

 Safety Data Sheet

 According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations

 Revision Date: 09/24/2015
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Version: 1.0

## **SECTION 1: IDENTIFICATION**

**1.1. Product Identifier Product Form:** Mixture

Product Name: Fleet<sup>®</sup> 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 <u>cbfleet.com</u>

#### 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)

|                                   | GH507  |
|-----------------------------------|--|
| 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 | %     | <b>Classification (GHS-US)</b>  |
|--|--------------------|-------|---|
| Quaternary ammonium compounds,<br>alkylbenzyldimethyl, chlorides                 | (CAS No) 8001-54-5 | < 0.1 | Acute Tox. 4 (Oral), H302<br>Acute Tox. 4 (Dermal), H312<br>Acute Tox. 4<br>(Inhalation:dust,mist), H332<br>Skin Corr. 1B, H314<br>Eye Dam. 1, H318<br>Aquatic Acute 1, H400<br>Aquatic Chronic 1, H410 |
| Glycine, N,N'-1,2-ethanediylbis[N-<br>(carboxymethyl)-, disodium salt, dihydrate | (CAS No) 6381-92-6 | < 0.5 | Acute Tox. 4 (Oral), H302<br>Acute Tox. 4 (Dermal), H312<br>Acute Tox. 4<br>(Inhalation:dust,mist), H332<br>Skin Irrit. 2, H315<br>Eye Irrit. 2A, H319<br>STOT SE 3, H335<br>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.

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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** 

**Personal Protective Equipment** 

Materials for Protective Clothing Hand Protection Eye Protection Skin and Body Protection Respiratory Protection  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.
 Gloves. Protective clothing. Protective goggles.



- : Chemically resistant materials and fabrics.
- : Wear protective gloves.
- : Chemical safety goggles.
- : Wear suitable protective clothing.
- : 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.

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| Other Information                      | : When using, do not eat, drink or smoke.   |  |
|--|---|--|
| SECTION 9: PHYSICAL AND CHEMIC         | AL PROPERTIES   |  |
| 9.1. Information on Basic Physical     | and Chemical Properties   |  |
| Physical State                         | : Liquid  |  |
| Appearance                             | : Clear, colorless solution   |  |
| Odor                                   | : Characteristic  |  |
| Odor Threshold                         | : No data available   |  |
| рН                                     | : 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 addition     | al information available  |  |
| SECTION 10: STABILITY AND REACTI       |   |  |
|  | will not occur under normal conditions.   |  |
| 10.2. Chemical Stability: Stable under | . Chemical Stability: Stable under recommended handling and storage conditions (see section 7). |  |

**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

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#### 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<sup>®</sup> Enema

| Persist | ence and Degradability           | May cause long-term adverse effects in the environment. |
|---------|----------------------------------|---|
| 12.3.   | <b>Bioaccumulative Potential</b> |   |
| 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 <sup>®</sup> 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 Other Information : 09/24/2015

: 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 |

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| 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)