



DOCUMENT NUMBER:

DOCUMENT TITLE:

DOCUMENT NOTES:

DRAFT

Document Information

Revision:

Vault:

Doc Type:

Status:

Date Information

Effective Date: _____ :

Next Review Date:

Release Date:

Expiration Date:

Control Information

Author:

Previous Number:

Owner:

Change Number:

SAFETY DATA SHEET

Revision: 04
Revision Date: 5-2017

1. Product and Company Identification

Material name Collagenase Santyl[®] Ointment
CAS #: Collagenase N/A, White Petrolatum 8009-03-8
MSDS Number: SNFT-MSDS-0004
Product use: Enzymatic debriding ointment
NDC: 50484-010-30, & 50484-010-90
DIN: 02063670
Manufacturer/Supplier Smith & Nephew Inc.
5600 Clearfork Main Street
Fort Worth, TX
76109
Contact: 1-800-441-8227

2. Hazard(s) Identification

Physical state: Semi-solid.
Appearance: White to off white, smooth ointment, free from separation
Emergency overview: The product may cause allergic or sensitivity reaction for individuals sensitive to one or more of the components.
OSHA regulatory status: This product is considered not hazardous under 29 CFR 1910.1200 (Hazard Communication).

Potential health effects

Routes of exposure:

Ingestion. 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 one year with a combination of collagenase and cortisone has been reported

Eyes:

May cause eye irritation on direct contact.

Skin:

The product contains a small amount of sensitizing substances which may provoke

<u>Inhalation:</u>	an allergic reaction among sensitive individuals in contact with skin. No inhalation hazard under normal conditions.
<u>Ingestion:</u>	Ingestion may cause irritation and malaise.
<u>Target organs:</u>	Eyes. Skin.
<u>Potential environmental effects:</u>	Not expected to be harmful to aquatic organisms

3. Composition/ Information on Ingredients

Formulation is proprietary. This information will be provided, as needed, to medical personnel in the event of an emergency. Hazardous ingredients or ingredients principally responsible for potentially hazardous qualities or pharmacological activity of this product are listed below

ACTIVE COMPONENT: Collagenase White Petrolatum

4. First-Aid Measures

Eye contact:	Flush eyes thoroughly with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Get medical attention if irritation develops and persists.
Skin contact:	Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing if required, then physically remove as much of the product as possible. Wash affected area with soap and water, and then thoroughly flush the area with water. If irritation persists, seek medical advice.
Inhalation:	No specific first aid measures noted.
Ingestion	Do not induce vomiting as aspiration of the product might occur. Drink large amounts of water. In cases where the ingestion of a large amount is suspected, experienced medical personnel may perform gastric lavage.
General advice:	If you feel unwell, seek medical advice (show the label where possible). Show this safety data sheet to the doctor in attendance

5. Fire-Fighting Measures

Flammable properties: No data available. No unusual fire or explosion hazards noted.

Suitable extinguishing media: Dry chemical, CO₂, foam, sand/earth, water fog

Unsuitable extinguishing media: Water spray is an unsuitable extinguishing agent. Protect against smoke inhalation. Do not release runoff from fire control methods to sewers and waterways.

Protection of firefighters: Wear suitable protective equipment.

Firefighting equipment/instructions: Water spray is an unsuitable extinguishing agent
Protect against smoke inhalation. Do not release runoff
from fire control methods to sewers and waterways

6. Accidental Release Measures

Personal precautions: Wear safety glasses with side shields if eye contact is likely, e.g., during clean large spill. Wear gloves if skin contact is likely, e.g., during cleanup of large spill.

Environmental precautions: Should not be released into the environment.

Methods for cleaning up

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

Other information: Clean up in accordance with all applicable regulations

7. Handling and Storage

Handling: Observe good industrial hygiene practices.

Storage: Store below 25°C (77°F)

8. Exposure Controls/ Personal Protection

Occupational exposure limits: No exposure limits noted for ingredient(s).

Engineering controls:

VENTILATION: Use general or local exhaust.

Personal protective equipment

Eye / face protection: Wear safety glasses with side shields

Skin protection: Chemical Gloves

Respiratory protection: No personal respiratory protective equipment normally required.

General hygiene considerations: Handle in accordance with good industrial hygiene and safety practice.

9. Physical and Chemical Properties

Appearance: A thick, white, homogeneous cream.

Color: White to off White

Odor: None or a slight petrolatum odor

Odor threshold: Not available.

Physical state: Semi-solid.

Form: Cream, smooth ointment

pH: Not available.

Melting point: 53-58 °C (127. - 136 °F)

Freezing point: Not available.

Boiling point: Not available.

Flash point: Greater than 199°C (390°F)

Evaporation rate: Not available.

Flammability limits in air, upper, % by volume: Not available.

Flammability limits in air, lower, % by volume: Not available.

Vapor pressure: Not available.

Vapor density: Not available.

Specific gravity: 0.815 - 0.880 at 60°C

Solubility (water): Nil

Partition coefficient (n-octanol/water): Not available.

Auto-ignition temperature: Not available.

Decomposition temperature: Not available.

10. Stability and Reactivity

Chemical stability: Material is stable under normal conditions.

Conditions to avoid: Temperatures > 199°C (390°F).

Incompatible materials: Keep away from flame, excess heat and strong oxidizing agents.

Hazardous decomposition products: Carbon Dioxide and Carbon Monoxide may be produced during pyrolysis.

11. Toxicological Information

Acute effects: Ingestion may cause irritation and malaise.

Sensitization: The product may cause allergic or sensitivity reaction for individuals sensitive to one or more of the components.

Chronic effects: No additional adverse health effects noted.

Carcinogenicity: This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Epidemiology: No epidemiological data is available for this product.

Mutagenicity: No data available.

Reproductive effects: No data available.

Further information: No other specific acute or chronic health impact noted

12. Ecological Information

Ecotoxicity: The product is not expected to be hazardous to the environment.

Persistence and degradability: No data is available on the degradability of this product.

Bioaccumulation / Accumulation: No data available.

Partition coefficient (n-octanol/water): Not available.

Mobility in environmental media: Solubility is Nil



13. Disposal Considerations

Waste codes: Not regulated.

Disposal instructions: Dispose in accordance with all applicable regulations. When this product as supplied is to be discarded as waste, it does not meet the definition of a RCRA waste under 40 CFR 261.

Waste from residues / unused products: Dispose in accordance with all applicable regulations

14. Transport Information

DOT: Not regulated as dangerous goods.

IATA: Not regulated as dangerous goods.

IMDG: Not regulated as dangerous goods.

TDG: Not regulated as dangerous goods

15. Regulatory Information

US Federal regulations	This product is not hazardous according to OSHA 29CFR 1910.1200	
TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)	Not regulated	
CERLA (Superfund) reportable quantity (lbs) (40 CFR 302.4)	None	
Superfund Amendments and Reauthorization Act of 1986 (SARA)		
Hazard categories	Immediate Hazard - No Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No	
Section 302 extremely hazardous substance (40 CRF 355, Appendix A)	No	
Section 311/312 (40 CFR 370)	No	
Drug Enforcement Administration (DEA) (21 CFR 1308.11-15)	Not controlled	
Canadian regulations	This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all the information required by the CPR.	
WHMIS status	Non-controlled	
Inventory status		
Country(s) or region	Inventory name	On inventory (yes/no)*

Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes
*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)		
State regulations	This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.	
Mexico regulations	This safety data sheet was prepared in accordance with the Official Mexican Standard (NOM-018-STPS-2000).	

16. Other Information

HMIS/GHS ratings® 4=Lowest Rating	Health: 4 Flammability: 4 Physical hazard:4
NFPA/GHS ratings 4=Lowest Rating	Health: 4 Flammability: 4 Instability: 4
Disclaimer	The information contained herein is furnished without warranty of any kind. The above information is believed to be correct but does not purport to be all-inclusive and should be used only as a guide. Users should make independent determinations of the suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees and customers
Issue date	4-2015

DRAFT