

PURE CLEAN HAND GEL- 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.

PURE CLEAN HAND Gel 500 ml : 74064-2570



Drug Facts	
Active Ingredient Alcohol 70% v/v	Purpose Antiseptic
Uses 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.	
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 15-30 °C (59-86 °F) ■ Avoid freezing and excessive heat above 40 °C (104 °F)	
Inactive Ingredients Water, Carbomer, Triethanolamine, Glycerin, Propylene Glycol, Sodium Hyaluronate, D-Panthenol, Aloe Vera gel, Tocopheryl Acetate, Dipotassium Glycyrrhizate	
Manufactured by KOREA COSPACK CO., LTD. 14 B 6L, 70, Namdongseo-ro, 316beon-gil, Namdong-gu, Incheon, 21630 Korea	
Manufactured for Sooin Cosmetic CO.,LTD. 12F, 13F, Gwangmyeong-tower, 92, Achanan-ro, Seongdong-gu, Seoul, 04782 Korea	
MADE IN KOREA	

PURE CLEAN HAND GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74064-2570
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
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)	

WATER (UNII: 059QF0K00R)	
DEXPANTHENOL (UNII: 1O6C93RI7Z)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74064-2570-1	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(74064-2570)

Revised: 4/2020

KOREA COSPACK CO.,LTD.