

**ADVANCED HAND SANITIZER FOAM WITH ALOE- alcohol solution**  
**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.*

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**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 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 help, or contact a Poison Control Center right away.

**Directions**

- Place enough product in your palm to thoroughly 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, PEG-12 Dimethicone, Caprylyl Glycol, Aloe Vera, Glycerin, Fragrance

## Package Label - Principal Display Panel

Drug Facts	
Active Ingredient	Purpose
Ethyl Alcohol 70% w/v	Antimicrobial
<b>Uses</b> • Hand Sanitizer to help reduce bacteria on the skin that could cause disease • recommended for repeat use	
<b>Warnings: Flammable, Keep away from heat or flame, For external use only.</b>	
<b>Do not use</b> In children less than 2 months of age • On open skin wounds	
<b>When using this product</b> do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water	
<b>Stop use and ask a doctor</b> if irritation or rash appears and lasts.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • 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.	
<b>Other Information</b> • Store between 110F (43C) • May discolor certain fabrics or surfaces	
<b>Inactive Ingredient</b> Water, PEG-12 Dimethicone, Caprylyl Glycol, Aloe Vera, Glycerin, Fragrance (Parfum)	

473.2 mL NDC: 78257-916-01

## ADVANCED HAND SANITIZER FOAM WITH ALOE

alcohol solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78257-916
<b>Route of Administration</b>	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
PEG-12 DIMETHICONE (UNII: ZEL54N6W95)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
GLYCERIN (UNII: PDC6A3C0OX)	

**WATER** (UNII: 059QF0KO0R)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78257-916-01	473.2 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

**Labeler** - DEALMED MEDICAL SUPPLIES LLC (078864775)

### Establishment

Name	Address	ID/FEI	Business Operations
PELICAN GROUP LLC, THE		078435913	manufacture(78257-916)

Revised: 2/2022

DEALMED MEDICAL SUPPLIES LLC