

SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: SALINE NASAL SPRAY

Synonym: 312

Manufacturer Name: Perrigo Company
Address: 515 Eastern Avenue
 Allegan, MI 49010 USA

Telephone number: 269-673-8451

Emergency phone number: 888-464-2986 (U.S. calls)
 +1 760-476-3962 Code 333304 (International calls)

Email Address: SDSRequest@perrigo.com

Recommended use: Human drug – For dry nasal membranes

Restrictions on use: Use only as directed.

Date of Preparation: November 22, 2014

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Not hazardous

Label Elements:

Not hazardous in accordance with the GHS and OSHA Hazcom 2012.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Sodium Chloride	7647-14-5	0.65%
Water	7732-18-5	Proprietary
Monobasic Sodium Phosphate	7558-80-7	Proprietary
Dibasic Sodium Phosphate	7558-79-4	Proprietary
Benzylkonium Chloride	68391-01-5	<0.1%
Benzyl Alcohol	100-51-6	Proprietary

The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST-AID MEASURES

Inhalation: No first aid should be needed.

Skin contact: No first aid should be needed.

Eye contact: No first aid should be needed.

Ingestion: No first aid should be needed.

Most important symptoms/effects, acute and delayed: May cause mild eye irritation.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is not required.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use any extinguishing media appropriate for the fire situation.

Specific hazards arising from the chemical: Product is not flammable or combustible.

Special protective equipment and precautions for fire-fighters: No special precautions required.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: No special procedures required.

Environmental Precautions: None required.

Methods and materials for containment and cleaning up: No special precautions required.

7. HANDLING AND STORAGE

Precautions for safe handling: No special precautions required.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Sodium Chloride	None Established
Water	None Established
Monobasic Sodium Phosphate	None Established
Dibasic Sodium Phosphate	None Established
Benzylkonium Chloride	None Established
Benzyl Alcohol	10 ppm TWA AIHA WEEL

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to minimize exposures levels.

Individual protection measures:

Respiratory protection: None needed under normal use conditions.

Skin protection: None required.

Eye protection: None required.

Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): Clear, colorless solution.
Odor: Slight but distinct almond odor

Odor threshold: Not applicable	pH: 6.7
Melting point/freezing point: No data available	Boiling Point: No data available
Flash point: None	Evaporation rate: Same as water
Flammability (solid, gas): Not applicable	VOC: 0%
Flammable limits: LEL: None	UEL: None
Vapor pressure: Same as water	Vapor density: Same as water
Relative density: No data available	Solubility(ies): Soluble in water
Partition coefficient: n-octanol/water: Not available	Auto-ignition temperature: Not applicable
Decomposition temperature: No data available	Viscosity: Same as water

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.
Chemical stability: Stable.
Possibility of hazardous reactions: None known.
Conditions to avoid: None known.
Incompatible materials: None known.
Hazardous decomposition products: None known.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:
Inhalation: No adverse effects are expected.
Ingestion: No adverse effects are expected.
Skin contact: No adverse effects are expected. Minor irritation is possible.
Eye contact: Contact may cause minor irritation.
Chronic Effects: None known.
Sensitization: Components are not skin sensitizers.
Germ Cell Mutagenicity: None of the components have been shown to cause germ cell mutagenicity.
Reproductive Toxicity: Components are not reproductive toxins.
Carcinogenicity: None of the components are listed as carcinogens by IARC, NTP or OSHA.

Acute Toxicity Values: Not acutely toxic

12. ECOLOGICAL INFORMATION

Ecotoxicity values: No data is available
Persistence and degradability: No data is available
Bioaccumulative potential: No data is available
Mobility in soil: No data is available.
Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Not Hazardous

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None

EPA TSCA Inventory: This product is a drug and not subject to TSCA.

CANADA:

Canadian CEPA: This product is a drug and not subject to CEPA regulations.

Canadian WHMIS Classification: Drugs are exempt from WHMIS

This product has been classified under the CPR and this SDS discloses information elements required by the CPR.

16. OTHER INFORMATION

NFPA Rating: Health = 0 Flammability = 0 Instability = 0
HMIS Rating: Health = 0 Flammability = 0 Physical Hazard = 0

SDS Revision History: New SDS

Date of preparation: November 22, 2014

Date of last revision: New SDS

Disclaimer : This SDS has been prepared for occupational exposure. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).