PRANAROM AROMAFORCE ALCOHOL ANTISEPTIC- alcohol liquid Veriditas Botanicals 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 Ingredient(s)

Ethyl Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Helps reduce bacteria on skin. Recommended for repeated use.

Warnings

For external use only.

Other information

- Flammable. Keep away from fire, sparks, and sources of ignition.
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

When using this product Keep out of eyes. In case of contact with eyes, fush thoroughly with water. Avoid contact with broken skin.

Stop use and ask a doctor if irritation and redness develop and persist for more than 72 hours.

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

Directions

Place enough product on hands to cover all surfaces. Rub hands together until dry. For children under 6, use adult

supervision. Not recommended for infants.

Inactive ingredients

Rosa x damascena (Rose) Flower Water,* Glycerin,* Ricinus communis (Castor) Seed Oil,* Citrus aurantium bergamia (Bergamot) Peel Oil,* Cedrus atlantica (Cedarwood) Bark Oil,* Mentha x piperita (Peppermint) Oil,* Melaleuca alternifolia (Tea Tree) Oil.* *CERTIFIED ORGANIC

Package Label - Principal Display Panel

PRANARÕM

HAND SANITIZER

Moisturizing Formula

Non-Sterile Solution

AROMAFORCE(TM)

Alcohol antiseptic 70% topical solution

xx fl. oz | xx ml

PRANAROM SCIENTIFIC AROMATHERAPY

Minneapolis, MN 55427 | pranarom.us

Certified Organic

by ECOCERT ICO.

Drug Facts

Active ingredient......Purpose

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RANARO



Non-Sterile Solution

AROMAFORCE™

Alcohol antiseptic 70% topical solution 1 fl. oz | 30 ml



Drug Facts

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RANARON



Moisturizing Formula

AROMAFORCE™

Alcohol antiseptic 70% topical solution 4 fl. oz | 120 ml

PRANA ROM SCIENTIFIC AROMATHERAPY Certified Organic by ECOCERT ICO. 021

PRANAROM AROMAFORCE ALCOHOL ANTISEPTIC

alcohol liquid

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:78596-001 |
| 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 | |
| GLYCERIN (UNII: PDC6A3C0OX) | | |
| CASTOR OIL (UNII: D5340 Y2I9 G) | | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | | |
| CEDRUS ATLANTICA BARK O IL (UNII: ZX5QRE4U60) | | |
| TEA TREE OIL (UNII: VIF565UC2G) | | |
| BERGAMOT OIL (UNII: 39W1PKE3JI) | | |
| WATER (UNII: 059QF0KO0R) | | |
| ROSA X DAMASCENA FLOWER OIL (UNII: 18920M3T13) | | |

| l | Packaging | | | |
|---|--------------------|---|-----------------------------|---------------------------|
| l | # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | 1 NDC:78596-001-01 | 30 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/12/2020 | |
| | 2 NDC:78596-001-02 | 120 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/12/2020 | |
| ı | | , J1 | | |

| Marketing Information | | | | |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part333E | 06/12/2020 | | |
| | | | | |

Labeler - Veriditas Botanicals LLC (174766845)

Registrant - Veriditas Botanicals LLC (174766845)

| Establishment | | | |
|-----------------------------|---------|-----------|---|
| Name | Address | ID/FEI | Business Operations |
| Veriditas Botanicals LLC | | 174766845 | manufacture(78596-001), analysis(78596-001), label(78596-001), pack(78596-001), relabel(78596-001), repack(78596-001) |

Revised: 6/2020 Veriditas Botanicals LLC