


Trade Name: Fresh Scent Disposable Douche

1. Product and Company Identification	
Product Name: Fresh Scent Disposable Douche	
Recommended Use: Vaginal irrigation; rinsing/cleansing of the vagina	
Synonyms: Fresh Scent Disposable Douche	
Manufacturer/Supplier	
Natureplex, LLC 11085 Airport Road Olive Branch, MS 38654-0221 662-874-1370 (Monday – Friday, 8:00 a.m. – 5:00 p.m. CST)	
Emergency Telephone Number: 1-866-323-0107	
CHEMTREC: 1-800-424-9300 (Transportation Spill Response 24 hours)	
2. Hazard Identification	
Classification of the product	
GHS Classification: Acute Toxicity – Category 4 – Inhalation Eye Irritation – Category 2	
	
Pictogram:	
Signal Word: Warning	
Hazard Statements:	
H319 Causes serious eye irritation.	
USH001 May form combustible dust concentrations in air.	
H302 Harmful if swallowed	
H319 Causes serious eye irritation.	
H411 Toxic to aquatic life with long lasting effects	
Precautionary Statements:	
P264 Wash skin thoroughly after handling.	
P270 Do not eat, drink or smoke when using this product.	
P273 Avoid release to the environment.	
P280 Wear eye protection/face protection.	
P301 + P312 + P330 If swallowed call a poison center or doctor/physician if you feel unwell. Rinse mouth.	
P305 + P351 + P338 If in eyes rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.	
P337 + P313 If eye irritation persists get medical advice/attention.	



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P391 Collect spillage.

P501 Dispose of contents/container to an approved waste disposal plant.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Percent
Citric Acid	77-92-9	Trade Secret
Disodium EDTA	6381-92-6	Trade Secret
Lavender fragrance	Mixture	Trade Secret
Octoxynol 9	68412-54-4	Trade Secret
Sodium Benzoate	532-32-1	Trade Secret
USP Purified Water	7732-18-5	Trade Secret

*Specific chemical identity and/or percentage of composition has been withheld as a trade secret.

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 media. Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Fire Fighting: Wear self-contained breathing apparatus for firefighting if necessary.

Hazard Combustion Products: Carbon oxides

6. Accidental Release Measures

Personal Precautions: Safety glasses or goggles when splash potential exists.

Environmental Precautions: Local authorities should be advised if a significant spill cannot be contained. Do not product enter drains.

Methods and materials for containment and cleaning up: Pickup and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

7. Handling and Storage

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

Storage: Keep container tightly closed. Store according to labeled instructions.

8. Exposure Controls/Personal Protection

Appropriate Engineering controls: Apply technical measures to comply with the occupational exposure guideline.



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Recommended personal protective measures (PPE): No special measures required under normal usage.

Special Requirements for PPE: No special measures required under normal usage.

9. Physical and Chemical Properties

Appearance

Physical state: Clear to slightly cloudy, water-like liquid

Form: Liquid

Color: Clear

Odor: Nectarine/Mango Scent

Odor threshold: NDA

pH: 3.5 – 4.3

Viscosity: NDA

Specific Gravity: 0.97 – 1.03

Acidity: 10- 20 ml

Melting point/freezing point: NDA

Initial boiling point and boiling range: NDA

Flash point: NDA

Evaporation rate: NDA

Flammability (solid, gas): NDA

Upper/lower flammability or explosive limits

Flammability limit - lower (%): NDA

Flammability limit - upper (%): NDA

Explosive limit - lower (%): NDA

Explosive limit - upper (%): NDA

Vapor pressure: NDA

Vapor density: NDA

Relative density: NDA

Solubility (water): Soluble

Partition coefficient (n-octanol/water): NDA

Auto-ignition temperature: NDA

Decomposition temperature: NDA

10. Stability and Reactivity

Reactivity: NDA

Chemical Stability: Stable under recommended storage conditions.

Conditions to Avoid: Light.

Materials to Avoid: Strong oxidizing agents.

Hazardous Decomposition Products: None under normal use.

Possibility of Hazardous Reactions: None under normal use

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11. Toxicological Information**Acute and Chronic Toxicity****Citric Acid Anhydrous**Density: 1.665 g/cm³ (68 °F)

Solubility(ies) Water solubility: ca. 1.450 g/l (68 °F)

Partition coefficient: n-octanol/water: log Pow: -1.8 - -0.2 Calculation

Ignition temperature: NDA

Decomposition temperature: NDA

Viscosity: NDA

Explosive properties: NDA

Oxidizing properties Molecular weight: 192.12 g/mol

Dust explosion class: St1

Disodium EDTA

Acute oral toxicity

Low toxicity if swallowed. Small amounts swallowed incidentally as a result of normal handling operations are not likely to cause injury; however, swallowing larger amounts may cause injury.

LDS0, Rat, male and female, 2,800 mg/kg

Acute dermal toxicity

Prolonged skin contact is unlikely to result in absorption of harmful amounts.

The dermal LDS0 has not been determined.

Acute inhalation toxicity

Prolonged excessive exposure to dust may cause adverse effects.

The LC50 has not been determined.

Skin corrosion/irritation

Brief contact may cause slight skin irritation with local redness.

May cause more severe response if skin is abraded (scratched or cut). May cause more severe response on covered skin (under clothing, gloves).

Serious eye damage/eye irritation

May cause slight temporary eye irritation.

Corneal injury is unlikely.

Sensitization

Did not cause allergic skin reactions when tested in guinea pigs.

For respiratory sensitization: No relevant data found.

Specific Target Organ Systemic Toxicity (Single Exposure)

Evaluation of available data suggests that this material is not an STOT-SE toxicant.

Specific Target Organ Systemic Toxicity (Repeated Exposure)Based on available data, repeated exposures are not anticipated to cause significant adverse effects.
larynx

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Carcinogenicity

The trisodium salt of EDTA did not cause cancer in laboratory animals.

Teratogenicity

EDTA and its sodium salts have been reported to cause birth defects in laboratory animals only at exaggerated doses that were toxic to the mother. These effects are likely associated with zinc deficiency due to chelation.

Reproductive toxicity

Limited data in laboratory animals suggest that the material does not affect reproduction.

Mutagenicity

Most data indicate that EDTA and its salts are not mutagenic. Minimal effects reported are likely due to trace metal deficiencies resulting from chelating by EDTA.

Aspiration Hazard

Based on physical properties, not likely to be an aspiration hazard.

COMPONENTS INFLUENCING TOXICOLOGY: Disodium salt of ethylenediaminetetraacetic acid dihydrate

Acute dermal toxicity

Prolonged skin contact is unlikely to result in absorption of harmful amounts. The dermal LD50 has not been determined.

Acute inhalation toxicity

Prolonged excessive exposure to dust may cause adverse effects.

LC50, Rat, 4 Hour, dusUmist, > 2.27 mg/l Estimated.

Sodium Benzoate

Chemical Name	Inhalation LC50	Species	Oral LD50	Species	Dermal LD50	Species
Sodium Benzoate	>12.2 mg/L (4hours, based on benzoic acid)	Rat/Adult	>2000 mg/kg (weight of evidence)	Rat/Adult	>2000 mg/kg (based on benzoic acid)	Rabbit/Adult

Skin corrosion/irritation: Not classified (based on available data, the classification criteria are not met).

Chemical Name	Skin Sensitizer	Species
Sodium Benzoate	Irritant (OECD 405)	Rabbit/adult

Serious eye damage/irritation: Causes serious eye irritation (Category 2A).

Chemical Name	Skin Sensitizer	Species
Sodium Benzoate	Irritant (OECD 405)	Rabbit/adult

Respiratory or skin sensitization: Not classified (based on available data, the classification criteria are not met). READ-ACROSS (BENZOIC ACID): Not a skin sensitizer in the mouse local lymph node assay or Buehler guinea pig test.

Chemical Name	Skin Sensitizer	Species



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Sodium Benzoate	Non-sensitizer (read-across)	Guinea Pig and Mouse local lymph node assay
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Carcinogenicity: Not classified (based on available data, the classification criteria are not met). SODIUM BENZOATE: In a 2-year animal feeding study (2% in food), sodium benzoate was not carcinogenic.

Carcinogenic status: Not listed or regulated by IARC (Group 1 or 2), NTP, OSHA, or ACGIH.

Germ cell mutagenicity: Not classified (based on available data, the classification criteria are not met). SODIUM BENZOATE: No mutagenic activity was observed in the in-vitro Ames tests. Positive mutagenic effects have been observed in most in-vitro chromosome aberration testing. Sodium benzoate showed no genotoxicity during in-vivo testing.

Reproductive toxicity: Not classified (based on available data, the classification criteria are not met).

BENZOIC ACID AND BENZOATE SAL TS: Reproductive toxicity (benzoic acid), 4-generation oral study in rats: NOAEL (no observed adverse effect level) 500 mg/kg bw/day. Developmental toxicity (sodium benzoate), oral, rats and mice: NOAEL of ≥ 175 mg/kg bw/day can be established for developmental effects.

Specific target organ toxicity (STOT) - single exposure: Not classified. (based on available data, the classification criteria are not met).

SODIUM BENZOATE: Repeated dose oral toxicity studies for salts of benzoic acids: NOAEL (no-observed-adverse-effect-level) 1000 mg/kg bw/day. **READ-ACROSS (BENZOIC ACID):** Repeated dose toxicity study, inhalation: NOAEC (No-Observed-Adverse-Effect-Concentration), inhalation, rat: 250 mg/m³ (systemic effects); 25 mg/m³ (local). Local effects including nasal redness, pulmonary fibrosis and inflammatory cell infiltrates in the lungs were observed at lowest dose of 25 mg and can be attributed to the irritant properties and to the physico-chemical properties of fine low-solubility particles of benzoic acid. NOAEL (No-Observed-Adverse-Effect-Level). dermal, rabbit - 2500 mg/kg bw/day. **BENZOIC ACID AND BENZOATE SAL TS:** At higher doses (oral) increased mortality, reduced weight gain, convulsions (central nervous system effects), liver and kidney effects were observed.

Aspiration hazard: Not classified (technical impossibility to obtain the data)

12. Ecological Information

Ecotoxicity effects: Avoid release to the environment

Aquatic toxicity effects: NDA

Bioaccumulative potential: NDA

13. Disposal Considerations

Waste Disposal Method: Dispose of in accordance with local and national regulations.

Waste Treatment Methods

Product Waste: Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Packaging Waste: Dispose of as unused product.

14. Transport Information

Transport Information This material is not classified as hazardous for transport.
U.S. Department of Transport (DOT) - Not regulated



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Canadian Transport of Dangerous Goods (TDG) - Not regulated
International Civil Aviation Organization (ICAO) - Not regulated
International Air Transport Association (IATA) - Not regulated
International Maritime Dangerous Goods (IMDG)/International Maritime Organization (IMO) - Not regulated
Transport of Dangerous Goods by Rail (RID) - Not regulated
Transport of Dangerous Goods by Road (ADR) - Not regulated
Transportation of Dangerous Goods via Inland Waterways (ADN) - Not regulated

15. Regulatory Information

OSHA Regulatory Status: This material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazardous Categorization

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

This product does not contain any HAPs.

State Regulations

California Proposition 65 - This product does not contain any Proposition 65 chemicals.
Canada -Not classified
WHMIS Hazard Class - Non-controlled
European Union - In accordance with EC directives or respective national laws, the product does not need to be classified nor labeled.

16. Other Information

Last Revision: 5 April 2016

Preparation Date: 3 July 2019

List of References: See Patient Package Insert for more information

Disclaimer: 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.

Key to abbreviations

NDA= No Data Available