

PerioStom™

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations
Date of Issue: 04/16/2024

Version: 1.0

SECTION 1: IDENTIFICATION

- 1.1. Product Identifier

Product Form: Mixture

Product Name: PerioStom™

Synonyms: Chitosan
- 1.2. Intended Use of the Product

Use of the Substance/Mixture: Medical Device – Oral Wound Dressing
- 1.3. Name, Address, and Telephone of the Responsible Party

Company,Manufacturer

Forward Science

10810 Craighead Drive

Houston, TX 77025

T: 855-696-7254

www.forwardscience.com
- 1.4. Emergency Telephone Number

Emergency Number : 855-696-7254 (Forward Science)

SECTION 2: HAZARDS IDENTIFICATION

- 2.1. Classification of the Substance or Mixture


GHS-US Classification

Hazardous to the aquatic environment – Acute Hazard Category 1 H400

Combustible Dust
- 2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US) :



GHS09

Signal Word (GHS-US) :

Warning

Hazard Statements (GHS-US) :

May form combustible dust concentrations in air.

H400 - Very toxic to aquatic life.

Precautionary Statements (GHS-US) :

P273 - Avoid release to the environment.

P391 - Collect spillage.

P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

Supplemental Information :

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Proper grounding procedures to avoid static electricity should be followed. Prevent dust accumulation (to minimize explosion hazard). Avoid generating dust.

2.3. Other Hazards

This product contains shellfish. Adverse reactions may occur in sensitive persons. 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

Not applicable

3.2. Mixture
- | Name | Synonyms | Product Identifier | % | GHS US classification |
|----------|--|---------------------|------|---|
| Chitosan | Poly-D-glucosamine / A linear polysaccharide of deacetylated .beta.-1,4-D-glucosamine / Poly-d-glucosamine / Poly(D-glucosamine, N-acetylated) / Poly(1,2,3,4)-2-amino-2-desoxy-.beta.-D-glucopyranose / Poliglusam / Poliglusam (Deacetylated chitin, a linear polysaccharide of deacetylated beta-1,4-D-glucosamine. It is used in hydrogel and to treat wounds.) / Deacetylated chitin / Poly(D-glucosamine, partly N-acetylated) / Chitosan oligosaccharide / Hydamer DCMF | (CAS-No.) 9012-76-4 | > 99 | Aquatic Acute 1, H400
Combustible Dust |
- 04/16/2024

EN (English US)

1/7

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Acetic acid	Acetic acid, glacial / Ethanoic acid / Ethylic acid / Vinegar acid / Acetic acid ... %	(CAS-No.) 64-19-7	< 1	Flam. Liq. 3, H226 Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402
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Full text of H-phrases: see section 16

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 advice (show the label where possible).

First-aid Measures After Inhalation: Using proper respiratory protection, immediately move the exposed person to fresh air. Encourage exposed person to cough, spit out, and blow nose to remove dust. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 5 minutes. Obtain medical attention if irritation develops or persists.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

First-aid Measures After Ingestion: This product is intended for oral use. Ingestion is not expected to be harmful. If large amounts are ingested: Rinse mouth. Do not induce vomiting. Call a POISON CENTER/doctor/physician if you feel unwell.

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: Dust may be harmful or cause irritation.

Symptoms/Injuries After Skin Contact: Skin contact with large amounts of dust may cause mechanical irritation.

Symptoms/Injuries After Eye Contact: Eye contact with dust may cause mechanical irritation.

Symptoms/Injuries After Ingestion: Ingestion of large quantities may cause adverse effects.

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: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical. 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: Dust explosion hazard in air.

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. Avoid raising dust.

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

Hazardous Combustion Products: Carbon oxides (CO, CO₂). Nitrogen oxides.

Other Information: Do not allow run-off from fire fighting to enter drains or water courses. Risk of dust explosion.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid prolonged contact with eyes, skin and clothing. Avoid breathing dust. Avoid generating dust. Remove ignition sources. Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking.

6.1.1. For Non-Emergency Personnel

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

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

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. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters. Avoid release to the environment. Collect spillage.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain solid spills with appropriate barriers and prevent migration and entry into sewers or streams. Avoid generation of dust during clean-up of spills.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Contact competent authorities after a spill. Use explosion proof vacuum during cleanup, with appropriate filter. Do not mix with other materials. Vacuum clean-up is preferred. If sweeping is required use a dust suppressant. Use only non-sparking tools.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Accumulation and dispersion of dust with an ignition source can cause a combustible dust explosion. Keep dust levels to a minimum and follow applicable regulations.

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. Avoid creating or spreading dust. Keep away from heat, sparks, open flames, and hot surfaces. No smoking.

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. Avoid creating or spreading dust. Use explosion-proof electrical, ventilating, lighting equipment. Proper grounding procedures to avoid static electricity should be followed.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

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

Storage Temperature: 15 - 30 °C (59° - 86 °F)

7.3. Specific End Use(s)

Medical Device – Oral Wound Dressing

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).

Acetic acid (64-19-7)		
USA ACGIH	ACGIH OEL TWA	10 ppm
USA ACGIH	ACGIH OEL STEL	15 ppm
USA NIOSH	NIOSH REL TWA	25 mg/m ³
USA NIOSH	NIOSH REL TWA	10 ppm
USA NIOSH	NIOSH REL STEL	37 mg/m ³
USA NIOSH	NIOSH REL STEL	15 ppm
USA IDLH	IDLH	50 ppm
USA OSHA	OSHA PEL TWA	25 mg/m ³
USA OSHA	OSHA PEL TWA	10 ppm

8.2. Exposure Controls

Appropriate Engineering Controls

: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed. Proper grounding procedures to avoid static electricity should be followed. Use explosion-proof equipment. Use local exhaust or general dilution ventilation or other suppression methods to maintain dust levels below exposure limits. Power equipment should be equipped with proper dust collection devices. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment.

Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.



Materials for Protective Clothing

: Chemically resistant materials and fabrics.

Hand Protection

: Wear protective gloves.

Eye and Face 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
Appearance	: Light yellow to golden yellow powder
Odor	: Slight vinegar odor
Odor Threshold	: No data available
pH	: 3 – 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, extremely high or low temperatures, and incompatible materials. Avoid creating or spreading dust. Sparks, heat, open flame and other sources of ignition. Dust accumulation (to minimize explosion hazard).

10.5. Incompatible Materials

Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products

Thermal decomposition may produce: Carbon oxides (CO, CO₂). Nitrogen oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity (Oral): Not classified.

Acute Toxicity (Dermal): Not classified.

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Acute Toxicity (Inhalation): Not classified.

Acetic acid (64-19-7)	
LD50 Oral Rat	3310 mg/kg (Source: JAPAN_GHS)
LD50 Dermal Rabbit	1060 mg/kg (Source: JAPAN_GHS)
LC50 Inhalation Rat	11.4 mg/l/4h

Skin Corrosion/Irritation: Not classified.

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: Dust may be harmful or cause irritation.

Symptoms/Injuries After Skin Contact: Skin contact with large amounts of dust may cause mechanical irritation.

Symptoms/Injuries After Eye Contact: Eye contact with dust may cause mechanical irritation.

Symptoms/Injuries After Ingestion: Ingestion of large quantities may cause adverse effects.

Chronic Symptoms: None known.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Very toxic to aquatic life.

Chitosan (9012-76-4)	
LC50 Fish	0.05 mg/l (Species: Oncorhynchus mykiss)
Acetic acid (64-19-7)	
LC50 Fish	79 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static] Source: EPA)
EC50 Crustacea	65 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
LC50 Fish	75 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static] Source: EPA)

12.2. Persistence and Degradability

PerioStöm™	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

PerioStöm™	
Bioaccumulative Potential	Not established.
Acetic acid (64-19-7)	
Partition coefficient n-octanol/water (Log Pow)	-0.17 at 25 °C (at pH 7)

12.4. Mobility in Soil

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.

Additional Information: Container may remain hazardous when empty. Continue to observe all precautions.

Ecology - Waste Materials: Avoid release to the environment. This material is hazardous to the aquatic environment. Keep out of sewers and waterways.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT

Proper Shipping Name : ENVIRONMENTALLY HAZARDOUS SUBSTANCES, SOLID, N.O.S. (Chitosan)

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Hazard Class : 9
Identification Number : UN3077
Label Codes : 9
Packing Group : III
Marine Pollutant : Marine pollutant
ERG Number : 171



14.2. In Accordance with IMDG

Proper Shipping Name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Chitosin)
Hazard Class : 9
Identification Number : UN3077
Packing Group : III
Label Codes : 9
EmS-No. (Fire) : F-A
EmS-No. (Spillage) : S-F
Marine Pollutant : Marine pollutant



14.3. In Accordance with IATA

Proper Shipping Name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Chitosin)
Packing Group : III
Identification Number : UN3077
Hazard Class : 9
Label Codes : 9
ERG Code (IATA) : 9L



SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

PerioStöm™	
SARA Section 311/312 Hazard Classes	Physical hazard - Combustible dust
Chitosan (9012-76-4)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711).
Acetic acid (64-19-7)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
CERCLA RQ	5000 lb

15.2. US State Regulations

Acetic acid (64-19-7)	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) List	
U.S. - Massachusetts - Right To Know List	
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List	

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

Date of Preparation or Latest Revision : 04/16/2024
Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

GHS Full Text Phrases:

H226	Flammable liquid and vapor
H290	May be corrosive to metals
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H400	Very toxic to aquatic life
H402	Harmful to aquatic life

Glossary of Data Source Abbreviations

ATSDR: Agency for Toxic Substances and Disease Registry (U.S. Department of Health and Human Services)
AU_WES: Australia WES

FOOD_JOURN: Food Research Journal (1956)
IARC: The International Agency for Research on Cancer
IDLH: National Institute for Occupational Health and Safety Immediately

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CHEMVIEW: ChemView (U.S. Environmental Protection Agency)	Dangerous to Life or Health Value Profiles
EC_RAR: European Commission Renewal Assessment Report	IUCLID: International Uniform Chemical Information Database
EC_SCOEL: European Commission Scientific Committee on Occupational Exposure Limits	JAPAN_GHS: Japan GHS Basis for Classification Data
ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals Reports	JP_J-CHECK: Japan J-Check
ECHA_API: European Chemicals Agency API	KR_NIER: South Korea National Institute of Environmental Research Evaluations
ECHA_RAC: ECHA Committee for Risk Assessment	NICNAS: Australia National Industrial Chemicals Notification and Assessment Scheme
EFSA: European Food Safety Authority	NIOSH: National Institute for Occupational Health and Safety (U.S. Department of Health and Human Services)
EPA: U.S. Environmental Protection Agency	NLM_CIP: National Library of Medicine ChemID plus database
EPA_AEGL: Acute Exposure Guideline Levels (U.S. Environmental Protection Agency)	NLM_HSDB: National Library of Medicine Hazardous Substance Data Bank
EPA_FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act Reregistration Eligibility Decision (U.S. Environmental Protection Agency)	NLM_PUBMED: National Library of Medicine PubMed database
EPA_HPVC: High Production Volume Chemicals (U.S. Environmental Protection Agency)	NTP: National Toxicology Program
EPA_TRED: Risk Assessment for Tolerance Reassessment Eligibility Decision (U.S. Environmental Protection Agency)	NZ_CCID: New Zealand Chemical Classification and Information Database
EU_CLH: European Union Harmonised Classification and Labelling Proposal	OECD_EHSP: Environment, Health, and Safety Publication (Organisation for Economic Co-operation and Development)
EU_RAR: European Union Risk Assessment Report	OECD_SIDS: Screening Information Data Sets (Organisation for Economic Co-operation and Development)
	WHO: World Health Organization

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SDS US (GHS HazCom)