## FRESHWORKS ANTISEPTIC HAND SANITIZER UNSCENTED- alcohol gel Envelope Group, 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.

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#### Freshworks Antiseptic Hand Sanitizer Unscented

#### **Drug Facts**

#### Active ingredient

Ethyl alcohol 65% v/v

#### **Purpose**

Antiseptic

#### Uses

- hand sanitizer to decrease bacteria on the skin
- recommended for repeated use
- for use when soap and water are not available

#### Warnings

#### Flammable, keep away from fire/flame For external use only

#### Do not use

- in children less than 2 months of age
- on open skin wounds

#### When using this product

do not get into eyes. In case of contact, rinse eyes thoroughly with water

#### Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours

#### Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

#### Directions

- wet hands thoroughly with product and allow to dry without wiping
- 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**

0,30% Carbomer 940 0.50% Aloe Vera Juice 0,50% Glycerine 0,20% Fragrance 0,03% Vitamin E 0,3 % TEA

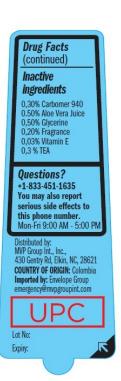
#### Questions?

+1-833-451-1635 You may also report serious side effects to this phone number. Mon-Fri 9:00 AM - 5:00 PM

#### Package Labeling:50ml

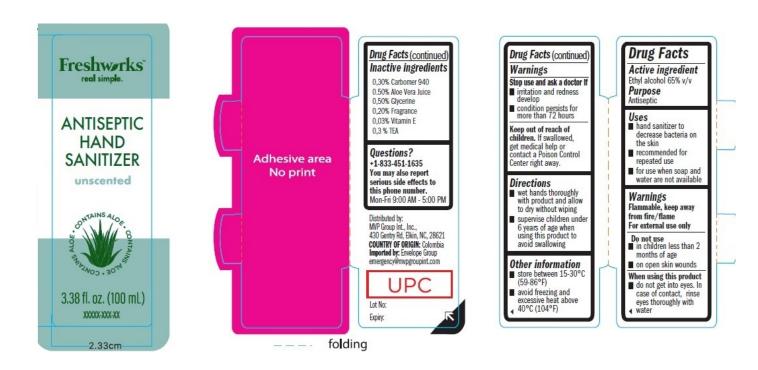








Package Labeling:100ml



#### Package Labeling:250ml



# FRESHWORKS ANTISEPTIC HAND SANITIZER UNSCENTED alcohol gel Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:80890-000 Route of Administration TOPICAL

| Active Ingredient/Active Moiety                                  |                   |                 |  |
|--|-------------------|-----------------|--|
| Ingredient Name  | Basis of Strength | Strength        |  |
| <b>ALCOHOL</b> (UNII: 3K9958 V90M) (ALCOHOL - UNII: 3K9958 V90M) | ALCOHOL           | 0.65 mL in 1 mL |  |

| Inactive Ingredients   |          |  |  |  |
|--|----------|--|--|--|
| Ingredient Name  | Strength |  |  |  |
| CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E) |          |  |  |  |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)  |          |  |  |  |
| GLYCERIN (UNII: PDC6A3C0OX)  |          |  |  |  |
| .ALPHATOCOPHEROL (UNII: H4N855PNZ1)  |          |  |  |  |
| TEA LEAF (UNII: GH42T47V24)  |          |  |  |  |

| I | Packaging        |   |                             |                    |  |  |
|---|------------------|---|-----------------------------|--------------------|--|--|
| # | Item Code        | Package Description                                   | <b>Marketing Start Date</b> | Marketing End Date |  |  |
| 1 | NDC:80890-000-01 | 50 mL in 1 BOTTLE; Type 0: Not a Combination Product  | 12/04/2020                  |                    |  |  |
| 2 | NDC:80890-000-02 | 100 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/04/2020                  |                    |  |  |
| 3 | NDC:80890-000-03 | 250 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/04/2020                  |                    |  |  |

| Marketing Information   |  |                      |                    |  |  |
|-------------------------|--|----------------------|--------------------|--|--|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |  |
| OTC monograph not final | part333E                                 | 12/04/2020           |                    |  |  |
|                         |  |                      |                    |  |  |

### Labeler - Envelope Group, LLC (833284370)

Revised: 12/2020 Envelope Group, LLC