

**CLEAN TO CLEAN HAND SANITIZER 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.*

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**80 ml : 74064-0080**

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

**Active Ingredient(s)**

Alcohol 62%. 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.

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

**Inactive ingredients**

Water, Carbomer, Triethanolamine, Glycerin, Propylene Glycol, Panthenol, Dipotassium Glycyrrhizate, Aloe Barbadensis Leaf Juice, Sodium Hyaluronate, Tocopheryl Acetate

**Package Label - Principal Display Panel**



**Hand Sanitizer gel**

Hand cleangel instant hand sanitizer

Non-sterile Solution Alcohol Antiseptic 62%

Topical Solution 80ml

<b>Drug Facts</b>	
<i>Active ingredient</i>	<i>Purpose</i>
Alcohol 62% v/v.....	Antiseptic
<b>Uses</b>	
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
<b>For external use only.</b>	
<b>Flammable.</b>	
<b>Keep away from heat or flame.</b>	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>■ in children less than 2 months of age</li> <li>■ on open skin wounds</li> </ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children</b> if swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>■ Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>■ Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>■ Store between 15-30 °C (59-86 °F)</li> <li>■ Avoid freezing and excessive heat above 40 °C (104 °F)</li> </ul>	
<b>Inactive ingredients</b> Water, Carbomer, Triethanolamine, Glycerin, Propylene Glycol, Panthenol, Dipotassium Glycyrrhizate, Aloe Barbadosensis Leaf Juice, Sodium Hyaluronate, Tocopheryl Acetate	

Manufactured by  
KOREA COSPACK CO., LTD.  
14B 6L, 70, Namdongseo-ro, 316beon-gil,  
Namdong-gu, Incheon, 21630 Korea



80 mL NDC: 74604-0080-1

**CLEAN TO CLEAN HAND SANITIZER GEL**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74064-0080
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	49.6 mL in 80 mL

**Inactive Ingredients**

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
WATER (UNII: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PANTHENOL (UNII: WV9CM0O67Z)	
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
PEG-9 DIGLYCIDYL ETHER/SODIUM HYALURONATE CROSSPOLYMER (UNII: 788QAG3W8A)	
TROLAMINE (UNII: 9O3K93S3TK)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74064-0080-1	80 mL in 1 TUBE; Type 0: Not a Combination Product	03/30/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

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

Name	Address	ID/FEI	Business Operations
KOREA COSPACK CO., LTD.		689059789	manufacture(74064-0080)

Revised: 4/2020

KOREA COSPACK CO., LTD.