

**BIO FRESH ANTIBACTERIAL HAND SANITIZER- ethanol spray  
KONEL**

*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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**ACTIVE INGREDIENT**

Ethanol 65% v/v

**INACTIVE INGREDIENTS**

Water, Glycerin, Propolis, Citric Extractives, Ascorbic acid, Lactic acid, Citric acid

**PURPOSE**

ANTISEPTIC

**WARNINGS**

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

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Do not use

- in children less than 2 months of age
  - on open skin wounds
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When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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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.

**Use**

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

**Directions**

- Spray 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)

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

의약품

Bio Fresh Spray Antibacterial Hand Sanitizer

Seoul Food R&D

# Bio Fresh

*Spray* Antibacterial Hand sanitizer

바이오 후레시 스프레이 손소독제


  
 프로폴리스, 감귤류 추출물, 식물성 곡물 발효 에탄올 70% 함유  
 피부에 안전하게 벡테리아 & 바이러스로부터 건강을 지키세요

500 ml

<b>Drug Facts</b>	
<b>Active Ingredients</b> Ethanol 65% v/v	<b>Purpose</b> ANTISEPTIC
<b>Uses</b> Hand sanitizer to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame	
<b>Do not use</b> • in children less than 2 months of age • on open skin wounds	
<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> • Spray 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.	
<b>Other information</b> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b> Water, Glycerin, Propolis, Citric Extractives, Ascorbic acid, Lactic acid, Citric acid	



## BIO FRESH ANTIBACTERIAL HAND SANITIZER

ethanol spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71059-050
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	
Ascorbic acid (UNII: PQ6CK8PD0R)	
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71059-050-01	500 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/01/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/01/2020	

**Labeler** - KONEL (689605036)

**Registrant** - KONEL (689605036)

## Establishment

Name	Address	ID/FEI	Business Operations
KONEL		689605036	manufacture(71059-050)

Revised: 6/2020

KONEL