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 Hand Gel

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



Product Information					
Product Type	HUMAN OTC DRUG	HUMAN OTC DRUG Item Code (Source)			
Route of Administration	e of Administration TOPICAL				
Active Ingredient/Activ	<i>v</i> e Moiety				
Ingred	ient Name	Basis of Strengt	n Stre	Strength	
LCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	150.97 g	n 266 mL	
UTYLENE GLYCOL (UNII: 3XU				J	
	Ingredient Nam	e		Strengt	
	S85KURA)				
LYCERIN (UNII: PDC6A3C0OX)	02000)				
OLYSORBATE 20 (UNII: 7T1F3	•				
LPHA-TOCOPHEROL ACETA					
ARBOMER HOMOPOLYMER,	· ·	45MM307FC)			
MMONIUM ACRYLOYLDIMET	HYLTAURATE, DIMETHYLAC COPOLYMER, TRIMETHYLOL	RYLAMIDE, LAURYL METHAC PROPANE TRIACRYLATE CRO			
		1\\\\\8\\\\			
YDROLYZED JOJOBA ESTERS	5 (ACID FORM) (UNII: UDR641	J V V V V /			

ltem Code	Package Description	Marketing Start Date	Marketing End Date		
		03/31/2020			
24	Product	03/31/2020			
NDC:54473-311- 16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2020			
		03/31/2020			
Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
C monograph not al	part333A	03/31/2020			
	NDC:54473-311- 09 NDC:54473-311- 24 NDC:54473-311- 16 NDC:54473-311- 18 arketing Category C monograph not	NDC:54473-311- 09 266 mL in 1 BOTTLE; Type 0: Not a Combination Product NDC:54473-311- 24 71 mL in 1 BOTTLE; Type 0: Not a Combination Product NDC:54473-311- 16 473 mL in 1 BOTTLE; Type 0: Not a Combination Product NDC:54473-311- 18 53 mL in 1 BOTTLE; Type 0: Not a Combination Product Marketing Category Application Number or Monograph Citation C monograph not part3334	NDC:54473-311- 09266 mL in 1 BOTTLE; Type 0: Not a Combination Product03/31/2020NDC:54473-311- 2471 mL in 1 BOTTLE; Type 0: Not a Combination Product03/31/2020NDC:54473-311- 16473 mL in 1 BOTTLE; Type 0: Not a Combination Product03/31/2020NDC:54473-311- 1653 mL in 1 BOTTLE; Type 0: Not a Combination Product03/31/2020NDC:54473-311- 1853 mL in 1 BOTTLE; Type 0: Not a Combination Product03/31/2020Marketing CategoryApplication Number or Monograph CitationMarketing Start DateC monograph notnart333403/31/2020		

Labeler - Melaleuca, Inc. (139760102)

Establishment					
Name	Address	ID/FEI	Business Operations		
Melaleuca, Inc.		079711683	manufacture(54473-311)		

Establishment

Name	Address	ID/FEI	Business Operations
Melaleuca - TN		805617610	manufacture(54473-311)

Revised: 1/2023

Melaleuca, Inc.