BESAFE HAND SANITIZER- alcohol solution Besafe Industries 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.

Active Ingredient(s)

Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic

Use

For hand washing to decrease bacterial on the skin

Warnings

For external use only. Flammable. Keep away from fire and flame.

Do not use in the eyes

Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more then 72 hours

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Wet hands thoroughly with product and allow to dry without wiping

For children under 6, use only under adults supervision

Not reommended for infants

Other information

Do not store above 105F

May discolor some fabrics

Harmful to wood finishes and plastics

Inactive ingredients

Water, carbomer, triethanolamine, glycerin, aloe barbadensis gel, propylene glycol, tocopheryl acetate (Vitamin E)

BF-HG1234-05 LABEL 1L.pdf





BESAFE HAND SANITIZER

alcohol solution

	Proc	uct In	formation	
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Product TypeHUMAN OTC DRUGItem Code (Source)NDC:77693-001

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)
ALCOHOL (UNII: 3K9958V90M) To mL in 100 mL

Inactive Ingredients				
Ingredient Name	Strength			
GLYCERIN (UNII: PDC6A3C0OX)				
CARBOMER 940 (UNII: 4Q93RCW27E)				
TROLAMINE (UNII: 9O3K93S3TK)				
ALOE VERA WHOLE (UNII: KIZ4X2EHYX)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)				

Pa	ckaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1 NDC:77693-0	0 1-0 1	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/14/2020	
2 NDC:77693-0	01-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/14/2020	
3 NDC:77693-0	001-03	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/14/2020	
4 NDC:77693-0	01-04	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/14/2020	
5 NDC:77693-0	01-05	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/14/2020	
6 NDC:77693-0	001-06	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/14/2020	
7 NDC:77693-0	001-07	1800 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/14/2020	
8 NDC:77693-0	001-08	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/14/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	07/14/2020		

Labeler - Besafe Industries LLC (117481216)

Establishment					
Name	Address	ID/FEI	Business Operations		
Zhejiang Shenying Technology Co., Ltd. Jiaojiang Branch		414137820	manufacture (77693-001)		

Revised: 7/2020 Besafe Industries LLC