

Material Safety Data Sheet

Section 1 - Chemical Product and Company Identification

Product/Chemical Name: *Collagenase Santyl® Ointment*

Formula: Contains 250 units of collagenase enzyme in form of a suspension per gram of white petrolatum, USP

CAS Number: N/A

Other Designations: N/A

General Use: Enzymatic debriding agent

Manufacturer: Advance Biofactures Corporation 35 Wilbur Street, Lynbrook, NY 11563 **Phone:** 1 516 593-7000

Distributor: Smith & Nephew, Inc. 11775 Starkey Road Largo, FL 33773-4727 **Phone:** 1800 876-1261

Date Reviewed: December 8, 2003

Section 2 - Composition Information on Ingredients

Ingredient Name	CAS Number	%wt or % Vol
White Petrolatum, USP	8009-03-8	Proprietary
Collagenase	N/A	Proprietary

Section 3 - Hazards Identification

☆☆☆☆☆ **Emergency Overview** ☆☆☆☆☆

HMIS	
H	1
F	1
R	1
PPE	0

Potential Health Effects

Primary Entry Routes: Ingestion, Eyes, Skin

Target Organs: N/A

Acute Effects

Skin: None Known

Eye: May cause slight irritation

Ingestion: May be hazardous

Medical Conditions Aggravated by Long-Term Exposure: Avoid contact if local or systemic hypersensitivity is noticed.

Chronic Effects: No allergic sensitivity or toxic reactions have been noted in the recorded clinical investigations. However, one case of systemic manifestation of hypersensitivity to collagenase in a patient treated for more than 1 year with a combination of collagenase and cortisone has been reported.

Section 4 - First Aid Measures

Eye Contact: Flush eyes (including under lids) with copious amounts of cold water for at least 15 minutes and contact a physician.

Skin Contact: Flush immediately with cold water and contact a physician.

Carcinogenicity: No data available

Ingestion: Contact a physician or poison control center immediately.

After first aid, get appropriate in-plant, paramedic, or community medical support.

Special Precautions/Procedures: None

Section 5 - Fire-Fighting

Flash Point: >390°F / >199°C

NFPA:

Flash Point Method: ASTM D-92

Burning Rate: Not determined

Autoignition Temperature: Not determined

LFL (% vol in air): Not determined

UFL (% vol in air): Not determined

Flammability Classification: Not determined

Extinguishing Media: Dry chemical, CO₂, foam, sand/earth, water fog

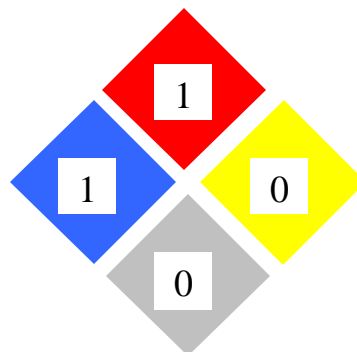
Unusual Fire or Explosion Hazards: None

Hazardous Combustion Products: Upon combustion, carbon dioxide and carbon monoxide are generated.

Fire-Fighting Instructions: Water spray is an unsuitable extinguishing agent. Protect against smoke inhalation. Do not release runoff from fire control methods to sewers or waterways.

Fire-Fighting Equipment: Self Contained Breathing Apparatus and protective clothing should be worn.

Wear heat-protective, impervious gloves when handling molten product.



Section 6 - Accidental Release Measures

Spill /Leak Procedures:

Small Spills: Scrape up ointment. Clean area with an oil absorbent material.

Large Spills

Containment: Not required

Cleanup: After cooling and solidification, scrape/shovel up material & then clean area with an oil absorbent material.

Regulatory Requirements: Follow applicable OSHA regulations (29 CFR 1910.120).

Section 7 - Handling and Storage

Handling Precautions: None

Storage Requirements: Store at <77°F (<25°C)

Regulatory Requirements: None

Section 8 - Exposure Controls / Personal Protection

Engineering Controls: N/A

Ventilation: N/A

Administrative Controls: N/A

Respiratory Protection: N/A

Protective Clothing/Equipment: Wear proper overalls. Eye protection & gloves recommended.

Comments: Never eat, drink, or smoke in work areas. Practice good personal hygiene after using this material, especially before eating, drinking, smoking, using the toilet, or applying cosmetics.

Section 9 - Physical and Chemical Properties

Appearance and Odor: Opaque with suspended dark enzyme particles. White to off-white. No odor.

Physical State: Semi-solid

Water Solubility: Nil

Other Solubilities: Not determined

Odor Threshold: N/A

Vapor Pressure (mm Hg @ 20°C): Not determined

Vapor Density (Air=1): N/A

pH @ 25° C: Not determined

Boiling Point: Not determined

Freezing Point: Not determined

Melting Point: 38 – 60° C (100-140° F)

Viscosity: Not determined

Refractive Index: Not determined

Formula Weight:N/A
Density: Not determined
Specific Gravity (H₂O=1, at 60° C): 0.815 – 0.880

Surface Tension: Not determined
% (by weight) Volatile: Not determined
Evaporation Rate: Not determined

Section 10 - Stability and Reactivity

Stability: Stable
Polymerization: Hazardous polymerization will not occur.
Chemical Incompatibilities: Strong oxidizing agents, excess heat, & flame.
Conditions to Avoid: Temperatures > 390° F (199°C)
Hazardous Decomposition Products: Upon combustion, carbon dioxide & carbon monoxide are generated.

Section 11 - Toxicological Information

Toxicity Data:
Eye Effects: None Known
Skin Effects: None
Acute Inhalation Effects: None Known
Acute Oral Effects: None Known
Chronic Effects: None Known
Carcinogenicity: None Known
Mutagenicity: None
Teratogenicity: None Known

Section 12 - Ecological Information

Ecotoxicity: Not determined
Environmental Fate: Not determined
Environmental Degradation: Not determined
Soil Absorption/Mobility: Not determined

Section 13 - Disposal Considerations

Disposal: Contact your supplier or a licensed contractor for detailed recommendations.
Disposal Regulatory Requirements: Follow applicable federal, state, and local regulations.
Container Cleaning and Disposal: Discard in suitable trash container

Section 14 - Transport Information

DOT Transportation Data (49 CFR 172.101):
Not Regulated

Section - 15 Regulatory Information

EPA Regulations: None known
OSHA Regulations: None known
State Regulations: May vary from state to state.

Section 16 - Other Information

Additional Hazard Rating Systems: None Known

NOTE: Information about reactivity and precautions for safe handling are provided strictly for hazard communication and are not designed to retain enzyme activity.

Note from the manufacturer: We believe the statements, technical information and recommendations contained herein are reliable, but they are given without warranty or guarantee of any kind, expressed or implied, and we assume no responsibility for any loss, damage or expense, direct or consequential, arising out of their use. Users should make their own investigations to determine the suitability of the information for their particular purpose.