

BATURALS HAND SANITIZER- ethyl alcohol gel
Guangdong Authenmole Biotech Inc.

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.

BATURALS HAND SANITIZER

Drug Facts

Active ingredient

Ethyl alcohol 75%

Purpose

Antiseptic

Use ▪ Helps decrease bacteria on skin. ▪ Recommended for repeated use.

Warnings **Flammable. Keep away from fire or flame. For external use only**

When using this product □do not use in or near the eyes.

In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or redness develops.

Keep Out of Reach of Children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions ▪ Place enough product in your palm to thoroughly cover your hands

- Rub hands together briskly until dry
- Children under 6 years of age use only under adult supervisions

Other information ▪ Store at 77°F (25°C) ▪ May discolor fabrics

Inactive ingredients

Water, Propylene, Glycerin, Fragrance, Carbomer, Triethanolamine, Tocopheryl Acetate

Kills 99.9% of Germs

Refreshing Gel

Packaging



| | |
|---|------------------------------|
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BATURALS HAND SANITIZER

ethyl alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:74218-001 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 75 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| PROPYLENE (UNII: AUG1H506LY) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:74218-001-50 | 50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 04/07/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 04/07/2020 | |

Labeler - Guangdong Authenmole Biotech Inc. (559966091)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------------|---------|-----------|------------------------|
| Guangdong Authenmole Biotech Inc. | | 559966091 | manufacture(74218-001) |

Revised: 4/2020

Guangdong Authenmole Biotech Inc.