FRESH AND SAFE HAND SANITIZER- alcohol gel KOREA COSPACK 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.

[SD Biotechnologies Co., Ltd.] 500 ml: 74064-7500

Active Ingredient(s)

Alcohol 70%. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months 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.

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Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Water, Carbomer, Triethanolamine, Glycerin, Propylene Glycol, Panthenol, Dipotassium Glycyrrhizate,

Package Label - Principal Display Panel



500 ml: 74064-7500-1

FRESH AND SAFE HAND SANITIZER

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74064-7500	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	350 mL in 500 mL

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6 A3C0 OX)		
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)		
WATER (UNII: 059QF0KO0R)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
PANTHENOL (UNII: WV9CM0O67Z)		
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0 FE3FX)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)		
HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)		

TROLAMINE (UNII: 9O3K93S3TK)

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:74064-7500-	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/31/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	03/31/2020		

Labeler - KOREA COSPACK CO,. LTD. (689059789)

Establishment					
Name	Address	ID/FEI	Business Operations		
KOREA COSPACK CO,. LTD.		689059789	manufacture(74064-7500)		

Revised: 4/2020 KOREA COSPACK CO,, LTD.