

CLEAR DEFENSE CITRUS SAGE- 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 Citrus Sunrise

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

Do not use in or near eyes. In case of contact, rinse eyes thoroughly with water.

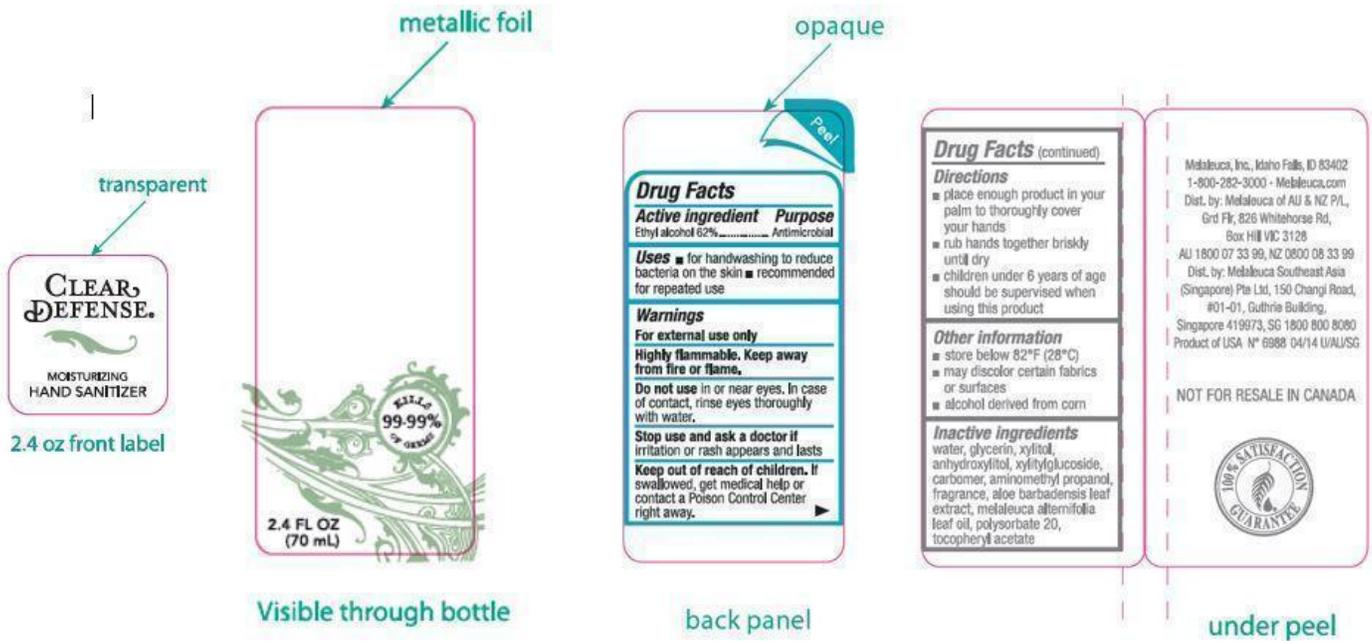
Stop use and ask a doctor if irritation or rash appears and lasts

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) ■ may discolor certain fabrics or surfaces ■ alcohol derived from corn

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 CITRUS SAGE

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-258
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	36.58 g in 59 mL

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
ANHYDROXYLITOL (UNII: 8XWR7NN42F)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
COCOA BUTTER (UNII: 512OYT1CRR)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
GLYCERIN (UNII: PDC6A3C0OX)	
MANGIFERA INDICA SEED BUTTER (UNII: 4OXD9M35X2)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
SHEA BUTTER (UNII: K49155WL9Y)	
TALC (UNII: 7SEV7J4R1U)	

TEA TREE OIL (UNII: VIF565UC2G)

WATER (UNII: 059QF0KO0R)

XYLITOL (UNII: VCQ006KQ1E)

XYLITYLGLUCOSIDE (UNII: O0IEZ166FB)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-258-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/15/2014	

Labeler - Melaleuca Inc (139760102)

Registrant - Melaleuca Inc (079711683)

Establishment

Name	Address	ID/FEI	Business Operations
Melaleuca Inc		079711683	manufacture(54473-258)

Revised: 2/2018

Melaleuca Inc