

# KLEAN GENIX ALCOHOL WIPES- alcohol cloth

## Custom Chemical Services, 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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### Active Ingredients

Alcohol 75% v/v

### Purpose

Antimicrobial

**Uses** Hand sanitizer to help reduce bacteria on the skin.

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

**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.

**Other Information** Store under 105°F.

**Directions:** Wet hands thoroughly with product and allow to dry.

**Inactive Ingredients** Purified water, Glycerin USP



#### Drug Facts

##### Active ingredient(s)

Alcohol 75% v/v ..... Antimicrobial

**Uses:** Hand sanitizer to help reduce bacteria on the skin.

**Warnings: For external use only. Flammable. Keep away from heat or flame.**

**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.

**Other Information:** Store under 105° F.

**Directions:** Wet hands thoroughly with product and allow to dry.

**Inactive Ingredients:** Purified Water, Glycerin USP

PACKAGED & DISTRIBUTED BY  
Custom Chemical Services, LLC  
8230 FM 2004 • Hitchcock, TX 77563  
(409) 925-7818

**KLEAN GENIX ALCOHOL WIPES**  
alcohol cloth

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:78174-047 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

## Active Ingredient/Active Moiety

| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b>    |
|---|--------------------------|--------------------|
| <b>ALCOHOL</b> (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL                  | 70.0984 L in 100 L |

## Inactive Ingredients

| <b>Ingredient Name</b>             | <b>Strength</b>    |
|------------------------------------|--------------------|
| <b>GLYCERIN</b> (UNII: PDC6A3C00X) | 0.0678 L in 100 L  |
| <b>water</b> (UNII: 059QF0KO0R)    | 29.8338 L in 100 L |

## Packaging

| <b>#</b> | <b>Item Code</b> | <b>Package Description</b>                                  | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|----------|------------------|---|-----------------------------|---------------------------|
| 1        | NDC:78174-047-08 | 1.109007 L in 1 CANISTER; Type 0: Not a Combination Product | 04/05/2021                  |                           |
| 2        | NDC:78174-047-09 | 1.55261 L in 1 CANISTER; Type 0: Not a Combination Product  | 04/05/2021                  |                           |

## Marketing Information

| <b>Marketing Category</b> | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph not final   | part333A  | 04/05/2021                  |                           |

**Labeler** - Custom Chemical Services, LLC (078305908)

## Establishment

| <b>Name</b>                   | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
|-------------------------------|----------------|---------------|----------------------------|
| Custom Chemical Services, LLC |                | 078305908     | manufacture(78174-047)     |

Revised: 4/2021

Custom Chemical Services, LLC