

WORTHAM LABORATORIES, INC.

Material Safety Data Sheet

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Section 1 - Product and Company Information

Product Name SeraSeal™

Product Number 4003

Company Wortham Laboratories, Inc.

Street Address 6340 Bonny Oaks Drive

City, State, Zip Code Chattanooga, TN 37416

Technical Phone 423 296 0090

Fax 423 296 0188

Section 2 - Composition/Information on Ingredient

Substance Name

SeraSeal™

Formula Bovine Proteins



Synonyms

Hemostatic Agent

Section 3 - Hazards Identification

Emergency Overview

Non-Toxic

HMIS Rating

Health: 0

Flammability: 0

Reactivity: 0

NFPA Ratings

Flammability: 0

Reactivity: 0

For additional information on toxicity, please refer to Section 11.

EU Rep: Wortham Laboratories, London

11 Dersingham Rd, NW21SN, UK

Section 4 - First Aid Measures

Oral Exposure

Not harmful

Inhalation Exposure

Not harmful

Dermal Exposure

Not harmful



Eye Exposure

Not harmful

Section 5 - Fire Fighting Measures

Autoignition Temp

N/A

Flammability

N/A

Extinguishing Media

Suitable

Noncombustible. Use extinguishing media appropriate to surrounding fire conditions.

Firefighting

Protective Equipment

Wear self-containing breathing apparatus, rubber boots, and heavy rubber gloves.

Special Hazard(s)

Not known to emit toxic fumes under fire conditions.

Section 6 - Accidental Release Measures

Procedure(s) of Personal Precaution(s)

Protective gear not necessary when cleaning up.

Methods for Cleaning Up

Mop up, place in a bag and hold for waste disposal. Clean area with 1% bleach. Treat as medical waste.



Section 7 - Handling and Storage

Handling

User Exposure

Avoid inhalation.

Storage

Keep sealed. Store as indicated on label.

Section 8 - Exposure Controls/PPE

Engineering Controls

Safety shower and eye bath.

Personal Protective Equipment

Respiratory

NIOSH/MSHA-approved respirator.

Hand

Vinyl or latex gloves.

Eye

Safety goggles.

General Hygiene Measures

Wash thoroughly after handling.

Section 9 - Physical/Chemical Properties



Appearance

Color	Form
Clear	Liquid

Property Value

pH 7.0 - 7.4

BP/BP Range 100° C

MP/MP Range 33° C

Freezing Point 0° C

Vapor Pressure N/A

Vapor Density N/A

Saturated Vapor Conc. N/A

SG/Density N/A

Bulk Density N/A

Odor Threshold N/A

Volatile % N/A

VOC Content N/A

Water Content 99%

Solvent Content N/A

Evaporation Rate N/A

Viscosity 1.002

Partition Coefficient N/A

Decomposition Temp. N/A

Flash Point °F N/A

Explosion Limits N/A

Autoignition Temp N/A

Optical Rotation N/A

Solubility

Solubility in Water: 1 M in H₂O, 20° C, complete, colorless



Section 10 - Stability and Reactivity

Stability

Stable

Stable

Conditions to Avoid

None

Materials to Avoid

None

Hazardous Decomposition Products

Hazardous Decomposition Products

None

Hazardous Polymerization

Hazardous Polymerization

Non-applicable

Section 11 - Toxicological Information

Route of Exposure

Skin Contact

Not harmful

Eye Contact

Not harmful

Inhalation

Not harmful



Multiple Routes

Harmful if introduced intravascularly. May induce Intravascular disseminated coagulation (DIC).

Signs and Symptoms of Exposure

Toxicological studies have demonstrated no sensitization, systemic toxicity, cytotoxicity, genotoxicity, or immunogenicity.

Section 12 - Ecological Information

Section 13 - Disposal Considerations

Appropriate Method of Disposal of Substance or Preparation

Bleach may be added to control biohazard exposure, and burn in an incinerator equipped with an afterburner and scrubber. Observe all federal, state, and local environmental regulations.

Section 14 - Transport Information

DOT

Proper Shipping Name: SeraSeal

This substance is considered to be non-hazardous for transport.

IATA

Proper Shipping Name: SeraSeal



Non-Hazardous for Air Transport

Section 15 - Regulatory Information

ISO 9000:2005, Quality Management Systems — Fundamentals and vocabulary

ISO 13485:2003, Medical Devices - Quality Management Systems

21 CFR Part 820 (Oct. 1996): Quality System Regulation for the manufacture of medical devices

Directive 93/42/EEC: EU Council Directive of June 14, 1993 concerning medical devices

MEDDEV 3/93: EC Guideline on a Medical Device Vigilance System (2.12-1 rev 8, January 2013)

F-27-SOR/98-282: Canada-Medical Devices Regulations

ISO 13488, 1996: Quality systems audits performed by CMDCAS recognized Registrars

21 CFR Part 820: Quality System Regulation (EFF. 6-1-97)

21 CFR 210: Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding Drugs

21 CFR 211: Current Good Manufacturing Practice for Finished Pharmaceuticals

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Section 16 - Other Information

Warranty

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Wortham Laboratories, Inc. shall not be held liable for any damage resulting from handling or from contact with the above product. See reverse side of invoice or packing slip for additional terms and conditions of sale. Copyright 2001 Wortham Laboratories, Inc. License granted to make unlimited paper copies for internal use only.

