# CLEAR DEFENSE- ethyl alcohol gel Melaleuca, Inc.

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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#### Clear Defense Hand Gel 9oz

## **Active ingredient**

Ethyl Alcohol 62%

## **Purpose**

**Antimicrobial** 

#### Uses

- to reduce bacteria on the skin
- recommended for repeated use

## Warnings

For External use only

Highly flammable. Keep away from fire or flame.

**Do not use** in or near 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 help or contact a Poison Control Center right away.

## **Directions**

- dispense a generous amount of gel in your palm
- spread gel over your hands until thoroughly coated
- rub your hands together briskly until dry
- children under 6 should be supervised when using this product

#### Other information

store below 82°F (28°C)

#### Other information

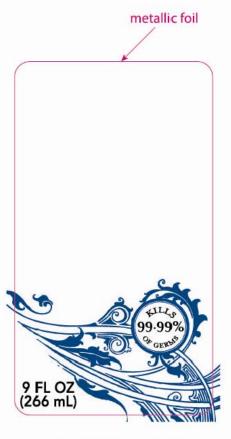
• may discolor certain fabrics or surfaces

## **Inactive ingredients**

water, glycerin, xylitol, anhydroxylitol, xylitylglucoside, carbomer, aminomethyl propanol, fragrance, aloe barbadensis leaf extract, melaleuca alternifolia (tea tree) leaf oil, polysorbate 20, tocopheryl acetate



9 oz front label



**Drug Facts** 

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- spread gel over your hands until thoroughly coated
   rub your hands together briskly until dry
- = children under 6 should be supervised when using this

#### Other information

- store below 82°F (28°C)
  may discolor certain fabrics or surfaces
- alcohol derived from corn

#### Inactive ingredients

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Melaleuca, Inc., Idaho Falls, ID 83402-6003 To order: 1-800-282-3000 · www Product of USA #5497 01/10U NOT FOR RESALE IN CANADA

Visible through bottle

back panel

## **CLEAR DEFENSE**

ethyl alcohol gel

#### **Product Information**

**Product Type** HUMAN OTC DRUG **Item Code (Source)** NDC:54473-296

**TOPICAL Route of Administration** 

## **Active Ingredient/Active Moiety**

**Ingredient Name Basis of Strength** Strength ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII: 3K9958V90M) ALCOHOL 150.97 g in 266 mL

## **Inactive Ingredients Ingredient Name** Strength WATER (UNII: 059QF0KO0R) **GLYCERIN** (UNII: PDC6A3C0OX) XYLITOL (UNII: VCQ006KQ1E) CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)

ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
TEA TREE OIL (UNII: VIF565UC2G)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:54473-296- 09	266 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2018		
2	NDC:54473-296- 24	71 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2020		
3	NDC:54473-296- 16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2020		
4	NDC:54473-296- 18	53 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2020		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/09/2010	

## Labeler - Melaleuca, Inc. (139760102)

Establishment				
Name	Address	ID/FEI	Business Operations	
Melaleuca, Inc.		079711683	manufacture(54473-296)	

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Melaleuca - TN		805617610	manufacture(54473-296)

Revised: 1/2023 Melaleuca, Inc.