

ADVANCED HAND SANITIZER- ethyl alcohol gel
Dong-A Pharmaceutical 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.

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)

Ethyl Alcohol 70%

Purpose

Antimicrobial

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease.

Warnings

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

Do not use in or near the eyes, ears, and mouth.

In case of contact, rinse thoroughly with water.

Do not use in the mouth, mucous membrane, or open skin wound as it may cause irritation.

Take precaution when using if allergic to Propylene Glycol.

Stop use and ask a doctor if irritation or rash occurs.

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.

Other information

- Store between 1-30C (33-86F)

Inactive ingredients

Water, Triethanolamine, Hydrogenated Castor Oil, Glycerol, Propylene Glycol, D-Panthenol, Polyacrylic Acid, Lemon, DL-alpha-Tocopherol Acetate

Package Label - Principal Display Panel

500 mL NDC: 77973-800-01

제품명	핸디가드	소재명	라벨
출고날짜		규격	220 x 120
인쇄도수			
후기공		재질	투명 PP
확인 사항	항목		체크
	표기 양구, 비로드		
비고	* 팬톤컬러에 맞춰주시기 바랍니다.		

HANDY GUARD



**ADVANCED
HAND SANITIZER**

Fresh Hand Sanitizer Gel

ETHYL ALCOHOL 70%

16.9 fl oz (500ml)

Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 70%	Antimicrobial

Use Hand Sanitizer to help reduce bacteria that potentially can cause disease

Warnings
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Other Information
• Store between 1-30C (33-86F)

Inactive Ingredients
Hydrogenated Castor Oil, D-Panthenol, DL-a-Tocopherol Acetate, Glycerol, Lemon, Polyacrylic Acid, Propylene Glycol, Triethanolamine, Water

Distributed by Dong-A Pharmaceutical Co., Ltd. EXPIRATION DATE:
64 Cheonho-daero, Dongdaemun-gu, South Korea LOT#:
Made in South Korea

ADVANCED HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77973-800
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
DEXPANTHENOL (UNII: 1O6C93RI7Z)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
LEMON (UNII: 24RS0A988O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77973-800-01	500 mL in 1 BOTTLE; 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 - Dong-A Pharmaceutical Co., Ltd. (688733015)**Registrant** - Dong-A Pharmaceutical Co., Ltd. (688733015)**Establishment**

Name	Address	ID/FEI	Business Operations
Dong-A Pharmaceutical Co., Ltd.		688733015	manufacture(77973-800)

Revised: 6/2020

Dong-A Pharmaceutical Co., Ltd.