## HAND SANITIZER- alcohol liquid CALI CHEM 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

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

### Warnings

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

#### Do not use

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

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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

#### **Directions**

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

#### Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

## **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

## Package Label - Principal Display Panel

3785 mL NDC: 74722-001-00



SOLUTIONS

# HAND SANITIZER SOLUTION

ALCOHOL ANTISEPTIC 80%
TOPICAL SOLUTION



ANTISEPTIC HAND RUB NON-STERILE SOLUTION

#### HAND SANITIZER SOLUTION

| Drug Facta   |   |
|--|---|
| Active ingredient[s]<br>Alcohol 80% v/v  | Purpose Antiseptic                      |
| <b>Use[s]</b><br>Hand Sanifizer to help reduce bacteris<br>For use when soap and water are not     |   |
| Warnings<br>For external use only. Flammable. Ke   | ep away from heat or flame.             |
| Do not use In children less than 2 months of age on open skin wounds                               |   |
| When using this product keep out of<br>contact with eyes, rinse eyes thorough                      |   |
| Stop use and sak a doctor if initiation<br>a serious condition.                                    | n or rash occurs. These may be signs of |
| Keep out of reach of children. If awa<br>Poison Control Center right away.                         | illowed, get medical help or contact a  |
| Directions Place enough product on hands to curtil dry. Supervise children under 6 years of        | · · · · · · · · · · · · · · · · · · ·   |
| swallowing.  Other Information  • Store between 15-30C (59-86F)                                    |   |
| Avoid freezing and excessive heat a<br>inactive ingredients: Giveenin, Hydrogen Peroxide, Purified | *************************************   |



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14271 CORPORATE DRIVE SUITE B. GARDEN GROVE, CA 82843.
TEL: (714) 265-3740 | BEBEAUTYPRODUCTS.COM
DUNS: 000021140 | NDC 74722-001-00

128 FL. OZ. @ 3785.41 ML

946 mL NDC: 74722-001-01



SOLUTIONS

# HAND SANITIZER SOLUTION

ALCOHOL ANTISEPTIC 80%
TOPICAL SOLUTION



ANTISEPTIC HAND RUB NON-STERILE SOLUTION



| Drug Facts  |  |
|---|--|
| Active ingredient[s]<br>Alcohol 80% v/v   | Purpose<br>Anisegic  |
| <b>Use(s)</b><br>Hand Sanitizer to help reduce bach<br>For use when soap and water are r      | eria that potentially can cause disease.   |
| Warnings<br>For external use only, Flammable, Ke  | ep away from heat or flame.  |
| Do not use • In children less then 2 months of ag • on open sidn wounds                       | 9.   |
| When using this product keep ou contact with eyes, rinse eyes thorough                        | t of eyes, ears, and mouth. In case of<br>ughly with water.  |
| Stop use and ask a doctor if irritate a serious condition.                                    | tion or rash occurs. These may be signs of   |
| Keep out of reach of children. If a<br>Poison Control Center right away.                      | swallowed, get medical help or contact a   |
|   | over all surfaces. Flub hands together until dry.<br>age when using this product to avoid swellowing |
| Other Information<br>, Store between 15-30C (59-88F)<br>, Avoid freezing and excessive heat i | above 40C (104F)   |
|   | (5 4.6%)   |



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DUNS: 606021140 | NDC 74722-001-01



32 FL. OZ. e 946 ML

236 mL NDC: 74722-001-02



SOLUTIONS

# HAND SANITIZER SOLUTION

ALCOHOL ANTISEPTIC 80%
TOPICAL SOLUTION



ANTISEPTIC HAND RUB NON-STERILE SOLUTION

## HAND SANITIZER SOLUTION

| Active ingredient(s)<br>Access 67% yly  | Purpose Artisepte  |
|---|--|
| Vien <b>jaj</b><br>Hend Senflizer to help reduce be<br>For une when accep and water are   | ciede that potentially one cause decase.<br>and available.                             |
| Warnings<br>For external use only. Flammable  | . Keep every too heat or terms.  |
| Do not use<br>• In children less than 2 moulier o<br>• on open sich weemde                | l age.   |
| When using this product law a<br>contact with eyes, time eyes the                         | at of eyes, was, and mouth. In case of<br>outsity with water.                          |
| Stop use and ask a steator if int<br>a serious condition.                                 | action or main occurs. These may be signs of   |
| Keep wat of reach of eldidren. I<br>Poison Control Center right assay                     | recellored, gel medice help or corriact a  |
| unil dry.   | to cover all surlame. Rub hands together<br>as of age when using this product to could |
| Other information<br>- Store between 15-300 (59-65P)<br>- Arold fracting and assessive to |  |
| Inactive ingrediente:<br>Biyoerin, Hydrogen Perceleia, Pur                                | filed Water USP  |



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DURS: 60621140 | NDC 74724-001-01



8 FL, OZ, @ 236 ML

### HAND SANITIZER

alcohol liquid

**Product Information** 

|   | Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:74722-001 |
|---|-------------------------|----------------|--------------------|---------------|
| ı | Route of Administration | TOPICAL        |                    |               |

| Active Ingredient/Active Moiety                               |                   |                 |
|---|-------------------|-----------------|
| Ingredient Name   | Basis of Strength | Strength        |
| <b>ALCOHOL</b> (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL           | 80 mL in 100 mL |

| Inactive Ingredients                   |                    |  |  |  |
|--|--------------------|--|--|--|
| Ingredient Name                        | Strength           |  |  |  |
| GLYCERIN (UNII: PDC6A3C0OX)            | 1.45 mL in 100 mL  |  |  |  |
| HYDRO GEN PERO XIDE (UNII: BBX060AN9V) | 0.125 mL in 100 mL |  |  |  |
| WATER (UNII: 059QF0KO0R)               |                    |  |  |  |

|   | Packaging        |  |                             |                    |  |
|---|------------------|--|-----------------------------|--------------------|--|
| 7 | # Item Code      | Package Description                                    | <b>Marketing Start Date</b> | Marketing End Date |  |
|   | NDC:74722-001-00 | 3785 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/2020                  |                    |  |
| : | NDC:74722-001-02 | 237 mL in 1 BOTTLE; Type 0: Not a Combination Product  | 03/30/2020                  |                    |  |
| : | NDC:74722-001-01 | 947 mL in 1 BOTTLE; Type 0: Not a Combination Product  | 03/30/2020                  |                    |  |

| Marketing Information   |  |                      |                    |
|-------------------------|--|----------------------|--------------------|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part333A                                 | 03/30/2020           |                    |
|                         |  |                      |                    |

## Labeler - CALICHEM INC (606021140)

## Registrant - CALICHEM INC (606021140)

| Establishment |         |           |                         |
|---------------|---------|-----------|-------------------------|
| Name          | Address | ID/FEI    | Business Operations     |
| CALI CHEM INC |         | 606021140 | manufacture (74722-001) |

Revised: 4/2020 CALI CHEM INC