

UNITED SPIRIT OF AMERICA HAND SANITIZER- ethyl alcohol gel
Prime Enterprises

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.

Warrior Hand Sanitizer Gel

Active Ingredient

Ethyl Alcohol 70% v/v

Purpose

Antiseptic

Use

For hand washing to decrease bacteria on the skin.

Warnings

For external use only.

Flammable: Do not use near hear, flame or while smoking.

When using this product: Keep put of eyes. If product gets into eyes, rinse with water to remove. Avoid contact with broken skin. Do not inhale or ingest.

Stop use and ask a doctor if rash or irritation develops and lasts.

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

Directions

- Wet hands thoroughly with product and allow to dry without wiping.
- For children under 6, use only under adult supervision.

Other Information

- Do not store above 104 °F.
- May discolor some fabrics, wood finishes and plastics.

Inactive ingredients

Aloe Barbadosis Leaf Juice, Aminomethyl Propanol, Carbomer, Glycerin, Isopropyl Myristate, Tocopherol, Water

Questions and comments

www.usaspiritgov.com - 866.295.0277

Warrior Hand Sanitizer Gel

UNITED SPIRIT OF AMERICA HAND SANITIZER

ethyl alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58443-0553 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 609 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| AMINOMETHYLPROPANOL (UNII: LU49E6626Q) | |
| CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |

WATER (UNII: 059QF0KO0R)

Product Characteristics

| | | | |
|-----------------|-------------------|---------------------|--|
| Color | white (Colorless) | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:58443-0553-9 | 3700 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/11/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 05/11/2020 | |

Labeler - Prime Enterprises (101946028)

Registrant - Prime Enterprises (101946028)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------|---------|-----------|---|
| Prime Enterprises | | 101946028 | manufacture(58443-0553) , pack(58443-0553) , label(58443-0553) , analysis(58443-0553) |

Revised: 5/2022

Prime Enterprises