ALOETOUCH PROTECT FRAGRANCE FREE- dimethicone cloth Medline Industries, LP

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

059 Remedy Essentials Skin Protectant Wipes

Active ingredient

Dimethicone 3.2% w/v

Purpose

Skin Protectant

Uses

- temporarily protects and helps relieve chapped or cracked skin
- protects minor skin irritation associated with perineal dermatitis

Warnings

For external use only

Do not use on

- deep or puncture wounds
- animal bites
- serious burns

When using this product

do not get into eyes

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Open package as designated
- Remove cloths and thoroughly cleanse soiled area
- Apply as needed

• Dispose of cloth in waste receptacle

Other information

- Protect from freezing, avoid excessive heat
- Keep lid tightly sealed
- Not made with natural rubber latex
- Do not flush
- Cloth: made of Rayon/Polyester

Inactive ingredients

Aloe Barbadensis Leaf Juice, Benzalkonium Chloride, Citric Acid, Cocamidopropyl PG-Dimonium Chloride Phosphate, Disodium EDTA, Linoleamidopropyl PG-Dimonium Chloride Phosphate, Simethicone, Sodium Benzoate, Polysorbate 20, Water (Aqua)

Manufacturing Information

Manufactured for: Medline Industries, Inc.

Three Lakes Drive, Northfield IL 60093 USA

Made in USA with Domestic and Foreign Materials

www.medline.com

1-800-MEDLINE

REF: MSC095223

V3 RH21MSC

Package Label



| ALOETOUCH PROTECT FRAGRANCE FREE dimethicone cloth | | | | | | | | | |
|--|----------------|-------------|------------------------|-----------------|------------|--|--|--|--|
| Product Information | | | | | | | | | |
| Product Type | HUMAN OTC DRUG | Item Code | (Source) | NDC | :53329-059 | | | | |
| Route of Administration | TOPICAL | | | | | | | | |
| | | | | | | | | | |
| Active Ingredient/Active Moiety | | | | | | | | | |
| Ingred | ient Name | | Basis of Streng | Jth | Strength | | | | |
| DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) | | DIMETHICONE | | 3.2 g in 100 mL | | | | | |
| | | | | | | | | | |

| Inactive Ingredients | | | | |
|---|----------|--|--|--|
| Ingredient Name | Strength | | | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | | | | |
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) | | | | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | | | | |
| COCAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE (UNII: H2KVQ74JM4) | | | | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | | | | |
| LINOLEAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE (UNII: 5Q87K461JO) | | | | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | | | | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | | | | |
| WATER (UNII: 059QF0KO0R) | | | | |

Packaging

| # | ltem Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------------------|---|-------------------------|-----------------------|
| 1 | NDC:53329- 059-02 | 3 in 1 PACKAGE | 07/01/2014 | |
| 1 | | 17 mL in 1 APPLICATOR; Type 0: Not a Combination Product | | |
| 2 | NDC:53329- 059-76 | 8 in 1 PACKAGE | 07/01/2014 | |
| 2 | | 19 mL in 1 APPLICATOR; Type 0: Not a Combination Product | | |
| 3 | NDC:53329- 059-58 | 24 in 1 PACKAGE | 07/01/2014 | |
| 3 | | 9.2 mL in 1 APPLICATOR; Type 0: Not a Combination Product | | |
| 4 | NDC:53329- 059-91 | 48 in 1 PACKAGE | 07/01/2014 | 11/01/2022 |
| 4 | | 9.2 mL in 1 APPLICATOR; Type 0: Not a Combination Product | | |
| 5 | NDC:53329- 059-62 | 60 in 1 PACKAGE | 08/01/2012 | 10/31/2016 |
| 5 | | 11 mL in 1 APPLICATOR; Type 0: Not a Combination Product | | |
| | | | | |
| Μ | larketing | Information | | |
| | Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |

Marketing
CategoryApplication Number of Monograph
CitationMarketing Start
DateMarketing End
DateOTC monograph finalpart34708/01/2012

Labeler - Medline Industries, LP (025460908)

Registrant - Medline Industries, LP (025460908)