	European Union	None Established

Biological Exposure Limits: None Established

8.2 Exposure Controls:

Appropriate Engineering Controls: No special controls required.

Individual Protection Measures (PPE)

Specific Eye/face Protection: Avoid eye contact. Safety glasses should be worn if contact is likely.

Specific Skin Protection: None normally required.

Specific Respiratory Protection: None required under normal use conditions.

Specific Thermal Hazards: Not applicable

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Various colored pastes	Explosive limits:	Not applicable
Odor:	Faint berry odor.	Vapor pressure:	Not applicable
Odor threshold:	Not available	Vapor density:	Not applicable
pH:	Not available	Relative density:	Not available
Melting/freezing point:	Not available	Solubility:	Nil
Initial boiling point and range:	>392°F / >200°C	Partition coefficient: noctanol/water:	Not available
Flash point:	>415°F / >212°C	Auto-ignition temperature:	Not available
Evaporation rate:	< 1	Decomposition temperature:	Not available
Flammability:	Not flammable	Viscosity:	Not available
Explosive Properties:	None	Oxidizing Properties:	None

10. STABILITY AND REACTIVITY

10.1 Reactivity: Will not polymerize or react dangerously

10.2 Chemical Stability: Stable.

10.3 Possibility of Hazardous Reactions: None known

10.4 Conditions to Avoid: Extreme heat.

10.5 Incompatible materials: Avoid oxidizing agents.

10.6 Hazardous Decomposition Products: Thermal decomposition may produce carbon oxides and silica.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Direct contact may cause mild irritation with redness and tearing.

Skin: No adverse effects are expected under normal use conditions.

Ingestion: No adverse effects are expected from swallowing small amounts. Large amounts may cause gastric upset with nausea.

Inhalation: None expected from normal use.

Chronic Health Effects: None known.

Carcinogenicity: Respirable crystalline silica, quartz is listed by IARC as a group 1 carcinogen (carcinogenic to humans) and by NTP as a “known to be a human carcinogen”. This component is encapsulated in a polymer matrix so no inhalable exposure occurs during use or disposal. None of the other components of this product are listed as carcinogens by OSHA, IARC, ACGIH, NTP or EU

Directives.

Mutagenicity: No mutagenic effects are expected.

Medical Conditions Aggravated by Exposure: None known.

Acute Toxicity Data:

No toxicity data available but the product is not expected to be acutely toxic.

Reproductive Toxicity Data: No reproductive or teratogenic effects are expected.

Specific Target Organ Toxicity (STOT):

Single Exposure: No data available, however, no adverse effects are expected.

Repeated Exposure: Inhalation of respirable crystalline silica may cause lung disease, however, no respirable silica is present

and the silica is inextricably bound in the polymer matrix so no exposure can occur.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

No adverse effects are expected on aquatic organisms

12.2 Persistence and Degradability: This product is expected to be removed by sedimentation or degradation

12.3 Bio-accumulative Potential: This product is not expected to bio-accumulate.

12.4 Mobility in Soil: No data is available.

12.5 Other Adverse Effects: None known.

12.6 Results of PBT/vPvB Assessment: Not required.

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Regulations: Dispose in accordance with local and national environmental regulations.

Properties (Physical/Chemical) Affecting Disposal: None known.

Waste Treatment Recommendations: None needed for normal anticipated use.

14. TRANSPORT INFORMATION

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
DOT	None	Not Regulated	None	None	No
ADR/RID	None	Not Regulated	None	None	No
IMDG	None	Not Regulated	None	None	Maine Pollutant - No
IATA/ICAO	None	Not Regulated	None	None	No

14.6 Special precautions for user: Not Applicable

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: Not applicable – product is transported only in packaged form.

15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

Toxic Substances Control Act (TSCA): This product is a medical device and not subject to chemical notification requirements.

Clean Water Act (CWA): Not Listed

Clean Air Act (CAA): Not Listed

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories:

Immediate Hazard:	No	Pressure Hazard:	No
Delayed Hazard:	No	Reactivity Hazard:	No
Fire Hazard:	No		

This product doesn't contain toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372)

State Regulations

California: This product doesn't contain chemicals(s) known to the State of California to cause cancer, birth defects or reproductive harm

International Regulations

EU REACH: The substances in this product comply with the EU REACH regulation as applicable.

16. OTHER INFORMATION

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The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall Pac-Dent be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if Pac-Dent has been advised of the possibility of such damages.