FRESH PROTECT HAND SANITIZER BERGAMONT LIME- alcohol gel Willspeed Technologies 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.

Fresh Protect Gel Scented Pump

Fresh Protect Gel Scented

Drug Facts

Active Ingredients

Ethyl Alcohol 80% v/v

Purpose

Antimicrobial

Uses

- hand sanitizing to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Do not drink.

Flammable. Keep away from heat and flame

Do not use

on children less than 2 years of age. - on open skin wounds

When using this product

keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor

if irritation or rash occurs. These may be signs of a serious condition

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product on hands to cover all surfaces - supervised children under 6 years of age when using this product to avoid swallowing.

Other information

- store at 15C to 30C (59F to 86F) - Avoid freezing and excessive heat above 40C (104F)

Inactive Ingredients

Water, Ammonium Acryloyldimethltaurate/VP Copolymer, Citrus Sinensis Peel Oil expressed, Citrus Aurantium Bergamia (Bergamot Peel Oil, Citrus Aurantifolia (Lime) Oil, Aloe Barbadensis Leaf Juice, Niacinamide, Hydrogen Peroxide, Maltodextrin, Tocopheryl Acetate, DL-Panthenol

PRINCIPAL DISPLAY PANEL

Fresh
PROTECT
HAND SANITIZER GEL
80% ALCOHOL
Non-sterile solution



FRESH PROTECT HAND SANITIZER BERGAMONT LIME alcohol gel Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69243-0110

Route of Administration TOPICAL

l	Active Ingredient/Active Moiety		
ı	Ingredient Name	Basis of Strength	Strength
ı	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.8 g in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
AMMONIUM ACRYLO YLDIMETHYLTAURATE/VP CO PO LYMER (UNII: W59 H9 29 6 ZG)		
ORANGE OIL TERPENELESS (UNII: L8B7EWV9I7)		

BERGAMOT OIL (UNII: 39 W1PKE3JI)	
LIME OIL (UNII: UZH29 XGA8 G)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
NIACINAMIDE (UNII: 25X51I8RD4)	
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
.ALPHATO COPHERO L ACETATE (UNII: 9E8X80D2L0)	
PANTHENOL (UNII: WV9CM0O67Z)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	LIME (Bergamot Lime)	Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69243-0110- 1	59 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/13/2020	
	NDC:69243-0110- 2	Product	08/13/2020	
3	NDC:69243-0110-3	237 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/13/2020	
4	NDC:69243-0110- 4	355 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/13/2020	
5	NDC:69243-0110- 5	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/13/2020	
6	NDC:69243-0110-	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/13/2020	
7	NDC:69243-0110-7	1893 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/13/2020	
8	NDC:69243-0110- 8	3785 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/13/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part356	08/13/2020	

Labeler - Willspeed Technologies LLC (019063540)