

AROMA GUARDIAN- anti bacterial instant hand sanitizer gel
Opal Cosmetics (Huizhou) Limited

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.

Opal, Hand Sanitizer, Gel, 75% Ethyl alcohol, 95mL

Active Ingredient(s)

Ethyl Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

Flammable. For external use only. Keep away from heat or flame.

Do not use

- on 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.

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

- Do not store above 105° (40.6°)
- May discolor some fabrics
- Harmful to wood finishes and plastics

Inactive ingredients

Water, Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Fragrance, t-Butyl Alcohol, Aminomethyl Propanol, Aloe Barbadensis Leaf Extract, Maltodextrin, Denatonium Benzoate.

Package Label - Principal Display Panel



AROMA GUARDIAN

anti bacterial instant hand sanitizer gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:42477-2022 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-------------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 71.25 mL in 95 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-------------------|
| CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO) | 0.475 mL in 95 mL |
| WATER (UNII: 059QF0KO0R) | 21.47 mL in 95 mL |
| GLYCERIN (UNII: PDC6A3C0OX) | 1.52 mL in 95 mL |
| TERT-BUTYL ALCOHOL (UNII: MD83SFE959) | 0.285 mL in 95 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:42477-2022-1 | 95 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 04/17/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333E | 04/17/2020 | |

Labeler - Opal Cosmetics (Huizhou) Limited (528178475)

Registrant - A03 Lab of BTS (548009541)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------------|---------|-----------|---|
| Opal Cosmetics (Huizhou) Limited | | 528178475 | label(42477-2022) , manufacture(42477-2022) |

Revised: 4/2020

Opal Cosmetics (Huizhou) Limited