

Material Safety Data Sheet

Material Name: Salkera Emollient Foam

*** Section 1 - Chemical Product and Company Identification ***

Manufacturer Information

Collegium Pharmaceutical, Inc.
400 Highland Corporate Drive
Cumberland, RI 02864

Emergency Number: 1-888-713-8154

*** Section 2 - Hazards Identification ***

Emergency Overview

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

Potential Health Effects: Eyes

May cause irritation and stinging or burning.

Potential Health Effects: Skin

Allergic or sensitivity reactions are possible, causing irritation or redness.

Potential Health Effects: Ingestion

Not a likely route of entry. If swallowed may cause gastrointestinal discomfort.

Potential Health Effects: Inhalation

May cause respiratory irritation in some sensitive individuals.

Medical Conditions Aggravated by Exposure

Known sensitivity to salicylates.

HMIS Ratings: Health: 1 Fire: 1 Physical Hazard: 0

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe * = Chronic hazard

*** Section 3 - Composition / Information on Ingredients ***

CAS #	Component
7732-18-5	Water
811-97-2	1,1,1,2-Tetrafluoroethane
69-72-7	Salicylic acid
56-81-5	Glycerin
515-98-0	Ammonium lactate
57-55-6	1,2-Propylene glycol
1310-73-2	Sodium hydroxide
67762-27-0	Alcohols, C16-18
8009-03-8	Petrolatum
50643-20-4	Ceteth-10 Phosphate
7695-91-2	2H-1-Benzopyran-6-ol, 3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-, acetate
99-76-3	Methyl p-hydroxybenzoate
2197-63-9	1-Hexadecanol, hydrogen phosphate
94-13-3	Propyl-p-hydroxybenzoate
8001-97-6	Aloe vera gel
6381-92-6	Ethylenediaminetetraacetic acid, disodium, dihydrate
Proprietary	Ceteth-20 Phosphate

Component Information/Information on Non-Hazardous Components

*** Section 4 - First Aid Measures ***

First Aid: Eyes

Salicylic acid is a severe ocular irritant. Remove contact lenses. Immediately flush eyes with water for at least 15 minutes, while holding eyelids open. Seek medical attention at once.

First Aid: Skin

Immediately take off all contaminated clothing. Physically remove as much of product as possible and thoroughly wash the area with soap and water. If irritation persists, get medical attention.

Material Safety Data Sheet

Material Name: Salkera Emollient Foam

First Aid: Ingestion

Product is water soluble with moderate toxicity. Do not induce vomiting unless directed to do so by medical personnel. Drink large amounts of water slowly. In cases where the ingestion of a large amount is suspected, experienced medical personnel may perform gastric lavage.

First Aid: Inhalation

None necessary.

* * * Section 5 - Fire Fighting Measures * * *

General Fire Hazards

See Section 9 for Flammability Properties.
None identified.

Hazardous Combustion Products

Acrolein, phenol and oxides of nitrogen and carbon may be produced.

Extinguishing Media

Use any media suitable for the surrounding fires.

Fire Fighting Equipment/Instructions

Fire fighters should wear full-face, self contained breathing apparatus and impervious protective clothing. Fire fighters should avoid inhaling any combustion products.

NFPA Ratings: Health: 1 Fire: 1 Reactivity: 0

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe

* * * Section 6 - Accidental Release Measures * * *

Containment Procedures

Contain the discharged material.

Clean-Up Procedures

Scoop material and place in a suitable container for disposal. Use soap and water to clean spill area.

Evacuation Procedures

None necessary.

Special Procedures

Wear appropriate personal protective equipment.

* * * Section 7 - Handling and Storage * * *

Handling Procedures

Avoid getting this material into contact with your eyes. Wash thoroughly after handling.

Storage Procedures

Controlled room temperature 59°F - 77°F (15°C - 25°C). Protect from freezing. Do not expose to temperatures above 120°F (49°C).

* * * Section 8 - Exposure Controls / Personal Protection * * *

A: Component Exposure Limits

Glycerin (56-81-5)

ACGIH: 10 mg/m³ TWA

OSHA: 10 mg/ m³ TWA (total dust); 5 mg/m³ TWA (respirable fraction)

Sodium hydroxide (1310-73-2)

ACGIH: 2 mg/ m³ Ceiling

OSHA: 2 mg/ m³ Ceiling

NIOSH: 2 mg/ m³ Ceiling

Engineering Controls

Use general ventilation and use local exhaust, where possible, in confined or enclosed spaces.

PERSONAL PROTECTIVE EQUIPMENT

Personal Protective Equipment: Eyes/Face

Wear safety glasses; chemical goggles (if splashing is possible).

Personal Protective Equipment: Skin

Wear chemical resistant gloves and other protective clothing (lab coat, apron, etc.) when cleaning a large spill.

Material Safety Data Sheet

Material Name: Salkera Emollient Foam

Personal Protective Equipment: Respiratory

Respiratory protection; not normally required for ambient air concentrations not exceeding the Occupational Exposure Limit.

Personal Protective Equipment: General

None.

***** Section 9 - Physical & Chemical Properties *****

Appearance:	White to Off-White Foam	Odor:	None
Physical State:	Solid	pH:	5-6
Vapor Pressure:	ND	Vapor Density:	ND
Boiling Point:	ND	Melting Point:	ND
Solubility (H2O):	Soluble	Specific Gravity:	ND
Evaporation Rate:	ND	VOC:	ND
Octanol/H2O Coeff.:	ND	Flash Point:	ND
Flash Point Method:	ND	Upper Flammability Limit (UFL):	ND
Lower Flammability Limit (LFL):	ND	Burning Rate:	ND
Auto Ignition:	ND		

***** Section 10 - Chemical Stability & Reactivity Information *****

Chemical Stability

Stable under normal conditions.

Chemical Stability: Conditions to Avoid

Excessive heat.

Incompatibility

Strong oxidizers, strong alkalis, iron salts, iodine.

Hazardous Decomposition

Acrolein, phenol, oxides of nitrogen, carbon dioxide and carbon monoxide may be produced.

Possibility of Hazardous Reactions

None identified.

***** Section 11 - Toxicological Information *****

Acute Dose Effects

A: General Product Information

None identified.

B: Component Analysis - LD₅₀/LC₅₀

Water (7732-18-5)

Oral LD₅₀ Rat: >90 mL/kg

1,1,1,2-Tetrafluoroethane (811-97-2)

Inhalation LC₅₀ Rat: 1500 g/m³/4H

Salicylic acid (69-72-7)

Inhalation LC₅₀ Rat: >0.9 mg/L/1H; Oral LD₅₀ Rat: 891 mg/kg; Dermal LD₅₀ Rat: >2 g/kg

Glycerin (56-81-5)

Inhalation LC₅₀ Rat: >570 mg/m³/1H; Oral LD₅₀ Rat: 12600 mg/kg; Dermal LD₅₀ Rat: >21900 mg/kg

1,2-Propylene glycol (57-55-6)

Oral LD₅₀ Rat: 20000 mg/kg; Dermal LD₅₀ Rabbit: 20800 mg/kg

Sodium hydroxide (1310-73-2)

Dermal LD₅₀ Rabbit: 1350 mg/kg

Material Safety Data Sheet

Material Name: Salkera Emollient Foam

Alcohols, C16-18 (67762-27-0)

Oral LD₅₀ Rat: >10000 mg/kg; Dermal LD₅₀ Rabbit: >8000 mg/kg

Petrolatum (8009-03-8)

Dermal LD₅₀ Rabbit: 3600 mg/kg

Methyl p-hydroxybenzoate (99-76-3)

Oral LD₅₀ Mouse: >8 g/kg

Propyl-p-hydroxybenzoate (94-13-3)

Oral LD₅₀ Mouse: 6332 mg/kg

Aloe vera gel (8001-97-6)

Oral LD₅₀ Rat: >5 g/kg

Carcinogenicity

A: General Product Information

Not listed by ACGIH, IARC, NIOSH, NTP OR OSHA.

B: Component Carcinogenicity

None of this product's components are listed by ACGIH, IARC, OSHA, NIOSH, or NTP.

* * * Section 12 - Ecological Information * * *
--

Ecotoxicity

A: General Product Information

No data available for this product.

B: Component Analysis - Ecotoxicity - Aquatic Toxicity

Salicylic acid (69-72-7)

Test & Species	Conditions
48 Hr LC ₅₀ Leuciscus idus	90 mg/L
5 min EC ₅₀ Photobacterium phosphoreum	214 mg/L
1 Hr EC ₅₀ Bacillus subtilis	138 mg/L
1 Hr EC ₅₀ Escherichia coli	552 mg/L
210 min EC ₅₀ Saccharomyces cerevisiae	78 mg/L
24 Hr EC ₅₀ Daphnia magna	105 mg/L

Glycerin (56-81-5)

Test & Species	Conditions
96 Hr LC ₅₀ Oncorhynchus mykiss	51000-57000 mg/L
24 Hr EC ₅₀ Daphnia magna	>500 mg/L

1,2-Propylene glycol (57-55-6)

Test & Species	Conditions
96 Hr LC ₅₀ Oncorhynchus mykiss	51600 mg/L [static]
96 Hr LC ₅₀ Pimephales promelas	51400 mg/L [static]
96 Hr EC ₅₀ Selenastrum capricornutum	19000 mg/L
30 min EC ₅₀ Photobacterium phosphoreum	710 mg/L
48 Hr EC ₅₀ water flea	>10000 mg/L

Sodium hydroxide (1310-73-2)

Test & Species	Conditions
96 Hr LC ₅₀ Oncorhynchus mykiss	45.4 mg/L [static]

Material Safety Data Sheet

Material Name: Salkera Emollient Foam

Alcohols, C16-18 (67762-27-0)

Test & Species

48 Hr EC₅₀ Daphnia magna

1666 mg/L

Conditions

*** Section 13 - Disposal Considerations ***

US EPA Waste Number & Descriptions

A: General Product Information

No information available for the product.

B: Component Waste Numbers

No EPA Waste Numbers are applicable for this product's components.

Disposal Instructions

All wastes must be handled in accordance with local, state and federal regulations.

See Section 7 for Handling Procedures. See Section 8 for Personal Protective Equipment recommendations.

*** Section 14 - Transportation Information ***

US DOT Information

Shipping Name: Not Regulated

*** Section 15 - Regulatory Information ***

US Federal Regulations

Component Analysis

This material contains one or more of the following chemicals required to be identified under SARA Section 302 (40 CFR 355 Appendix A), SARA Section 313 (40 CFR 372.65) and/or CERCLA (40 CFR 302.4).

Sodium hydroxide (1310-73-2)

CERCLA: 1000 lb final RQ; 454 kg final RQ

State Regulations

Component Analysis - State

The following components appear on one or more of the following state hazardous substances lists:

Component	CAS	CA	MA	MN	NJ	PA	RI
1,1,1,2-Tetrafluoroethane	811-97-2	No	No	Yes	No	No	No
Glycerin	56-81-5	No	Yes	Yes	No	Yes	Yes
1,2-Propylene glycol	57-55-6	No	No	Yes	No	Yes	Yes
Sodium hydroxide	1310-73-2	Yes	Yes	Yes	Yes	Yes	Yes

Material Safety Data Sheet

Material Name: Salkera Emollient Foam

Additional Regulatory Information

Component Analysis - Inventory

Component	CAS #	TSCA
Water	7732-18-5	Yes
1,1,1,2-Tetrafluoroethane	811-97-2	Yes
Salicylic acid	69-72-7	Yes
Glycerin	56-81-5	Yes
Ammonium lactate	515-98-0	Yes
1,2-Propylene glycol	57-55-6	Yes
Sodium hydroxide	1310-73-2	Yes
Alcohols, C16-18	67762-27-0	Yes
Petrolatum	8009-03-8	Yes
2H-1-Benzopyran-6-ol, 3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-, acetate	7695-91-2	Yes
Ceteth-10 Phosphate	50643-20-4	No
1-Hexadecanol, hydrogen phosphate	2197-63-9	Yes
Methyl p-hydroxybenzoate	99-76-3	Yes
Propyl-p-hydroxybenzoate	94-13-3	Yes
Aloe vera gel	8001-97-6	No
Ethylenediaminetetraacetic acid, disodium, dihydrate	6381-92-6	No

*** Section 16 - Other Information ***

Other Information

The information herein is presented in good faith and believed to be accurate as of the effective date given. However, no warranty, expressed or implied, is given. It is the buyer's responsibility to ensure that its activities comply with Federal, State or provincial and local laws.

Key/Legend

EPA = Environmental Protection Agency; TSCA = Toxic Substance Control Act; ACGIH = American Conference of Governmental Industrial Hygienists; IARC = International Agency for Research on Cancer; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration, NJTSR = New Jersey Trade Secret Registry; ND = Not Determined