

**70% BIOKEN HAND SANITIZER WITH ALOE- ethyl alcohol gel
Orange Lab**

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.

Bioken Hand Sanitizer with Aloe 70% 16oz

Active Ingredient

| Active Ingredient | Purpose |
|--------------------------|----------------|
| Ethyl alcohol 70% | Antiseptic |

Stop use and ask a doctor if skin irritation develops.

Stop use and ask a doctor if skin irritation develops.

Keep out of reach of children.

Keep out of reach of children: If swallowed, get medical help or contact a Poison Control Center right away.

Purpose : Antiseptic

| Drug Facts | |
|--------------------------|----------------|
| Active Ingredient | Purpose |
| Ethyl alcohol 70% | Antiseptic |

Questions ?

Questions ? - Call 1-877-654-6200

Stop use and ask a doctor if skin irritation develops.

Stop use and ask a doctor if skin irritation develops.

When using this product section

When using this product : keep out of eyes. In case of contact with eyes, flush thoroughly with water. Avoid contact with broken skin. Do not inhale or ingest.

Directions section

Directions : Wet hands thoroughly with product and allow to dry without wiping. For children under 6, use only under adult supervision. Not recommended for infants.

Other safety information

Other information : Do not store above 105F. May discolor some fabrics. Harmful to wool finishes and plastics.

Inactive ingredients

Inactive ingredients : Aloe barbadensis leaf juice(aloe vera inner leaf gel)*, glycerin, panthenol, acrylates/C10-30 alkyl acrylate crosspolymer, aminomethyl propanol.

*USDA Certified Organic

Warnings section

Warnings: For external use only-hands.

Flammable, keep away from heat and flame.

Dosage & Administration section

Drug Facts

| Active Ingredient | Purpose |
|-------------------------|------------|
| Ethyl alcohol 70% | Antiseptic |

Uses : to decrease bacteria on the skin that could cause disease. Recommended for repeated use.

Warnings: For external use only-hands.

Flammable, keep away from heat and flame.

When using this product : keep out of eyes. In case of contact with eyes, flush thoroughly with water. Avoid contact with broken skin. Do not inhale or ingest.

Indications & Usage section

When using this product : keep out of eyes. In case of contact with eyes, flush thoroughly with water. Avoid contact with broken skin. Do not inhale or ingest.

Stop use and ask a doctor if skin irritation develops.

Keep out of reach of children: If swallowed, get medical help or contact a Poison Control Center right away.

Directions : Wet hands thoroughly with product and allow to dry without wiping. For children under 6, use only under adult supervision. Not recommended for infants.

Package front label

BIOKEN®

**HAND
SANITIZER**



with aloe



Ethyl Alcohol 70%

16 FL.OZ.(473ML)

70% BIOKEN HAND SANITIZER WITH ALOE

ethyl alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71331-107 |
| 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 |
|--|-------------------|
| AMINOMETHYLPROPANOL (UNII: LU49E6626Q) | 0.3 mL in 100 mL |
| GLYCERIN (UNII: PDC6A3C0OX) | 4 mL in 100 mL |
| PANTHENOL (UNII: WW9CM0067Z) | 0.5 mL in 100 mL |
| CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L) | 0.3 mL in 100 mL |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | 25.1 mL in 100 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:71331-107-01 | 473 mL in 1 BOTTLE, PLASTIC; 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 | part333A | 06/01/2020 | |

Labeler - Orange Lab (004862271)

Registrant - Orange Lab (004862271)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------|---------|-----------|------------------------|
| Orange Lab | | 004862271 | manufacture(71331-107) |

Revised: 2/2022

Orange Lab