SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Fleet® Enema

1.2. Intended Use of the Product

Use of the substance/mixture: Saline laxative enema

1.3. Name, Address, and Telephone of the Responsible Party

Company

Fleet Laboratories, a division of C.B. Fleet Company, Inc.
4615 Murray Place
Lynchburg, VA 24502
T 434-528-4000
cbfleet.com

1.4. Emergency Telephone Number

Emergency Number : 1-866-255-6960 (Monday – Friday 8:30 AM to 5:30 PM);
INFOTRAC: Within USA, 800-535-5053; International, 352-323-3500

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Classification (GHS-US)

Skin Irrit. 2	H315
Eye Irrit. 2B	H320
Aquatic Acute 2	H401
Aquatic Chronic 3	H412

Full text of H-phrases: see section 16

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)

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US) :



GHS07

Signal Word (GHS-US) : Warning

Hazard Statements (GHS-US) : H315 - Causes skin irritation.
H320 - Causes eye irritation.
H401 - Toxic to aquatic life.
H412 - Harmful to aquatic life with long lasting effects.

Precautionary Statements (GHS-US) : P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.
P273 - Avoid release to the environment.
P280 - Wear protective gloves, protective clothing, and eye protection.
P302+P352 - If on skin: Wash with plenty of water.
P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P321 - Specific treatment (see section 4 on this SDS).
P332+P313 - If skin irritation occurs: Get medical advice/attention.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P362 - Take off contaminated clothing and wash it before reuse.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

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2.3. Other Hazards
Exposure may aggravate those with pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US)
No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance
Not applicable

3.2. Mixture

Name	Product Identifier	%	Classification (GHS-US)
Quaternary ammonium compounds, alkylbenzyldimethyl, chlorides	(CAS No) 8001-54-5	< 0.1	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation:dust,mist), H332 Skin Corr. 1B, H314 Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate	(CAS No) 6381-92-6	< 0.5	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation:dust,mist), H332 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335 Aquatic Chronic 3, H412

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures
First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.
First-aid Measures After Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.
First-aid Measures After Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.
First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most important symptoms and effects, both acute and delayed
Symptoms/Injuries: Causes eye irritation. Causes skin irritation.
Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.
Symptoms/Injuries After Skin Contact: Redness, pain, swelling, itching, burning, dryness, and dermatitis.
Symptoms/Injuries After Eye Contact: May cause moderate irritation, including burning sensation, tearing, redness or swelling.
Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed
If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media
Suitable Extinguishing Media: Water spray, dry chemical, foam, carbon dioxide.
Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture
Fire Hazard: Not considered flammable but may burn at high temperatures.
Explosion Hazard: Product is not explosive.
Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters
Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.
Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.
Other Information: Do not allow run-off from fire fighting to enter drains or water courses.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid breathing (vapor, mist, spray). Avoid all contact with skin, eyes, or clothing.

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).
Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection.
Emergency Procedures: Ventilate area. Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental Precautions

Prevent entry to sewers and public waters. Avoid release to the environment.

6.3. Methods and Material for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.
Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Heading 8. Exposure controls and personal protection. See Section 13. Disposal Considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid breathing vapors, mist, spray. Avoid contact with skin, eyes and clothing.
Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.
Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.
Incompatible Products: Strong acids, strong bases, strong oxidizers.

7.3. Specific End Use(s)

Saline laxative enema

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), NIOSH (REL), or OSHA (PEL).

8.2. Exposure Controls

Appropriate Engineering Controls : Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment : Gloves. Protective clothing. Protective goggles.



Materials for Protective Clothing : Chemically resistant materials and fabrics.
Hand Protection : Wear protective gloves.
Eye Protection : Chemical safety goggles.
Skin and Body Protection : Wear suitable protective clothing.
Respiratory Protection : If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information : When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Clear, colorless solution
Odor	: Characteristic
Odor Threshold	: No data available
pH	: 5 - 5.8
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20 °C	: No data available
Relative Density	: No data available
Specific Gravity	: 1.12 g/ml
Solubility	: Completely miscible.
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity: Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability: Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

10.4. Conditions to Avoid: Direct sunlight, extremely high or low temperatures, and incompatible materials.

10.5. Incompatible Materials: Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products: Oxides of phosphorus, irritating and toxic fumes and gases, sodium oxide

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

Quaternary ammonium compounds, alkylbenzyldimethyl, chlorides (8001-54-5)	
LD50 Oral Rat	304.5 mg/kg
LD50 Dermal Rat	1420 mg/kg

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate (6381-92-6)	
ATE (Oral)	500.00 mg/kg body weight
ATE (Dermal)	1,100.00 mg/kg body weight
ATE (Dust/Mist)	1.50 mg/l/4h

Skin Corrosion/Irritation: Causes skin irritation.
pH: 5 - 5.8

Serious Eye Damage/Irritation: Causes eye irritation.
pH: 5 - 5.8

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified
Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.
Symptoms/Injuries After Skin Contact: Redness, pain, swelling, itching, burning, dryness, and dermatitis.
Symptoms/Injuries After Eye Contact: May cause moderate irritation, including burning sensation, tearing, redness or swelling.
Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Toxic to aquatic life. Harmful to aquatic life with long lasting effects.

Quaternary ammonium compounds, alkylbenzyldimethyl, chlorides (8001-54-5)	
LC50 Fish 1	0.223 - 0.46 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 Daphnia 1	0.018 mg/l
LC 50 Fish 2	0.823 - 1.61 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

12.2. Persistence and Degradability

Fleet® Enema	
Persistence and Degradability	May cause long-term adverse effects in the environment.

12.3. Bioaccumulative Potential

Fleet® Enema	
Bioaccumulative Potential	Not established.

12.4. Mobility in Soil No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.
Additional Information: Container may remain hazardous when empty. Continue to observe all precautions.
Ecology – Waste Materials: Avoid release to the environment. This material is hazardous to the aquatic environment. Keep out of sewers and waterways.

SECTION 14: TRANSPORT INFORMATION

14.1. In Accordance with DOT Not regulated for transport
14.2. In Accordance with IMDG Not regulated for transport
14.3. In Accordance with IATA Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1 US Federal Regulations

Fleet® Enema	
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate (6381-92-6)	
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard

15.2 US State Regulations

Neither this product nor its chemical components appear on any US state lists.

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date : 09/24/2015
Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Chronic 1	Hazardous to the aquatic environment - Chronic Hazard Category 1

Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Eye Irrit. 2B	Serious eye damage/eye irritation Category 2B
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H302	Harmful if swallowed
H312	Harmful in contact with skin
H315	Causes skin irritation
H319	Causes serious eye irritation
H320	Causes eye irritation
H332	Harmful if inhaled
H335	May cause respiratory irritation
H400	Very toxic to aquatic life
H401	Toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
H412	Harmful to aquatic life with long lasting effects

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SDS US (GHS HazCom)