LONG LASTING HAND SANITIZER- benzalkonium chloride gel Safe Palms, 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.

Drug Facts

Active Ingredients

Benzalkonium Chloride 0.13%

Purpose

Antimicrobial

Use

Hand sanitizer to help reduce bacteria on the skin that can cause disease.

Warnings

For external use only.

When using this product avoid contact with the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation and redness appears and lasts

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

Directions

Apply liberally to front and back of hands. Allow to dry. Repeat daily.

Other Information

Store above 0°C (32°F)

Inactive Ingredients

Aloe Barbadensis Leaf Juice, Caesalpinia Spinosa Gum, Ethylhexylglycerin, Glycerin, Phenoxyethanol, Purified Water, Silicon Dioxide

Safe + Palms

LONG LASTING HAND SANITIZER

Extra Layer of Protection

Lasts Through 10 Washes*

NON-ALCOHOL

Gel Formula

Next Generation Technology

Kills 99.99% of Germs and Bacteria

Hypoallergenic Patented Formula

MADE IN USA

16 fl oz (480ml) • safepalms.com



LONG LASTING HAND SANITIZER

benzalkonium chloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:90117-204
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL		
Inactive Ingredients				
Ingredient Name		Strength		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)				
CAESALPINIA SPINO SA RESIN (UNII: WL3883U2PO)				
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)				
GLYCERIN (UNII: PDC6A3C0OX)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
WATER (UNII: 059QF0KO0R)				
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)				

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:90117-204- 01	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/25/2020	
2	NDC:90117-204- 02	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/25/2020	
3	NDC:90117-204- 03	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/25/2020	
4	NDC:90117-204- 04	480 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/25/2020	
5	NDC:90117-204- 05	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/25/2020	
6	NDC:90117-204- 06	1892 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/25/2020	
7	NDC:90117-204- 07	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/25/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/25/2020	

Labeler - Safe Palms, LLC (117609055)

Establishment				
Name	Address	ID/FEI	Business Operations	
Music City Laboratories, Llc		117409349	MANUFACTURE(90117-204)	

Revised: 8/2020

Safe Palms, LLC