

1. IDENTIFICATION OF THE SUBSTANCE/ PREPARATION & THE COMPANY/ UNDERTAKING

GHS Product Identifier

Product Name: NeilMed Sinus Rinse Kit

Other Means of Identification

Synonyms: Sinus Irrigation Kit

Recommended Use of the Chemical & Restrictions on Use

Recommended Use: Is intended to provide a spray-bottle treatment to help temporarily relieve nasal congestion due to:

- common cold
- sinusitis
- hay fever
- upper respiratory allergies

Uses Advised Against:

For intranasal use only.

Use only as directed.

Product should not be shared by more than one [1] person.

Product should not be used on babies or children under the age of twelve [12].

Product should not be used by persons suffering from:

- Heart disease
- High blood pressure
- Thyroid disease
- Diabetes

Manufacturer's Details

Manufacturer Address	Distributor Address
NeilMed Pharmaceuticals, Inc. 601 Aviation Blvd. Santa Rosa, CA 95403 Telephone: +1 707-525-3784 Fax: +1 707-525-3785 Email: quality@neilmed.com	NeilMed Pharmaceuticals, Inc. 601 Aviation Blvd. Santa Rosa, CA 95403 Telephone: +1 707-525-3784 Fax: +1 707-525-3785 Email: quality@neilmed.com

Emergency Telephone Number

Company Emergency Phone Number: +1 707-525-3784


2. HAZARD IDENTIFICATION

Classification

This chemical is considered hazardous according to the OSHA Hazard Communication Standard 2012 [29 CFR 1910.1200].

Skin Corrosion/Irritation:	3 (salt mixture)
Eye Damage/ Irritation:	2B (salt mixture)

GHS Label Elements, Including Precautionary Statements

EMERGENCY OVERVIEW					
Signal Word:		Warning			
Hazard Statements:		H316: Causes Mild Skin Irritation H320: Causes Eye Irritation			
Hazard Pictograms:					
This product contains no substances which at their given concentration are considered hazardous to health.					
Appearance:	White	Physical State:	Solid	Odor:	Salty

Precautionary Statements

- This product is to be used by an adult with a full understanding of the instructions and warnings.
- Read instructions before use.
- Do not use it until all safety precautions have been read and understood.
- Wash face and hands before use.
- Avoid direct contact of salt mixture powder with eyes.
- Please retain the box for instructions and other important information.
- Store in a cool and dry environment.
- Do not use it if the container is leaking or broken.
- If symptoms persist, see your doctor/ healthcare professional.

Directions for Use

1. Please wash your hands before use.
2. Fill the clean bottle with the designated volume (see bottle) of either distilled, micro-filtered (through 0.2 micron filter), commercially bottled or previously boiled and cooled down water.
3. Before use, spray a quick stream of solution into the air to clear nozzle.
4. Cut the Sinus Rinse™ mixture packet at the corner and pour its contents into the bottle. Tighten the cap and tube on the bottle securely. Place one finger over the tip of the cap and shake the bottle gently to dissolve the mixture.
5. Standing in front of a sink, bend forward to your comfort level and tilt your head down. Keeping your mouth open without holding your breath, place the cap snugly against your nasal passage.
6. Squeeze the bottle gently until the solution starts draining from the opposite nasal passage. Keep squeezing the bottle gently until at least a fourth [¼] to a half [½] of the bottle is used. Do not swallow the solution.
7. Blow your nose very gently without pinching your nose completely to avoid pressure on eardrums. If tolerable, sniff in gently any residual solution remaining in the nasal passage one [1] or two [2] times.
8. Now repeat the above steps five [5] through seven [7] for your other nasal passage.
9. Clean the bottle and cap. Air dry the bottle, cap, and tube on a clean paper towel, a lint free towel, or use NasaDock® (sold separately) to store the bottle, cap and tube.

General Advice

- If Exposed or Concerned: Get medical advice/ attention.

EYES

- If in EYES: Check for and remove any contact lens.
Flush eyes with plenty of warm water for at least fifteen [15] minutes.
- If EYE Irritation Persists: Get medical advice/ attention.

SKIN

- If on SKIN: Wash affected area with soap and water for ten [10] minutes.
- If SKIN Irritation Occurs: Get medical advice/ attention.

Storage

- Special Instructions: Store away from children's reach.
- Environment: Store in a cool & dry environment.
Store out of direct sunlight.

Disposal: Dispose of contents to an approved waste disposal plant.

Hazard Not Otherwise Classified (HNOC)

N/A

Other Information: N/A

3. COMPOSITION/ INFORMATION ON INGREDIENTS

A. Salt Mixture:

Chemical Name	CAS-No.	Weight by %*
Sodium Chloride (USP)	7647-14-5	80-100%
Sodium Bicarbonate (USP)	144-55-8	0-20%

**The exact percentages (concentrations) of composition have been withheld as a trade secret.*

4. FIRST AID MEASURES

Description of Necessary First Aid Measures

General Advice:	N/A
Eye Contact:	Immediately flush eyes with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least fifteen [15] minutes. If irritation persists, get medical advice/ attention immediately.
Skin Contact:	If irritation occurs, wash skin with soap and water for at least ten [10] minutes. If irritation persists, get medical attention.
Inhalation:	If inhaled, move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen and get medical advice/ attention If irritation persists, get medical attention.

Ingestion:	<p>Never give anything to an unconscious person by mouth.</p> <p>Do not induce vomiting unless directed to do so by a medical professional.</p> <p>Loosen any tight clothing such as collars, ties, belts, or waistbands.</p> <p>If symptoms appear, get medical advice/ attention especially when large amounts have been swallowed.</p>
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Most Important Symptoms/ Effects, Acute & Delayed

Most Important Symptoms/Effects: N/A

Indication of Immediate Medical Attention & Special Treatment Needed, if necessary

Notes to Physician: N/A

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media

Use extinguishing measures that are appropriate to local circumstances and surrounding environment.

Unsuitable Extinguishing Media: N/A

Specific Hazards Arising from the Chemical

No Information Available.

Explosive Data

Sensitivity to Mechanical Impact: N/A

Sensitivity to Static Discharge: N/A

Protective Equipment & Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precaution, Protective Equipment, & Emergency Procedures

Personal Precautions: N/A

Environmental Precautions

Environmental Precautions: Avoid release into the environment.
Dispose of contents/ container to an approved waste disposal plant.
See the Ecological Information (Section 12) for additional details.

Methods & Materials for Containment & Cleaning Up

Methods for Containment: N/A

Methods for Cleaning Up: In general, dilute with water, wipe away with an absorbent material, and discard properly.

7. HANDLING & STORAGE

Precautions for Safe Handling

Handling: Avoid contact with skin and eyes.

Conditions for Safe Storage, including any incompatibilities

Storage: Store away from children's reach.
Store in a cool & dry environment.

Incompatible Products: N/A

8. EXPOSURE CONTROL & PERSONAL PROTECTION

Control Parameters

Exposure Guidelines: This product does not contain any hazardous materials with occupational exposure limits established by the region-specific regulatory bodies.

Appropriate Engineering Controls

Engineering Measures: Showers.
Eyewash stations.
Ventilation systems.

Individual Protections Measures, such as personal protective equipment

Eye/ Face Protection: Safety glasses with side shields. If splashes are likely to occur, wear glasses.
Skin & Body Protection: For repeat or prolonged contact, wear protective gloves.
Respiratory Protection: None required under normal usages.
Hygiene Measures: Handle in accordance with good industry hygiene and safety practices.

9. PHYSICAL & CHEMICAL PROPERTIES

Information on Basic Physical & Chemical Properties

A. Salt Mixture:

Physical State:	Solid	Appearance:	White
Odor:	Salty	Odor Threshold:	No information available

Property	Values	Remarks/ Method
pH:	6.5 to 8.5	When mixed with 240mL of water.
Melting Point/ Range:	No data available	None known
Boiling Point/ Boiling Range:	No data available	None known
Flash Point:	No data available	None known
Evaporation Rate:	No data available	None known
Flammability (solid, gas):	No data available	None known
<u>Flammability Limits in Air</u>		
Upper Flammability Limit:	No data available	None known

Lower Flammability Limit:	No data available	None known
Vapor Pressure:	No data available	None known
Vapor Density:	No data available	None known
Relative Density:	No data available	None known
Specific Gravity:	No data available	None known
Water Solubility:	No data available	None known
Solubility in Other Solvents:	No data available	None known
Partition Coefficient; n-octanol/water:	No data available	None known
Auto-Ignition Temperature:	No data available	None known
Decomposition Temperature:	No data available	None known
Viscosity:	No data available	None known
Flammable Properties:	Not flammable	
Explosive Properties:	No data available	
Oxidizing Properties:	No data available	
<u>Other Information</u>		
VOC Content (%):	No data available	

10. STABILITY & REACTIVITY

Reactivity

No data available.

Chemical Stability

Stable under the recommended storage conditions.

Possibility of Hazardous Reactions

None under normal processing.

Conditions to Avoid

None known based on information provided.

Incompatible Materials

N/A

Hazardous Decomposition Products

N/A

11. TOXICOLOGICAL INFORMATION

Information on Likely Routes of Exposure

<u>Product Information:</u>	No acute toxicological information is available for this product.
– Inhalation:	No known effects based on information supplied.
– Eye Contact:	May cause eye irritation.
– Skin Contact:	May cause mild skin irritation.
– Ingestion:	Ingestion may cause gastrointestinal irritation, nausea, vomiting, and diarrhea.

Component Information

A. Salt Mixture:

Chemical Name	CAS-No.	LD50 Oral	LD50 Dermal	LC50 Inhalation
Sodium Chloride (USP)	7647-14-5	3,000 mg/Kg (rat)	No data available	No data available
Sodium Bicarbonate (USP)	144-55-8	4,220 mg/Kg (rat)	No data available	No data available

Symptoms Related to the Physical, Chemical, & Toxicological Characteristics

Symptoms: No information available.

Delayed & Immediate Effects & Also Chronic Effects from Short & Long Term Exposure

Skin Corrosion/ Irritation: May cause mild irritation.
Eye Damage/ Irritation: May cause irritation.
Sensitization: None known.
Mutagenic Effects: None known.
Acute Toxicity Estimate: No data available.

Carcinogenicity

The table below indicates whether each agency has listed any ingredient as a carcinogen.

A. Salt Mixture:

Chemical Name	CAS-No.	ACGIH	NIOSH	OSHA
Sodium Chloride (USP)	7647-14-5	N/A	N/A	N/A
Sodium Bicarbonate (USP)	144-55-8	N/A	N/A	N/A

Numerical Measures of Toxicity – Product

The following are calculated based on Chapter 3.1 of the GHS document.

LD50 Oral: No data available

12. ECOLOGICAL INFORMATION

Exotoxicity

Potentially toxic to aquatic life with long lasting effects.

Persistence & Degradability:	No information available
Bioaccumulation:	No information available
Other Adverse Effects:	No information available

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods: This material, as supplied, is not a hazardous waste according to federal regulations [40 CFR 261]. This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult the federal regulations [40 CFR 261] to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

Contaminated Packaging: Dispose of in accordance with local regulations.
CA Hazardous Waste Codes: N/A

14. TRANSPORT INFORMATION

Transport Classifications

DOT:	Not regulated.	ICAO:	Not regulated.	RID:	Not regulated.
TGD:	Not regulated.	IATA:	Not regulated.	ARD:	Not regulated.
MEX:	Not regulated.	IMDG/ IMO:	Not regulated.	AND:	Not regulated.

15. REGULATORY INFORMATION

International Inventories

A. Salt Mixture:

Chemical	CAS-No.	TSCA	DSL	NDSL
Sodium Chloride (USP)	7647-14-5	Listed	Listed	Not Listed
Sodium Bicarbonate (USP)	144-55-8	Listed	Listed	Not Listed

16. OTHER INFORMATION

NFPA

Health Hazard:	0	Flammability:	0	Instability:	0	Physical/Chemical Hazards:	X
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HMIS

Health Hazard:	0	Flammability:	0	Physical Hazard:	0	Personal Protection:	-
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LEGEND

TSCA – United States Toxic Substances Control Act Section 8(b) Inventory
DSL / NDSL – (Canadian) Domestic Substances List / Non-Domestic Substances List

U.S. Federal Regulations

This product does not contain any chemicals which are subject to the reporting requirements of the Clean Water Act, Part 372 of Title 40 of the Code of Federal Regulations [40 CFR 372], or Section 313 of Title III of the Superfund Amendments & Reauthorization Act of 1986 (SARA).

SARA 311/312 Hazard Categories

Acute Health Hazard:	No
Chronic Health Hazard:	No
Fire Hazard:	No
Sudden Release of Pressure Hazard:	No
Reactive Hazard:	No

Clean Water Act

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act [40 CFR 122.21 & 40 CFR 122.42].

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation & Liability Act (CERCLA) [40 CFR 302] or the Superfund Amendments & Reauthorization Act (SARA) [40 CFR 355]. There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

U.S. State Regulations

California Proposition 65

This product does not contain any CA Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated by state right-to-know regulations.

U.S. EPA Label Information

EPA Pesticide Registration Number: N/A

Prepared By: Birendra Das

Quality Department
NeilMed Pharmaceuticals, Inc.
601 Aviation Blvd.
Santa Rosa, California 95404
United States of America
Phone: (707) 525-3784

General Disclaimer

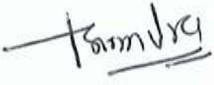


The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and it is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

END OF SAFETY DATA SHEET

HISTORY OF CHANGES

Rev#	Effective Date	Change Summary
05	08/30/2024	<ul style="list-style-type: none"> Removed all details of squeeze bottle from all sections of SDS since it is related to product formulation. Remove Carcinogenicity from Hazard classification in section 2.
04	2020-03-10	<ul style="list-style-type: none"> Section 01: Removed "Product should not be used by men with prostate disease" from the Uses Advised Against. Section 01: Removed "Product should not be used by women who are pregnant or breast-feeding unless directed otherwise the physician" from the Uses Advised Against. Overall: Minor changes to general formatting, syntax, diction, punctuation, spelling, and grammar.
03	2020-02-28	<ul style="list-style-type: none"> Section 02: Changed the classification for Skin Erosion/Irritation from "2" to "3" in order to match with the severity of the H316 Hazard Statement. Overall: Minor changes to general formatting, syntax, diction, punctuation, spelling, and grammar.
02	2019-07-19	<ul style="list-style-type: none"> Start of Document: Removed redundant fields for "Revision Number", "Revision Date", and "Initials" as these are not located in the History of Changes and Approval sections. Section 02: Changed "This chemical is not considered hazardous..." to "This chemical is considered hazardous..." in the Classification. Section 03: Added labels to the Squeeze Bottle section of the Composition to denote which specific component of the Squeeze Bottle (bottle/cap/tube) corresponded to which chemical. Section 11: Added labels to the Squeeze Bottle section of the Composition to denote which specific component of the Squeeze Bottle (bottle/cap/tube) corresponded to which chemical. Section 15: Added labels to the Squeeze Bottle section of the Composition to denote which specific component of the Squeeze Bottle (bottle/cap/tube) corresponded to which chemical. Legend: Removed redundant fields for "Revision Number", "Revision Date", and "Initials" as these are not located in the History of Changes and Approval sections. Overall: Minor changes to general formatting, syntax, diction, punctuation, spelling, and grammar.
01	2018-09-12	<ul style="list-style-type: none"> Section 14: Changed formatting of Transport Classification to simply state the product is "not regulated".
00	2018-09-12	<ul style="list-style-type: none"> Initial Release.

APPROVALS

Approvers	Name	Title	Signature	Date
Prepared By:	Birendra Das	Quality Specialist		08/30/2024
Reviewed By:	George Nguyen	Director of Quality		08/30/2024
Approved By:	Dinesh Patel	VP of QA / RA / Automaton		8/31/2024