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.

Clear Defense 2.4 oz Content of Label

Active Ingredient

Ethyl alcohol 62%

Purpose

Antimicrobial

Uses

- for handwashing 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

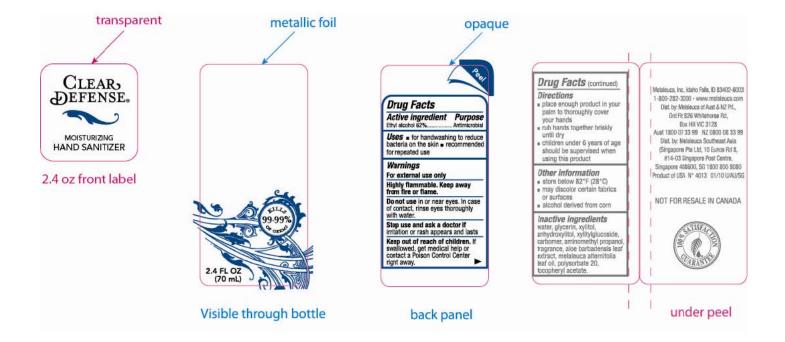
- place enough product in your palm to thoroughly cover your hands
- rub hands together briskly until dry
- children under 6 years of age should be supervised when using this product

Other information

• Store 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 leaf oil, polysorbate 20, tocopheryl acetate

CLEAR DEFENSE				
ethyl alcohol gel				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:54473-141
Route of Administration	TOPICAL			
Active Ingredient/Active Moi	ety			
Ingredient Name			Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)			ALCOHOL	39.184 g in 70 mL
T T				
Inactive Ingredients				
	Ingredient Name			Strength
Water (UNII: 059QF0KO0R)				

Glycerin (UNII: PDC6A3C0OX)	
XYLITOL (UNII: VCQ006KQ1E)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
Tea Tree Oil (UNII: VIF565UC2G)	
Polysorbate 20 (UNII: 7T1F30V5YH)	
ALPHA-TO COPHEROL ACETATE (UNII: 9E8 X80 D2L0)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-141-03	70 mL in 1 BOTTLE		

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.		139760102	manufacture	

Revised: 1/2011 Melaleuca, Inc.