

HAND SANITIZER- alcohol gel
Dongguang Shuoguo Silicone Products Co., Ltd.

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.

70939-004 65% Alcohol Hand Sanitizer

Active ingredient

Alcohol 65%

Purpose

Antiseptic

Use

Use for hand-washing to decrease bacteria on the skin

Warnings

For etemal use only
Flammabl, keep away from fife and fames
Do not use in the eyes
Stop use and ask a doctor if
1 riation and rednes develop
1 cndition perists for more than72
hours

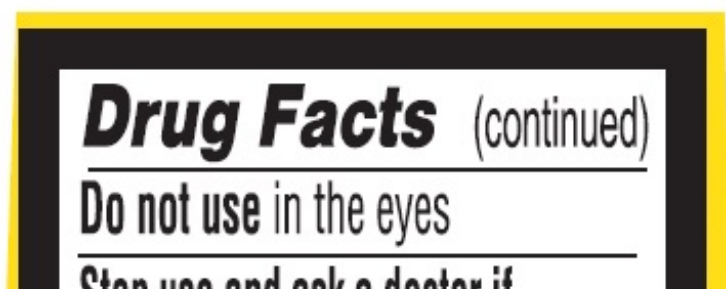
Keep out of reach of children

Keep out of reach of cilden. if sallowed, get medical help or contact a Poison ControlCenter right away

Directions

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ayltasC10-00 ayacylata crspoly
mer, honey, lemon peel ol, limmene ciral.



Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 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

Other information

Store in cool and dry place, out of direct sunlight.

Inactive ingredients

Water, glycerin, betaine, triethanolamine, acrylates/C10-300 alkyl acrylate crosspolymer, honey, lemon peel oil, limonene, citral.

Questions or comments?

(310) 538-2298

Drug Facts

Active ingredient Purpose

Ethyl alcohol 65% Antiseptic

Use For hand washing to decrease bacteria on the skin

Warnings

For external use only

Flammable, keep away from fire or flame. ▶

DISTRIBUTED BY U.S. JACLEAN, INC.
1816 W 135TH ST., GARDENA, CA 90249
PRODUCT OF NEW ZEALAND



HBP-14



HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70939-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BETAINE (UNII: 3SCV180C9W)	
GLYCERIN (UNII: PDC6A3C0OX)	
LIMONENE, (+/-)- (UNII: 9MC3B4447)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
TROLAMINE (UNII: 9O3K93S3TK)	
CITRAL (UNII: T7EU0O9VPP)	
HONEY (UNII: Y9HIV576FH)	
LEMON PEEL (UNII: 72O054U628)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70939-004-02	200 in 1 BOX	05/07/2020	
1		40 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70939-004-01	200 in 1 BOX	05/07/2020	
2		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:70939-004-03	200 in 1 BOX	05/07/2020	
3		50 mL in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:70939-004-04	200 in 1 BOX	05/07/2020	
4		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:70939-004-05	150 in 1 BOX	05/07/2020	
5		100 mL in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:70939-004-06	100 in 1 BOX	05/07/2020	
6		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:70939-004-07	100 in 1 BOX	05/07/2020	
7		150 mL in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:70939-004-08	48 in 1 BOX	05/07/2020	
8		250 mL in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:70939-004-09	24 in 1 BOX	05/07/2020	
9		500 mL in 1 BOTTLE; Type 0: Not a Combination Product		
10	NDC:70939-004-10	400 in 1 BOX	05/07/2020	
10		15 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/06/2020	

Labeler - Dongguang Shuoguo Silicone Products Co., Ltd. (544426629)

Establishment

Name	Address	ID/FEI	Business Operations
Dongguang Shuoguo Silicone Products Co., Ltd.		544426629	manufacture(70939-004)

Revised: 5/2020

Dongguang Shuoguo Silicone Products Co., Ltd.