

**HAND SANITIZER- alcohol liquid**  
**Tekna Fill, Inc.**

*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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This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

**Active Ingredient(s)**

Alcohol 80% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**Use**

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

**Warnings**

Flammable. Keep away from fire or flame. For external use only.

**Do not use**

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

**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.

**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**

- 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**

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

**Inactive ingredients**

Glycerin, hydrogen peroxide, purified water USP

**Package Label - Principal Display Panel**

18900 mL NDC: 77183-5195-0

18900mL in ONE PAIL



**SANITIZER**  
**Alcohol 80%**

*Kills 99.99% of Most Common Germs  
That May Cause Illness*

**DO NOT DRINK**  
Non-aerosol • Dye-free

|  |                              |
|--|------------------------------|
| <b>Drug Facts</b>  |                              |
| <b>Active ingredient</b><br>Alcohol 80% v/v .....  | <b>Purpose</b><br>Antiseptic |
| <b>Uses</b> • Sanitizer to help reduce bacteria on the skin that could cause disease<br>• Recommended for repeated use |                              |
| <b>Warnings</b><br><b>Flammable. Keep away from fire or flame.</b>   |                              |
| <b>For external use only</b>   |                              |
| <b>When using this product</b> do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.   |                              |
| <b>Stop use and ask a doctor if</b> irritation or rash appears and lasts   |                              |
| <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.    |                              |

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| <b>Drug Facts (cont.)</b>  |
| <b>Directions</b> • Place enough product in your palm to thoroughly cover your hands<br>• Rub hands together briskly until dry<br>• Children under 6 years of age should be supervised when using this product |
| <b>Other information</b><br>• Store below 110°F (43°C)<br>• May discolor certain fabrics or surfaces   |
| <b>Inactive ingredients</b><br>Glycerin, hydrogen peroxide, purified water USP   |
| <b>MADE IN THE USA</b><br>Distributed by MICROBE BUSTERS<br>Miami, FL  |

|                                |                |                           |                               |
|--------------------------------|----------------|---------------------------|-------------------------------|
| <b>HAND SANITIZER</b>          |                |                           |                               |
| alcohol liquid                 |                |                           |                               |
| <b>Product Information</b>     |                |                           |                               |
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:77183-5195(NDC:74120-519) |
| <b>Route of Administration</b> | TOPICAL        |                           |                               |

**Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength | Strength        |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL           | 80 mL in 100 mL |

**Inactive Ingredients**

| Ingredient Name                      | Strength |
|--------------------------------------|----------|
| GLYCERIN (UNII: PDC6A3C0OX)          |          |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) |          |
| WATER (UNII: 059QF0K00R)             |          |

**Packaging**

| # | Item Code        | Package Description                                   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:77183-5195-1 | 18900 mL in 1 PAIL; Type 0: Not a Combination Product | 06/29/2020           |                    |

**Marketing Information**

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A                                 | 06/29/2020           |                    |

**Labeler** - Tekna Fill, Inc. (081509076)**Establishment**

| Name             | Address | ID/FEI    | Business Operations |
|------------------|---------|-----------|---------------------|
| Tekna Fill, Inc. |         | 081509076 | repack(77183-5195)  |

Revised: 6/2020

Tekna Fill, Inc.