



SAFETY DATA SHEET

Prepared Date: June 16, 2022

Trade Name: Saline Enema

1 Product and Company Identification

Product Identifier

Recommended Uses: Constipation Relief

Trade name: Saline Solution Enema

Synonym: Saline Enema

Manufacturer/Supplier

Natureplex, LLC

11085 Airport Road

Olive Branch, MS 38654-0221

(662) 874-1370 (8:00 a.m. – 5:00 p.m. CST; M-F)

Emergency Telephone Number: 1-866-323-0107

CHEMTREC: 1-800-424-9300 (Transportation Spill Response 24 hours)

2 Hazard(s) Identification

Classification of the Product

OSHA Hazards: Corrosive

GHS Classification: Acute toxicity – Inhalation, Oral - Category 4

Skin corrosion/irritation – Category 1B

Serious eye damage/eye irritation – Category 1

Hazard to the aquatic environment – Category 1

Pictogram:



Signal Word: Danger

Hazard Statements: Harmful if swallowed.

Harmful if inhaled.

Precautionary Statements:

Wash hands thoroughly after handling.

Wear protective gloves/protective clothing/eye protection/face protection.

IF SWALLOWED: Call a POISON CENTER/doctor.

IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.



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Potential Health Effects

Inhalation: Excessive inhalation of this material causes headache, dizziness, nausea and incoordination.

Skin: May be corrosive to skin. This product may be harmful if it is absorbed through the skin.

Eyes: May be corrosive to eyes

Ingestion: This product may be harmful or fatal if swallowed.

Patients/Consumers: Please refer to the product label for appropriate consumer-specific information about this product when used according to the directions. Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk.

This product is a drug as defined by the U.S. Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.). It is in final form for direct use by consumers. Therefore it is exempt from the U.S. 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(5)(iii)

3 Composition / Information on Ingredients

Chemical Name	CAS #	%
USP Purified Water	7732-18-5	Proprietary
Disodium Phosphate, Anhydrous	7558-79-4	Proprietary
Monosodium Phosphate, Anhydrous	7558-80-7	Proprietary
Disodium EDTA	139-33-3	Proprietary
Benzalkonium Chloride 50%	63449-41-2	Proprietary

4 First Aid Measures

Emergency and First Aid Procedures

Inhalation: Move victim to fresh air. If signs/symptoms continue, get medical attention.

Eye Contact: Do not rub eyes. Flush eyes thoroughly with water for 15 minutes. If condition worsens or irritation persists contact physician.

Skin Contact: Wash with plenty of soap and water. If skin irritation occurs: get medical advice/attention.

Ingestion: Do not induce vomiting. Contact a physician or Poison Control Center.

5 Fire Fighting Measures

Extinguishing media

Suitable extinguishing agents: Not combustible. Use extinguishing media suitable for surrounding fire.

Fire and/or Explosion Hazards: None-combustible.

Hazardous Combustion Products: Oxides of sodium, oxides phosphorus.

Special Fire Fighting Procedures: No special measures required.



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6 Spill or Leak Procedures

Personal Precautions: Do not touch or walk through spilled material.

Environmental Precautions: Large Spills: Prevent entry into waterways, sewers, or confined areas.

Steps to Take in Case Product Is Released or Spilled: Sweep or vacuum up and place in an appropriate closed container. Clean up residual material by washing area with water and detergent. Collect washings for disposal.

7 Handling and Storage

Handling

- Avoid breathing fume/mist/vapors/spray.
- Avoid direct or prolonged contact with skin and eyes.

Storage

- Store in a cool, dry place.
- Keep container tightly closed.
- Avoid freezing conditions.

8 Exposure Controls / Personal Protection

Exposure Parameters

Personal Protective Equipment: No special measures required under normal usage.

Exposure Controls

Engineering Measures/Controls

- Adequate ventilation systems as needed to control concentrations of airborne contaminants below applicable threshold limit values.

Personal Protective Equipment

Respiratory

- For limited exposure use an N95 dust mask. For prolonged exposure use an air-purifying respirator with high efficiency particulate air (HEPA) filters. Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or symptoms are experienced.

Eye/Face

- Wear safety glasses.

Skin/Body

- Wear appropriate gloves.

General Industrial Hygiene Considerations

- Do not use, and/or consume foods, beverages, tobacco products, or cosmetics in areas where this material is stored. Wash hands and face carefully before eating, drinking, using tobacco, applying cosmetics, or using the toilet.

Environmental Exposure Controls

- Follow best practice for site management and disposal of waste.



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9 Physical and Chemical Properties

Physical Form: Liquid	Appearance: Clear, water-like liquid
Color: Colorless	Odor: None
Taste: N/A	pH (at 25°C): 4-6
Specific Gravity (at 25°C): 1.12	VOC: 0%

10 Stability and Reactivity

10.1 Reactivity

- No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

- Stable under normal temperatures and pressures.

10.3 Possibility of hazardous reactions

- Hazardous polymerization will not occur.

10.4 Conditions to avoid

- Moisture.

10.5 Incompatible materials

- None known.

10.6 Hazardous decomposition products

- Oxides of phosphorus. Oxides of sodium.



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11 Toxicological Information

	CAS	
Monosodium Phosphate, anhydrous Food Grade	7558-80-7	Acute Toxicity: Ingestion/Oral-Rat LD50 • 8290 mg/kg; Irritation: Eye-Rabbit • 150 mg/kg • Mild irritation • Comments: Standard Draize Test.

GHS Properties	Classification
Acute toxicity	EU/CLP • Classification criteria not met OSHA HCS 2012 • Classification criteria not met
Aspiration Hazard	EU/CLP • Classification criteria not met OSHA HCS 2012 • Classification criteria not met
Carcinogenicity	EU/CLP • Classification criteria not met OSHA HCS 2012 • Classification criteria not met
Germ Cell Mutagenicity	EU/CLP • Classification criteria not met OSHA HCS 2012 • Classification criteria not met
Skin corrosion/Irritation	EU/CLP • Classification criteria not met OSHA HCS 2012 • Classification criteria not met
Skin sensitization	EU/CLP • Classification criteria not met OSHA HCS 2012 • Classification criteria not met
STOT-RE	EU/CLP • Classification criteria not met OSHA HCS 2012 • Classification criteria not met
STOT-SE	EU/CLP • Classification criteria not met OSHA HCS 2012 • Classification criteria not met
Toxicity for Reproduction	EU/CLP • Classification criteria not met OSHA HCS 2012 • Classification criteria not met
Respiratory sensitization	EU/CLP • Classification criteria not met OSHA HCS 2012 • Classification criteria not met
Serious eye damage/Irritation	EU/CLP • Classification criteria not met OSHA HCS 2012 • Classification criteria not met

Medical Conditions Aggravated by Exposure

- Disorders of the lungs. Skin/Dermal .

Potential Health Effects

Inhalation

- Acute (Immediate) • Exposure to dust may cause irritation.
- Chronic (Delayed) • No data available.

Skin

- Acute (Immediate) • May cause irritation.
- Chronic (Delayed) • No data available.

Eye

- Acute (Immediate) • May cause irritation.
- Chronic (Delayed) • No data available.

Ingestion

- Acute (Immediate) • May cause irritation, nausea, vomiting, diarrhea, abdominal pain.
- Chronic (Delayed) • No data available.

Carcinogenic Effects

- This product does not contain any ingredient designated by IARC, NTP, AC OSHA as probable or suspected human carcinogens.



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12 Ecological Information

12.1 Toxicity

- No data found for product.

12.2 Persistence and degradability

- No data found for product.

12.3 Bioaccumulative potential

- No data found for product.

12.4 Mobility in Soil

- No data found for product.

12.5 Results of PBT and vPvB assessment

- PBT and vPvB assessment has not been carried out.

12.6 Other adverse effects

Ecological Fate

- No data found for product.

13 Disposal Considerations

No special considerations when disposed according to local, state and Federal regulations.

14 Transport Information

	14.1 UN number	14.2 UN proper shipping name	14.3 Transport hazard class(es)	14.4 Packing group	14.5 Environmental hazards
DOT	NDA	Not Regulated	NDA	NDA	NDA
TDG	NDA	Not Regulated	NDA	NDA	NDA
IMO/IMDG	NDA	Not Regulated	NDA	NDA	NDA
IATA/ICAO	NDA	Not Regulated	NDA	NDA	NDA

14.6 Special precautions for user • None specified.



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15 Regulatory Information

TSCA: All ingredients are listed or exempt per reference 15 USC 2602 (2)(B)(iv).
Complies with current FDA regulations for cosmetic and/or over-the-counter drug products.

United States

Labor

U.S. - OSHA - Process Safety Management - Highly Hazardous Chemicals

• Monosodium Phosphate, Anhydrous	7558-80-7	Not Listed
• Monosodium Phosphate, anhydrous Food Grade as Particulates not otherwise classified (PNOC)		Not Listed

U.S. - OSHA - Specifically Regulated Chemicals

• Monosodium Phosphate, Anhydrous	7558-80-7	Not Listed
• Monosodium Phosphate, anhydrous Food Grade as Particulates not otherwise classified (PNOC)		Not Listed

Environment

U.S. - CAA (Clean Air Act) - 1990 Hazardous Air Pollutants

• Monosodium Phosphate, Anhydrous	7558-80-7	Not Listed
• Monosodium Phosphate, anhydrous Food Grade as Particulates not otherwise classified (PNOC)		Not Listed

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Monosodium Phosphate, Anhydrous	7558-80-7	Not Listed
• Monosodium Phosphate, anhydrous Food Grade as Particulates not otherwise classified (PNOC)		Not Listed

Canada - WHMIS - Ingredient Disclosure List

• Monosodium Phosphate, Anhydrous	7558-80-7	Not Listed
• Monosodium Phosphate, anhydrous Food Grade as Particulates not otherwise classified (PNOC)		Not Listed

Environment

Canada - CEPA - Priority Substances List

• Monosodium Phosphate, Anhydrous	7558-80-7	Not Listed
• Monosodium Phosphate, anhydrous Food Grade as Particulates not otherwise classified (PNOC)		Not Listed

16 Additional Information

Notice: The information herein is based on data considered to be accurate as of the date of preparation of this safety data sheet. However, no warranty or representation, expressed or implied, is made as to the accuracy or completeness of the foregoing data and safety information. The user assumes all liability for any damage or injury resulting from abnormal use, from any failure to adhere to recommended practices or from any hazards inherent in the nature of the product.