

PREMIER DENTAL PRODUCTS COMPANY

Safety Data Sheet BufferPro™

SECTION 1: Identification

1.1 GHS Product identifier

Product name	BufferPro™
Brand	Premier® BufferPro™
Manufacturer's details	

Name Address

1.2

Telephone Fax email 610-239-6000 610-239-6171 regulatory@premierdentalco.com

Premier Dental Products Company

Plymouth Meeting PA 19462

1710 Romano Drive

UŚA

1.3 Distributor's details

Name	
Address	

Septodont Inc. 205 Granite Run Drive. Suite 150 Lancaster PA 17601 USA

1.4 Emergency phone number

610-239-6000

SECTION 2: Hazard identification

General hazard statement

No Significant Hazard

2.1 Classification of the substance or mixture

GHS classification in accordance with: OSHA (29 CFR 1910.1200)

- Skin corrosion/irritation, Cat. 2
- Acute toxicity, oral, Cat. 4

2.2 GHS label elements, including precautionary statements

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Pictograms



Hazard statement(s)	
H302	Harmful if swallowed
H315	Causes skin irritation
Precautionary statement(s)	
P264	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P280	Wear protective gloves.
P301+P312	IF SWALLOWED: Call a POISON CENTER /doctor/dentist if you feel unwell,
P302+P352	IF ON SKIN: Wash with plenty of water.
P330	Rinse mouth.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P501	Dispose of contents/container within a sharps container in accordance to
	facility or institutional guidelines/procedures

2.3 Other hazards which do not result in classification

Medical Conditions Aggravated by Exposure: Individuals with pre-existing skin disease may be at increased risk from exposure.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Hazardous components

1. Sodium Bicarbonate, USP	
Concentration	1 - 8.4 % (weight), Proprietary
EC no.	205-633-8
CAS no.	144-55-8

2. Sterile Water for Injection Concentration CAS no.

1 - 91.6 % (weight), Proprietary 7732-18-5

SECTION 4: First-aid measures

4.1 Description of necessary first-aid measures

If inhaled

Inhalation may cause coughing, tightness of the chest and irritation of the respiratory system.

	Move the exposed person to fresh air. Seek medical attention if irritation or symptoms persist
In case of skin contact	May cause irritation to skin. Rinse immediately with plenty of water. Remove contaminated clothing. Seek medical attention if irritation or symptoms persist.
In case of eye contact	May cause irritation to eyes. Rinse immediately with plenty of water. Seek medical attention if irritation or symptoms persist.
If swallowed	Ingestion may cause nausea and vomiting. May cause irritation to mucous membranes. DO NOT INDUCE VOMITING unless advised to do so by a doctor. Seek medical attention if irritation or symptoms persist.

SECTION 5: Fire-fighting measures

5.1 Suitable extinguishing media Use extinguishing media appropriate to the surrounding fire conditions.

- **5.2** Specific hazards arising from the chemical Burning produces irritating, toxic and obnoxious fumes.
- **5.3** Special protective actions for fire-fighters Wear suitable respiratory equipment when necessary.

SECTION 6: Accidental release measures

6.1 **Personal precautions, protective equipment and emergency procedures** Ensure adequate ventilation of the working area. Wear suitable protective equipment.

6.2 Environmental precautions

Prevent further spillage if safe. Do not flush into surface water. Do not let product contaminate subsoil.

6.3 Methods and materials for containment and cleaning up Absorb with inert, absorbent material. Sweep up. Transfer to suitable, labelled containers for disposal. Clean spillage area thoroughly with plenty of water.

Reference to other sections

See section 2 and 8 for further information.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Adopt best Manual Handling considerations when handling, carrying and dispensing. Avoid contact with eyes. Avoid contamination of food or feedstuffs. Refer to label for complete indications, dosing, storage, and handling.

7.2 Conditions for safe storage, including any incompatibilities Store at room temperature between 15°C (59°F) to 25°C (77°F). Keep in dry, well-ventilated area. Do not store at

temperature above 30°C (86°F). Keep sealed until ready to use. Do NOT allow it to freeze.

Specific end use(s)

See Instructions for Use (IFU) at www.premierdentalco.com

SECTION 8: Exposure controls/personal protection

8.2 Appropriate engineering controls

Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation.

Individual protection measures, such as personal protective equipment (PPE) 8.3

Eye/face protection

Wear chemical goggles or safety glasses.

Skin protection

Wear protective gloves.

Body protection

Use as appropriate: Chemical resistant clothing. Do not eat, drink or smoke during use.

Respiratory protection

In case of insufficient ventilation, wear suitable respiratory equipment.

SECTION 9: Physical and chemical properties

Appearance, such as physical state and colour	
Odour	Odorless
Odour threshold	No data available
pH	7 - 8.5
Melting point and freezing point	N/A and 0°C
Initial boiling point and boiling range	100°C
Flash point	No data available
Evaporation rate	No data available
Flammability, in the case of solids and gases	No data available
Upper and lower flammability or explosive limits	No data available
Vapour pressure	No data available
Vapour density	No data available
Relative density	No data available
Solubility	Soluble in water
Partition coefficient — n-octanol/water	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Viscosity	No data available
Additional properties	
Physical state	Liquid

Physical state Colour Explosive properties Oxidising properties

Particle characteristics No data available

LIQUIA Clear/Colorless No data available

No data available

SECTION 10: Stability and reactivity

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- **10.1 Reactivity** No data available
- **10.2 Chemical stability** No data available
- **10.3 Possibility of hazardous reactions** No data available
- **10.4 Conditions to avoid** Keep away from sources of ignition - No smoking. Keep in a cool place away from direct sunlight.
- **10.5 Incompatible materials** Strong oxidizing agents.
- **10.6 Hazardous decomposition products** Carbon oxides.

SECTION 11: Toxicological information

Information on toxicological effects

Acute toxicity

Prolonged or repeated exposure may cause: Damage to organs.

Skin corrosion/irritation

May cause irritation to skin.

Serious eye damage/irritation

May cause eye irritation.

Respiratory or skin sensitization

May cause allergic reactions in susceptible people.

Germ cell mutagenicity

No mutagenic effects reported.

Carcinogenicity

Not found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs, Volumes 1-112. Not listed in the National Toxicology Program (NTP) 13th Report on Carcinogens. Not listed in the OSHA standard 1910.1003 Carcinogens.

Reproductive toxicity

No teratogenic effects reported.

Specific target organ toxicity (STOT) - single exposure

May cause irritation to respiratory system.

Specific target organ toxicity (STOT) - repeated exposure Avoid prolonged or repeated exposure.

SECTION 12: Ecological information

Toxicity No data available.

Persistence and degradability No data available.

Bioaccumulative potential No data available.

Mobility in soil No data available.

Results of PBT and vPvB assessment No data available.

Endocrine disrupting properties No data available.

Other adverse effects

No data available.

SECTION 13: Disposal considerations

Disposal methods

Product disposal

Dispose of contents/container within a sharps container in accordance to facility or institutional guidelines/procedures

Packaging disposal

Do NOT reuse empty containers. Empty containers can be sent for disposal or recycling.

Other disposal recommendations

Dispose of in compliance with all local and federal/national regulations. Do not contaminate water by cleaning of equipment or disposal of wastes.

SECTION 14: Transport information

DOT (US)

UN Number: The product is not classified as dangerous for carriage. Class: Packing Group: Proper Shipping Name: Reportable quantity (RQ): Marine pollutant: Poison inhalation hazard:

IMDG

UN Number: The product is not classified as dangerous for carriage. Class: Packing Group:

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EMS Number: Proper Shipping Name:

IATA

UN Number: The product is not classified as dangerous for carriage. Class: Packing Group: Proper Shipping Name:

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations specific for the product in question

Regulations

Hazard Communication Standard: 29 Code of Federal Regulations 1910.1200: Occupational Safety and Health Standards: Z: Toxic and Hazardous Substances: Hazard Communication. All chemicals in this product are TSCA listed or excluded from listing, on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory. TSCA - United States Toxic Substances Control Act Section 8(b) Inventory. Materials are exempt from TSCA under Section 3(2)(B)(vi) when used for pharmaceutical application. US State Regulations:

This material contains no reportable components.

SECTION 16: Other information

Text of Hazard Statements: Compressed gas - Contains gas under pressure; may explode if heated.

16.1 Further information/disclaimer

The labeling requirements of the Federal Food, Drug, and Cosmetic Act differ from the classification criteria and hazard information required for safety data sheets and for workplace labels under the OSHA Hazard Communication Standard 29 CFR 1910.1200. Prescription device, Rx Only.

DISCLAIMER: The information and recommendations set forth herein ("Information") are presented in good faith and believed to be correct as of the date issued. No representation is made regarding the completeness or accuracy of the Information. Further, because of the many factors that affect the use of this product, the Information is supplied upon the condition that the person(s) receiving it will make their own determination regarding its suitability for their own unique purpose(s), prior to use.