AGELLA BEAUTY BOTANICAL EXTRACTS HAND SANITIZER- ethyl alcohol gel Agella Beauty LLC

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.

Hand Sanitizer

Active Ingredients

Alcohol 70%. Purpose: Antimicrobial

120mL NDC: 77001-0416-1



Dosage and Administration Section

Agella Beauty Botanical Extracts Hand Sanitizer

Alcohol 70%. Purpose: Antimicrobial

120 mL NDC: 77001-0416-1



Indications and Usage Section.

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes throughly 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.



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.



Hand Sanitizer Inactive Ingredients.

Inactive Ingredients:aqua, gylcerin, *co glycerin, *co humulus lupulus (Hops)Extract, *co lavandula (Lavender) flower/leaf/stem extract, *co calendula officinalis flower extract, *co citrus limon (lemon) peel extract, *co cucummis sativus (cucumber) seed extrac, *co camellia sinensis leaf extract, *co pyrus malus (apple) fruit extract, *co spirulina platensis extract, xanthan gum. *CO Certified Organic.



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 Section

Hand Sanitizer to help reduce bacteria that potentially can cause disease.



Principal Display panel

Botanical Extracts Hand Sanitizer



AGELLA BEAUTY BOTANICAL EXTRACTS HAND SANITIZER

ethyl alcohol gel

| Product Information | | | |
|----------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:77001-0416 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | |
|--|-------------------|-----------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M) | ALCOHOL | 70 mL in 100 mL | |

| Inactive Ingredients | | | |
|-----------------------------|----------------|--|--|
| Ingredient Name | Strength | | |
| GLYCERIN (UNII: PDC6A3C0OX) | 2 mL in 100 mL | | |

| Packaging | | | | |
|------------------------|---|-------------------------|-----------------------|--|
| # Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 NDC:77001- 0416-1 | 00 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/15/2020 | 12/31/2020 | |
| | | | | |

| Marketing Information | | | | |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part333A | 05/15/2020 | 12/31/2020 | |
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Labeler - Agella Beauty LLC (128605597)

Revised: 5/2020 Agella Beauty LLC