SAFETY DATA SHEET
BioCoat™ Bioactive Pit & Fissure Sealant

1. Product and Company Identification

Trade Name: BioCoat™ Bioactive Pit & Fissure Sealant

Premier® Dental Products Company
1710 Romano Drive
Plymouth Meeting, PA 19462
Phone: 610-239-6000 Fax: 610-239-6171
Emergency Phone: 610-239-6000

Indications for Use: BioCoat™ Bioactive Pit and Fissure Sealant, a prescription only medical device used for prophylactic sealing of pits and fissures. It may also be used for micro-restorative or as an "initial layer" for composite restorations.

Contraindications: This product contains substances that may cause an allergic reaction by skin contact in certain individuals. Avoid use of this product in patients with known acrylate allergies. If prolonged contact with oral soft tissue occurs, flush with large amounts of water. If allergic reaction occurs, seek medical attention as needed, remove the product if necessary and discontinue future use of the product with this patient.

Cautions:

- Rx Only
- Keep out of reach of children.

2. Hazard(s) Identification

Classification of the substance or mixture:

GHS07

Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2B H320 Causes eye irritation.

Label elements:
GHS label elements
The product is classified and labeled according to the Globally Harmonized System (GHS).
Hazard pictograms:

GHS07

Signal word: Warning

Hazard-determining components of labeling:
Calcium Donor
Hazard statements:
H315+H320 Causes skin and eye irritation.
Precautionary statements:

P261	Avoid breathing dust/fume/gas/mist/vapors/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P264	Wash thoroughly after handling.
P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P305+P351+P338	If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P321 Specific treatment (see supplementary first aid instructions on this Safety Data Sheet).
P312 Call a POISON CENTER/doctor if you feel unwell.
P332+P313 If skin irritation occurs: Get medical advice/attention.

Unknown acute toxicity:
This value refers to knowledge of known, established toxicological or ecotoxicological values.
57 % of the mixture consists of component(s) of unknown toxicity.

Classification system: NFPA/HMIS Definitions: 0-Least, 1-Slight, 2-Moderate, 3-High, 4-Extreme
NFPA ratings (scale 0 - 4)

Health = 1
Fire = 0
Reactivity = 0

HMIS-ratings (scale 0 - 4)

Health = 1
Fire = 0
Reactivity = 0

Hazard(s) not otherwise classified (HNOC): None known

3. Composition/Information on Ingredients

Chemical characterization: Mixtures
Description: Mixture of substances listed below with non-hazardous additions.

Dangerous Components:		
Barrium Aluminoborosilicate	Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	≤ 60%
Calcium Donor	Eye Dam. 1, H318; Acute Tox. 4, H302	≤ 2%
Photo-Initiator	Repr. 2, H361	≤ 2.5%

Additional information:
The exact percentages of the ingredients of this mixture are considered to be proprietary and are withheld in accordance with the provisions of paragraph (i) of §1910.1200 of 29 CFR 1910.1200 Trade Secrets.

4. First-Aid Measures

Description of first aid measures:
After inhalation: In case of unconsciousness place patient stably in side position for transportation.
After skin contact:
Immediately wash with water and soap and rinse
thoroughly. If skin irritation occurs, consult a doctor.
After eye contact:
Rinse opened eye for at least 15 minutes under running water. If symptoms persist, consult a doctor.
If easy to do so, remove contact lenses if worn.
After swallowing:
Do not induce vomiting without medical advice.
If swallowed and symptoms occur, consult a doctor.
Information for doctor:
Most important symptoms and effects, both acute and delayed: No further relevant information available.
Indication of any immediate medical attention and special treatment needed:
No further relevant information available.

5. Fire-Fighting Measures

Extinguishing media:
Suitable extinguishing agents: Use fire fighting measures that suit the environment.
Special hazards arising from the substance or mixture: No further relevant information available.

Advice for firefighters:
Protective equipment:
As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent) and full protective gear to prevent contact with skin and eyes.

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Not required.
Environmental precautions: Do not allow to enter sewers/surface or ground water.
Methods and material for containment and cleaning up:
Absorb with liquid-binding material (i.e. sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.
Dispose of the collected material according to regulations.
Reference to other sections:
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment. See Section 13 for disposal information.
Protective Action Criteria for Chemicals

PAC-1:	
Barrium Aluminoborosilicate	15 mg/m3
Triethylene glycol dimethacrylate	33 mg/m3
Calcium Donor	12 mg/m3
Phosphate Donor	13 mg/m3
Fumed Silica	18 mg/m3
PAC-2:	
Barrium Aluminoborosilicate	170 mg/m3
Triethylene glycol dimethacrylate	360
Calcium Donor	130 mg/m3
Phosphate Donor	140 mg/m3
Fumed Silica	740 mg/m3
PAC-3:	
Barrium Aluminoborosilicate	990 mg/m3
Triethylene glycol dimethacrylate	2,100 mg/m3
Calcium Donor	770 mg/m3
Phosphate Donor	830 mg/m3
Fumed Silica	4,500 mg/m3

7. Handling and Storage

Handling
Precautions for safe handling:
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
Information about protection against explosions and fires: No special measures required.

Conditions for safe storage, including any incompatibilities:
Storage
Requirements to be met by storerooms and receptacles: No special requirements.
Information about storage in one common storage facility: Not required.
Further information about storage conditions: Keep receptacle tightly sealed.
Specific end use(s): No further relevant information available.

8. Exposure Controls/Personal Protection

Additional information about design of technical systems: No further data; see section 7.

Control parameters:
Components with occupational exposure limits:
The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.
At this time, the other constituents have no known exposure limits.

Barrium Aluminoborosilicate	
PEL	Short-term value: 5 mg/m^3 Long-term value: 15mg/m^3
TLV	Short-term value: 3 mg/m^3 Long-term value: 10mg/m^3

Additional information: The lists that were valid during the creation of this SDS were used as basis.

Exposure controls:
Personal protective equipment:
General protective and hygienic measures:
The usual precautionary measures for handling chemicals should be followed.
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing and wash before reuse.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
Breathing equipment: Not required.
Protection of hands:

Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/the preparation/the chemical mixture.
Select glove material based on penetration times, rates of diffusion and degradation.
Material of gloves:
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.
Penetration time of glove material:
The exact break-through time has to be determined and observed by the manufacturer of the protective gloves.
Eye protection:

Safety glasses

Body protection: Not required.

9. Physical and Chemical Properties

Information on basic physical and chemical properties
General Information
Appearance:

Form:	Liquid Paste
Color:	White
Odor:	Slightly acrylic
Odor threshold:	Not determined.
pH-value:	Not applicable.
Change in condition	
Melting point/Melting range:	Not determined.
Boiling point/Boiling range:	Not determined.
Flash point:	None
Flammability (solid, gaseous):	Not applicable.
Ignition temperature:	Not determined.
Decomposition temperature:	Not determined.

Auto igniting:	Product is not self-igniting.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapor pressure:	Not determined.
Density:	
Relative density:	Not determined.
Vapor density:	Not determined.
Evaporation rate:	Not determined.
Solubility in / Miscibility with:	
Water:	Not miscible or difficult to mix.
Partition coefficient (n-octanol/water):	Not determined.
Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
Solvent content:	
Organic solvents:	0.0 %
Solids content:	58.5 %
Other information:	No further relevant information available.

10. Stability and Reactivity

Reactivity: No further relevant information available.
Chemical stability: Stable under normal conditions.
Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
Possibility of hazardous reactions: No dangerous reactions known.
Conditions to avoid: Keep out of direct sunlight
Incompatible materials: No further relevant information available.
Hazardous decomposition products: No dangerous decomposition products known.

11. Toxicological Information

Information on toxicological effects:
Acute toxicity:

LD/LC50 values that are relevant for classification:		
Calcium Donor		
Oral	LD50	302 mg/kg (Rat)

Primary irritant effect:
On the skin: Irritant to skin and mucous membranes.
On the eye: Irritating effect.
Additional toxicological information:
The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant

Carcinogenic categories:

IARC (International Agency for Research on Cancer):	
Barrium Aluminoborosilicate	
Fumed Silica	3
NTP (National Toxicology Program):	
None of the ingredients are listed.	
OSHA-Ca (Occupational Safety & Health Administration):	
None of the ingredients are listed.	

12. Ecological Information

Toxicity:
Aquatic toxicity: No further relevant information available.
Persistence and degradability: No further relevant information available.
Behavior in environmental systems:
Bioaccumulative potential: No further relevant information available.
Mobility in soil: No further relevant information available.
Additional ecological information:
General notes:
Do not allow undiluted product or product that has not been neutralized to reach ground water, water course or sewage system.
Results of PBT and vPvB assessment:
PBT: Not applicable.
vPvB: Not applicable.
Other adverse effects: No further relevant information available.

13. Disposal Considerations

Waste treatment methods:
Recommendation:
Observe all federal, state and local environmental regulations when disposing of this material.
Uncleaned packagings
Recommendation: Disposal must be made according to official regulations.

14. Transport Information

UN-Number:	
DOT, ADR/ADN, ADN, IMDG, IATA	Non-Regulated Material
UN proper shipping name:	
DOT, ADR/ADN, ADN, IMDG, IATA	Non-Regulated Material
Transport hazard class(es):	
DOT, ADR/ADN, ADN, IMDG, IATA	
Class:	Non-Regulated Material
Packing group:	
DOT, ADR/ADN, IMDG, IATA	Non-Regulated Material
Environmental hazards:	Not applicable.
Special precautions for user:	Not applicable.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:	Not applicable.
UN "Model Regulation":	Non-Regulated Material

15. Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture:
SARA (Superfund Amendments and Reauthorization):

Section 355 (extremely hazardous substances):
None of the ingredients are listed.

Section 313 (Specific toxic chemical listings):
Calcium Donor

TSCA (Toxic Substances Control Act):
Barrium Aluminoborosilicate
Triethylene glycol dimethacrylate
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)]bismethacrylate
Photo-Initiator
Photo-Initiator
Fumed Silica

California Proposition 65:

Chemicals known to cause cancer:
None of the ingredients are listed.

Chemicals known to cause reproductive toxicity for females:
None of the ingredients are listed.

Chemicals known to cause reproductive toxicity for males:
None of the ingredients are listed.

Chemicals known to cause developmental toxicity:
None of the ingredients are listed.

New Jersey Right-to-Know List:
None of the ingredients are listed.

New Jersey Special Hazardous Substance List:
None of the ingredients are listed.

Pennsylvania Right-to-Know List:
Fumed Silica

Pennsylvania Special Hazardous Substance List:
None of the ingredients are listed.

Carcinogenic categories:

EPA (Environmental Protection Agency):
None of the ingredients are listed.

TLV (Threshold Limit Value established by ACGIH):
None of the ingredients are listed.

NIOSH-Ca (National Institute for Occupational Safety and Health):
None of the ingredients are listed.

GHS label elements
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Hazard pictograms:

GHS07

Signal word: Warning

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Hazard statements:
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P321	Specific treatment (see supplementary first aid instructions on this Safety Data Sheet).
P312	Call a POISON CENTER/doctor if you feel unwell.
P332+P313	If skin irritation occurs: Get medical advice/attention.

National regulations:
The product is subject to be classified according with the latest version of the regulations on hazardous substances.

Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16. Other Information

Premier's revision date: 03/08/2017
Revision Number: 2
Abbreviations and acronyms:
ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety and Health
OSHA: Occupational Safety & Health Administration
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Acute Tox. 4: Acute toxicity – Category 4
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
Eye Irrit. 2B: Serious eye damage/eye irritation – Category 2B
Repr. 2: Reproductive toxicity – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
· *** Data compared to the previous version altered.**
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