BIO FRESH ANTIBACTERIAL HAND SANITIZER- ethanol gel
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.

ACTIVE INGREDIENT

Ethanol 65% v/v

INACTIVE INGREDIENTS

Water, Glycerin, Methylcellulose, 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

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.

Use

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

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)

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

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Bio Fresh Gel Antibacterial Hand Sanitizer

Drug Facts

Active ingredients — **Purpose**
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ethanol gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71059-060
Route of Administration	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)	
METHYLCELLULOSE, UNSPECIFIED (UNII: Z944H5SN0H)	
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:71059-060-01	500 mL in 1 BOTTLE, PUMP; 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(71059-060)

Revised: 6/2020 KONEL