

HAND SANITIZER- alcohol gel
Avaria Health & Beauty Corp

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.

Kalaya Antiseptic Hand Sanitizer

Active Ingredient(s)

Ethyl Alcohol 70%. 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

For external use only

Flammable. Keep away from heat and flame.

Do not use

- In 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

- Store between 15 - 40C (59 - 86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Water, Carbomer, Hyaluronic Acid, Aminomethyl Propanol ,Isopropyl Myristate

Questions or comments?

Call toll-free 1.888.829.7165

Package Label - Principal Display Panel

13.5 fl oz (400 ml)

NDC 43493-0000-0

NDC 43493-0000-0

Kalaya.
ANTISEPTIC
HAND SANITIZER
WITH HYALURONIC ACID

KILLS HARMFUL BACTERIA & GERMS
with HYALURONIC ACID
to prevent dry skin

70% USP ETHYL ALCOHOL
13.5 fl oz (400 mL)

Drug Facts

| | |
|--|------------------------------|
| Active ingredient Ethyl Alcohol 70% v/v | Purpose Antiseptic |
| Uses • 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 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 the 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 • Store between 15-30°C (59-86°F). • Avoid freezing and excessive heat above 40°C (104°F). | |
| Inactive ingredients Water, Carbomer, Glycerin, Hyaluronic Acid, Aminomethyl Propanol | |
| Questions or comments? Call toll-free 1.888.829.7165 | |
| Manufactured for: Avaria Health & Beauty Corp. Unit 5, 650 Jamieson Pky, Cambridge, ON N3C 0A5, CA MADE IN CANADA www.kalaya.ca | |
| 6 91808 11020 8 | |

HAND SANITIZER

alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:43493-0000 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------|-------------------|----------|
|-----------------|-------------------|----------|

| | | |
|---|---------|------------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 280 mL in 400 mL |
|---|---------|------------------|

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) | |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | |
| HYALURONIC ACID (UNII: S270N0TRQY) | |
| WATER (UNII: 059QF0KO0R) | |
| AMINOMETHYLPROPANOL (UNII: LU49E6626Q) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:43493-0000-0 | 400 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 03/30/2020 | |
| 2 | NDC:43493-0000-1 | 250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 03/30/2020 | |
| 3 | NDC:43493-0000-2 | 60 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 03/30/2020 | |
| 4 | NDC:43493-0000-3 | 1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 02/05/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 03/30/2020 | |

Labeler - Avaria Health & Beauty Corp (251366043)

Revised: 12/2022

Avaria Health & Beauty Corp