

## **BIOCEF HAND SANITIZER- alcohol gel**

### **ABDULALIM ALISMIS-IHLAS KIMYA TEMIZLIK MADDELERI IMALATI**

*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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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 70% v/v. 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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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 , Glycerin, Triethanolamine, Carbomer, Fragrance

### Package Label - Principal Display Panel

250ml gel



### Drug Fact:

**Active Ingredient.....Purpose**  
Ethyl Alcohol 70%.....Antimicrobial  
**Uses:** Helps reduce bacteria on the skin that could cause diseases.

**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.

**Drug Fact (continued):**  
**Directions:** Place enough product into the palm of your hands to thoroughly cover your hands. Rub hands together briskly until product is completely absorbed and hands are dry.

**Other information:** • After unseal, tighten the cap and use product within the validity period.  
• After use, seal and keep away from light and moisture.  
• Store in a cool and dry place. Do not store above 37 °C (98.6°F).

**Inactive Ingredients:** Water, Glycerin, Carbomer, Triethanolamine, Fragrance.

PROD. DATE : 16.07.2020

EXP. DATE : 16.07.2023

LOT : 250PL002

Distributed by:  
Soloway Global LLC  
Virginia, USA  
(757) 756 8288  
www.solowayglobal.com



Made in TURKEY



PRODUCED BY : ABDULALIM ALISMIS  
IHLAS KIMYA TEMIZLIK URUNLERI IMALATI  
www.ihlaskimya.com

100ml gel



\* Bacterium,  
\* Fungal,  
\* Virus  
destroys

**Biocef**<sup>®</sup>

**HAND SANITIZER**

**70% ALCOHOL  
CONTENT**

**Kills 99,9% of all germs**

**3,4 FL OZ (100 mL e)**

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PRODUCED BY : ABDULALIM ALISMIS  
IHLAS KIMYA TEMIZLIK URUNLERI IMALATI  
www.ihlaskimya.com

## BIOCEF HAND SANITIZER

alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80043-070
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
GLYCERIN (UNII: PDC6A3C0OX)	3 mL in 100 mL
WATER (UNII: 059QF0KO0R)	26.35 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.3 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.3 mL in 100 mL
FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF)	0.05 mL in 100 mL

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80043-070-25	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:80043-070-10	100 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** - ABDULALIM ALISMIS-IHLAS KIMYA TEMIZLIK MADDELERI IMALATI (365808186)

## Establishment

Name	Address	ID/FEI	Business Operations
ABDULALIM ALISMIS-IHLAS KIMYA TEMIZLIK MADDELERI IMALATI		365808186	manufacture(80043-070)

Revised: 8/2020

ABDULALIM ALISMIS-IHLAS KIMYA TEMIZLIK MADDELERI IMALATI