

IMK HAND SANITIZER- ethyl alcohol gel

Biopontis inc

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:

- 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.
- Glycerol (1.45% v/v).
- Hydrogen peroxide (0.125% v/v).
- 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 70% v/v.

Active Ingredient	Purpose
Ethyl Alcohol 70% v/v	Antimicrobial

Purpose: Antiseptic

Purpose

Use ■ Hand sanitized to help reduce bacteria on the skin

Antiseptic, Hand Sanitizer

Use

Hand sanitized to help reduce bacteria on the skin

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Warnings

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

Do not use

Stop use and ask a doctor if irritation or rash appears and lasts

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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Directions

- Put as needed in your palms and rub your hands together briskly until dry
- Children under 6 years of age should be supervised when using this product

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Other information

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

Inactive ingredients

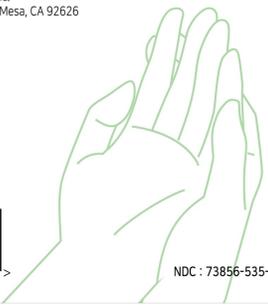
Water(aqua), Glycerin, Aloe Vera Leaf, Tromethamine, Carbomer

Inactive Ingredients

Water (Aqua), Glycerin, Aloe Vera Leaf, tromethamine, carbomer

Package Label - Principal Display Panel

500 ml NDC:73856-535-18

I'm K Hand Sanitizer Refreshing Gel	 ADVANCED Hand Sanitizer Refreshing Gel with ALOE Kills more than 99.99% of most common germs 70% ethanol  16.9 FL OZ (500ml)	I'm K Kills more than 99.99% of most common germs																																				
<p>Manufactured by : K.Boeun Pharmaceutical Co., Ltd. 114, Jangjayeongje-ro, Sinbuk-myeon, Pocheon-si, Gyeonggi-do, Republic of Korea Tel : +62-31-536-7990</p> <p>Distributed by : Biopontis Inc. 2940 Grace In. Ste E, Costa Mesa, CA 92626 Tel : 1-412-915-2433</p> <p>MADE IN KOREA</p>	 NDC : 73856-535-18	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th colspan="2" style="text-align: left; padding: 2px;">Drug Facts</th> </tr> <tr> <td style="padding: 2px;">Active Ingredient</td> <td style="padding: 2px;">Purpose</td> </tr> <tr> <td style="padding: 2px;">Ethyl Alcohol 70% w/v</td> <td style="padding: 2px;">Antimicrobial</td> </tr> <tr> <td colspan="2" style="padding: 2px;">Use ■ Hand sanitized to help reduce bacteria on the skin</td> </tr> <tr> <td colspan="2" style="padding: 2px;">Warnings</td> </tr> <tr> <td colspan="2" style="padding: 2px;">Flammable. Keep away from fire or flame.</td> </tr> <tr> <td colspan="2" style="padding: 2px;">For external use only.</td> </tr> <tr> <td colspan="2" style="padding: 2px;">When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.</td> </tr> <tr> <td colspan="2" style="padding: 2px;">Stop use and ask a doctor if irritation or rash appears and lasts</td> </tr> <tr> <td colspan="2" style="padding: 2px;">Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</td> </tr> <tr> <td colspan="2" style="padding: 2px;">Directions</td> </tr> <tr> <td colspan="2" style="padding: 2px;">■ Put as needed in your palms and rub your hands together briskly until dry</td> </tr> <tr> <td colspan="2" style="padding: 2px;">■ Children under 6 years of age should be supervised when using this product</td> </tr> <tr> <td colspan="2" style="padding: 2px;">Other Information</td> </tr> <tr> <td colspan="2" style="padding: 2px;">■ Store below 110°F (43°C)</td> </tr> <tr> <td colspan="2" style="padding: 2px;">■ May discolor certain fabrics or surfaces</td> </tr> <tr> <td colspan="2" style="padding: 2px;">Inactive Ingredients</td> </tr> <tr> <td colspan="2" style="padding: 2px;">Water (Aqua), Glycerin, Aloe Vera Leaf, tromethamine, carbomer</td> </tr> </table>	Drug Facts		Active Ingredient	Purpose	Ethyl Alcohol 70% w/v	Antimicrobial	Use ■ Hand sanitized to help reduce bacteria on the skin		Warnings		Flammable. Keep away from fire or flame.		For external use only.		When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.		Stop use and ask a doctor if irritation or rash appears and lasts		Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.		Directions		■ Put as needed in your palms and rub your hands together briskly until dry		■ Children under 6 years of age should be supervised when using this product		Other Information		■ Store below 110°F (43°C)		■ May discolor certain fabrics or surfaces		Inactive Ingredients		Water (Aqua), Glycerin, Aloe Vera Leaf, tromethamine, carbomer	
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IMK HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73856-535
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: PDC6A3C0OX)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
WATER (UNII: 059QF0KO0R)	
TROMETHAMINE (UNII: 023C2WHX2V)	
ALOE (UNII: V5VD430YW9)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73856-535-18	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part333A	04/20/2020	

Labeler - Biopontis inc (884060547)

Registrant - Biopontis inc (884060547)

Establishment

Name	Address	ID/FEI	Business Operations
K.Boeun Pharmaceutical Co.,Ltd.		695674074	manufacture(73856-535)

Establishment

Name	Address	ID/FEI	Business Operations
Biopontis inc		884060547	relabel(73856-535)

Revised: 6/2020

Biopontis inc