ADVANCED HAND SANITIZER- alcohol gel DEALMED MEDICAL SUPPLIES LLC

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.

Active Ingredient(s)

Ethyl Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria on the skin that can cause disease. recommended for repeat use

Warnings

Flammable. Keep away from heat or flame, For external use only.

Do not use

- in children less than 2 months of age
- on open skin wounds

Do not use in or near the eyes. in case of contact, rinse thorougly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product in your palm to thorougly cover your hands. Rub hands together until dry.
- Children under 6 years of age should be supervised when using this product.

Other information

- Store below 110FC (43C)
- May discolor certain fabrics or surfaces.

Inactive ingredients

Water, Carprylyl Glycol, Aloe Vera, Glycerin, Carbomer, Aminomethyl Propanol, Fragrance, Yellow 5 and Blue 1.

Package Label - Principal Display Panel





HAND SANITIZER

WITH ALOE





Leaves hands feeling soft

1 GALLON (3.78 L)



Drug Facts

Active Ingredient

Purpose

Uses • Hand Sanitizer to help reduce bacteria on the skin that could cause disease • recommended for repeat use

Warnings: Flammable, Keep away from heat or flame, For external use only.

Do not use In children less than 2 months of age

On open skin wounds

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water

Stop use and ask a doctor if irritation or rash appears and lasts.

Keep out of reach of children. If swallowed, get medical

Reep out of reach of children. It swallowed, get medic help or contact a Poison Control Center right away.

Directions • Place enough product in your palm to thoroughly cover your hands. Rub hands together briskly until dry • Children under 6 years of age should be supervised when using this product.

Other Information • Store between 110F (43C) • May discolor certain fabrics or surfaces

Inactive Ingredient Water, Carpryly Glycol, Aloe Vera, Glycerin, Carbomer, Aminomethyl Propanol, Fragrance, Yellow 5, Blue 1

ITEM # 782919 NDC# 78257-919-01 Manufactured for: Dealmed Brooklyn, NY 11234 www.dealmed.com



3.78 L NDC: 78257-919-01

ADVANCED HAND SANITIZER

alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:78257-919

Route of Administration TOPICAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 70 mL in 100 mL |

Inactive Ingredients Ingredient Name Strength CAPRYLYL GLYCOL (UNII: 00 YIU5438 U) GLYCERIN (UNII: PDC6A3C0OX) WATER (UNII: 059QF0KO0R) AMINOMETHYLPROPANOL (UNII: LU49E6626Q)

| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |
|--|--|
| FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF) | |
| CARBOMER 940 (UNII: 4Q93RCW27E) | |
| FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM) | |
| ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X) | |

| Packaging | | | | |
|-----------|----------------------|--|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 [| NDC:78257-919-)1 | 3780 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 11/23/2020 | |

| Marketing Information | | | | | |
|-------------------------|--|----------------------|--------------------|--|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | | |
| OTC monograph not final | part333A | 11/16/2020 | | | |
| | | | | | |

Labeler - DEALMED MEDICAL SUPPLIES LLC (078864775)

| Establishment | | | | |
|------------------------|---------|-----------|------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| PELICAN GROUP LLC, THE | | 078435913 | manufacture(78257-919) | |

Revised: 11/2020 DEALMED MEDICAL SUPPLIES LLC