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.

70939-003 62% Alcohol Hand Sanitizer

Active ingredient

Alcohol 62%

Purpose

Antiseptic

Use

Use for hand-washing to decrease bacteria on the skin, only when water is not available

Warnings

For etemal use only
Flammabl, keep away from fife and fames
When using this poduct

do not get intoeyes.
iicnacocur, inine eyes hrougwth water
Stop use and aska doctorif
iritation and redness develop

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

■wethands trougly with poduotd and alw todry wthout wiping

Water, PEG-40 Hydrogenated Castor Oil, Fragrance, AcylatesC10-30 Alkyl Acrylate Crospolymer, Sodium Hydroxide, Denatonium Benzoate.



HAND SANITIZER

alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70939-003

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients Ingredient Name Strength WATER (UNII: 059QF0KO0R) PEG-40 STEARATE (UNII: ECU18C66Q7) GLYCERIN (UNII: PDC6A3C0OX) SODIUM HYDROXIDE (UNII: 55X04QC32I) CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L) HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)

Pa	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70939-003-	300 in 1 BOX	05/07/2020	

1		15 mL in 1 BOTTLE; Type 0: Not a Combination Product		
	NDC-70020 002 01		05/07/2020	
2	NDC:70939-003-01		05/07/2020	
2		250 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:70939-003- 03	200 in 1 BOX	05/07/2020	
3		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:70939-003- 04	200 in 1 BOX	05/07/2020	
4		40 mL in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:70939-003- 05	200 in 1 BOX	05/07/2020	
5		50 mL in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:70939-003- 06	200 in 1 BOX	05/07/2020	
6		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:70939-003- 07	150 in 1 BOX	05/07/2020	
7		100 mL in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:70939-003- 08	150 in 1 BOX	05/07/2020	
8		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:70939-003- 09	24 in 1 BOX	05/07/2020	
9		500 mL in 1 BOTTLE; Type 0: Not a Combination Product		
10	NDC:70939-003-10	12 in 1 BOX	05/07/2020	
10		1000 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 (70939-003)	

Revised: 5/2020 Dongguang Shuoguo Silicone Products Co., Ltd.