

HAND SANITIZER GEL- ethyl alcohol gel

NV Labs

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.

Amber and Black HAND SANITIZER GEL (8 Fl. Oz Tube.)

Active Ingredient

Active Ingredient Purpose

Ethyl Alcohol 70% v/v Antimicrobial

USES

- Hand Sanitizer to help reduce bacteria on the skin that could cause disease
- Recommended for repeated use

WARNING

Warnings

Flammable Keep away from 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 rash appears and lasts

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

Directions

Directions

- Place enough product in your palm to thoroughly cover your hands
- Rub hands together briskly until dry
- Children under 6 years of age should be supervised when using this product

Other information

Other Information

- Store below 110F (43C) May discolor certain fabrics or surfaces

In active Ingredients

Water (Aqua) , Glycerin, Aloe Barbadensis Leaf Juice, Isopropyl Myristate, Tocopheryl Acetate, Carbomer, Triethanolamine, Fragrance (Parfum)

**Manufactured By:
Questions or Comments**

Manufactured By: Reforma Group, Southfield, Michigan 48033

Questions or comments? Call 1-248-358-9022

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

Antimicrobial

Principle Display Panel



Amber and Black

Hand Sanitizer

Made in USA

Kills 99.99% of Germs

16 fl oz (473 mL)

HAND SANITIZER GEL

ethyl alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:73696-102 |
| 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 |
|---|---------------------|
| TROLAMINE (UNII: 9O3K93S3TK) | 0.12 mL in 100 mL |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | 0.001 mL in 100 mL |
| CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) | 0.35 mL in 100 mL |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | 0.25 mL in 100 mL |
| WATER (UNII: 059QF0KO0R) | 29.278 mL in 100 mL |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | 0.001 mL in 100 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:73696-102-18 | 236 mL in 1 TUBE; 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 | part333A | 03/31/2020 | |

Labeler - NV Labs (019662814)

Registrant - NV Labs (019662814)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|----------------|---------------|----------------------------|
| NV Labs | | 019662814 | manufacture(73696-102) |