

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.

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Directions

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

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| 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

| 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: 9O3K93S3TK) | 0.2 mL in 100 mL |
| WATER (UNII: 059QF0KO0R) | |
| LAVENDER OIL (UNII: ZBP1YXW0H8) | 0.7 mL in 100 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:86943-001-01 | 500 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 - OZVERI KOZMETIK ITHALAT IHRACAT SAN TIC LTD STI(533135933)

Registrant - OZVERI KOZMETIK ITHALAT IHRACAT SAN TIC LTD STI(533135933)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---------|-----------|------------------------|
| OZVERI KOZMETIK ITHALAT IHRACAT SAN TIC LTD STI | | 533135933 | manufacture(86943-001) |

Revised: 7/2020

OZVERI KOZMETIK ITHALAT IHRACAT SAN TIC LTD STI