

SECTION 1: IDENTIFICATION
1.1. Product Identifier

Product Name: Gem 21S® (Growth-Factor Enhanced Matrix)

Product Code: 21-0005

1.2. Intended Use of the Product

Use of the substance/mixture: GEM 21S® is indicated to treat the following periodontally related defects: intrabony periodontal defects; furcation periodontal defects; and gingival recession associated with periodontal defects.

1.3. Name, Address, and Telephone of the Responsible Party
Company

Luitpold Pharmaceuticals, Inc.

Osteohealth Division

One Luitpold Drive

P.O. Box 9001

Shirley, NY 11967

1-800-645-1706

www.luitpold.com

1.4. Emergency Telephone Number

Emergency Number : CHEMTREC 1-800-424-9300

SECTION 2: HAZARDS IDENTIFICATION
2.1. Classification of the Substance or Mixture
GHS-US classification

Not classified

2.2. Label Elements
GHS-US Labeling

No labeling applicable

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS
3.1. Substance

β-TCP (beta-tricalcium phosphate)	Product Identifier	%	GHS-US classification
Phosphoric acid, calcium salt (2:3)	(CAS No) 7758-87-4	100	Not classified
rhPDGF-BB	Product Identifier	%	GHS-US classification
Recombinant Human Platelet-Derived Growth Factor-BB (rhPDGF-BB)	(CAS No) Not available	0.03	Not classified

3.2. Mixture

Not applicable

SECTION 4: FIRST AID MEASURES
4.1. Description of First Aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical attention (show the label where possible).

First-aid Measures After Inhalation: Go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty.

First-aid Measures After Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/Injuries: Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

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Chronic Symptoms: None known.

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

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid all unnecessary exposure.

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Material for Containment and Cleaning Up

For Containment: Contain solid spills with appropriate barriers and prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Recover the product by vacuuming, shoveling or sweeping. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8, Exposure Controls and Personal Protection. See Section 13, Disposal Considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing dust.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Refrigerate at 2° - 8°C (36° - 46°F). Do not freeze. Store away from incompatible materials.

Incompatible Products: Strong acids, strong bases, strong oxidizers.

7.3. Specific End Use(s) Pharmaceutical/Dental

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

8.2. Exposure Controls

Appropriate Engineering Controls : Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

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Personal Protective Equipment

: Gloves. Protective goggles.



Materials for Protective Clothing

: Chemically resistant materials and fabrics.

Hand Protection

: Wear protective gloves.

Eye Protection

: Chemical safety goggles.

Skin and Body Protection

: Wear suitable protective clothing.

Respiratory Protection

: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information

: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State

: Solid and liquid (two component package)

Appearance

: Two component package:
rhPDGF-BB: Clear, colorless and odorless solution
 β -TCP: White, porous, odorless granules

Odor

: Odorless

Odor Threshold

: No data available

pH

: rhPDGF-BB: 5.5 - 6.5

Evaporation Rate

: No data available

Melting Point

: No data available

Freezing Point

: No data available

Boiling Point

: No data available

Flash Point

: No data available

Auto-ignition Temperature

: No data available

Decomposition Temperature

: No data available

Flammability (solid, gas)

: No data available

Vapor Pressure

: No data available

Relative Vapor Density at 20 °C

: No data available

Relative Density

: No data available

Solubility

: No data available

Partition Coefficient: N-Octanol/Water

: No data available

Viscosity

: No data available

9.2. Other Information

No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity: Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability: Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

10.4. Conditions to Avoid: Direct sunlight, high or low temperatures (product must be refrigerated but not frozen) and incompatible materials.

10.5. Incompatible Materials: Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products: Beta Tricalcium Phosphate thermally decomposes to form oxides of Calcium and Phosphorous. Recombinant Human Platelet Derived Growth Factor thermally decomposes to form Carbon Monoxide, Carbon Dioxide, oxides of Nitrogen and Sulfur.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

Phosphoric acid, calcium salt (2:3) (7758-87-4)

Additional information

This compound is listed by the FDA as generally recognized as safe (GRAS) and may be used as a food additive, for both human food and ruminant feed, according to prescribed conditions.

Skin Corrosion/Irritation: Not classified

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Serious Eye Damage/Irritation: Not classified
Respiratory or Skin Sensitization: Not classified
Germ Cell Mutagenicity: Not classified
Carcinogenicity: Not classified
Reproductive Toxicity: Not classified
Specific Target Organ Toxicity (Single Exposure): Not classified
Specific Target Organ Toxicity (Repeated Exposure): Not classified
Aspiration Hazard: Not classified
Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.
Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.
Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.
Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.
Chronic Symptoms: None known.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

12.2. Persistence and Degradability Not established

12.3. Bioaccumulative Potential Not established

12.4. Mobility in No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

Ecology – Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1 US Federal Regulations

Phosphoric acid, calcium salt (2:3) (7758-87-4)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2 US State Regulations Neither this product nor its chemical components appear on any US state lists.

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date : 11/30/2015

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

Refer to Luitpold/Osteohealth's prescribing information for further information at: <http://www.ostehealth.com/GEM21S.aspx>

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