BIOGENIX HAND SANITIZER GEL- alcohol gel OZVERI KOZMETIK ITHALAT IHRACAT SAN TIC LTD STI

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.

BIOGENIX HAND SANITIZER GEL

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) (70%, 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 (1.2% v/v).
- c. Triethanolamin (0.2% v/v).
- d. EDTA (0.2% v/v).
- e. Carbomer (0.5% v/v).
- f. Lavander Oil (0.7% v/v).
- g. 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% (v/v), Antimicrobial

Purpose

Antimicrobial, 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 do not use in or near the eyes. 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.

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.

Directions

- Put enough product in your palm to cover hands and rub hands together briskly until dry.
- •

Other information

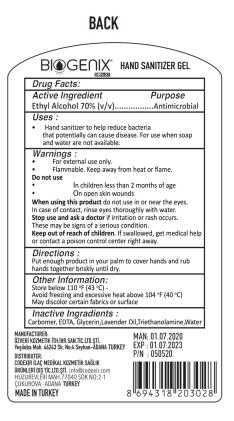
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Carbomer, EDTA, Glycerin, Lavander Oil, Triethanolamine, purified water

Package Label - Principal Display Panel





BIOGENIX HAND SANITIZER GEL

alcohol gel

Pro	duct	Information	
FIU	uucı	IIIIVI IIIauvii	

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:86943-001
--------------	----------------	--------------------	---------------

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

interve ingredients		
Ingredient Name	Strength	
CARBOMER 940 (UNII: 4Q93RCW27E)	0.5 mL in 100 mL	
ETIDRONATE TETRASODIUM (UNII: CZZ9T1T1X4)	0.2 mL in 100 mL	
GLYCERIN (UNII: PDC6A3C0OX)	1.2 mL in 100 mL	
TROLAMINE (UNII: 903K93S3TK)	0.2 mL in 100 mL	
WATER (UNII: 059QF0KO0R)		
LAVENDER O IL (UNII: ZBP1YXW0H8)	0.7 mL in 100 mL	

Packaging

П		- manual 8			
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1	NDC-96042 001 01	500 mL in 1 POTTLE: Type 0: Not a Combination Product	0.2/20/2020	

1 NDC:86943-001-01 \mid 500 mL in 1 BOTTLE; Type 0: Not a Combination Product \mid 03/30/2020

Marketing Information

OZVERI KOZMETIK ITHALAT IHRACAT SAN TIC LTD STI

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - OZVERI KOZMETIK ITHALAT IHRACAT SANTIC LTD STI (533135933)

$\textbf{Registrant -} \ \, \text{ozverikozmetik ithalat ihracat santic LTD Sti} (533135933)$

Establishment Name Address ID/FEI Business Operations

Revised: 7/2020 OZVERI KOZMETIK ITHALAT IHRACAT SAN TIC LTD STI

533135933

manufacture (86943-001)