

## **HAND SANITIZER- alcohol liquid**

**Naturelab, S. de R.L. de C.V.**

*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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away.

**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**

500 mL NDC: 77877-001-01



$\text{CH}_3 \text{CH}_2 \text{OH}^{\text{®}}$

*Hand Spray Sanitizer, Non-sterile  
Solution*

**ALCOHOL ANTISEPTIC 80%**  
**TOPICAL SOLUTION**  
**GLOBAL TECHNOLOGY<sup>®</sup>**

**16.9 FL OZ**  
**(500 ML)** | **+ Glycerin**  
**Hand Rub**



**PANTONE Process Cyan C**

## Drug Facts

### Active Ingredient [s]

Ethyl alcohol 80% v/v . . . . . Antiseptic

### Purpose

### Use [s]

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

### Warnings

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### Other information

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

**Inactive ingredients:** Purified Water USP, Glycerin, Hydrogen Peroxyde.

MANUFACTURED BY NATURELAB S. DE R.L. DE C.V.  
CERRO DEL AIRE #46 COL. ROMERO DE TERREROS,  
ALCALDÍA COYOACÁN C.P. 04310 CDMX. MADE IN MEXICO

[www.defend-x1.com](http://www.defend-x1.com)



7 503018 047980




**PANTONE Process Cyan C**



250 mL NDC: 77877-001-02


10 mL NDC: 77877-001-03



**CH<sub>3</sub> CH<sub>2</sub> OH<sup>®</sup>**

*Hand Spray Sanitizer, Non-sterile Solution*

ALCOHOL ANTISEPTIC **80%** 0.3 FL OZ (10 ML)



7 503018 047980

## **Drug Facts**

| <b>Active Ingredient [s]</b>    | <b>Purpose</b> |
|---------------------------------|----------------|
| Ethyl alcohol 80% v/v . . . . . | Antiseptic     |

### **Use [s]**

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

### **Warnings**

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#### **Do not use**

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## **Drug Facts** (continued)

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### **Directions**

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### **Other information**

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■ Avoid freezing and excessive heat above 40°C  
(104 °F)

***Inactive ingredients:*** Purified Water USP,  
Glycerin, Hydrogen Peroxyde.

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ROMERO DE TERREROS, ALCALDÍA COYOACÁN C.P. 04310 CDMX. MADE IN MEXICO

[www.defend-x1.com](http://www.defend-x1.com)

3785 mL NDC: 77877-001-04



$\text{CH}_3 \text{CH}_2 \text{OH}^{\text{®}}$

*Hand Spray Sanitizer, Non-sterile  
Solution*

**ALCOHOL ANTISEPTIC 80%**  
**TOPICAL SOLUTION**  
**GLOBAL TECHNOLOGY<sup>®</sup>**

**1 GAL**  
**(3.79 L)** | **+ Glycerin**  
**Hand Rub**



**PANTONE Process Cyan C**



## Drug Facts

### Active Ingredient [s]

### Purpose

Ethyl alcohol 80% v/v .....Antiseptic

### Use [s]

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

### Warnings

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**Inactive ingredients:** Purified Water USP,  
Glycerin, Hydrogen Peroxyde.

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ALCALDÍA COYOACÁN C.P. 04310 CDMX. MADE IN MEXICO

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7 503018 047980



**PANTONE Process Cyan C**

1000 mL NDC: 77877-001-05



CH<sub>3</sub> CH<sub>2</sub> OH<sup>®</sup>

Hand Spray Sanitizer, Non-sterile  
Solution

ALCOHOL ANTISEPTIC 80%  
TOPICAL SOLUTION  
GLOBAL TECHNOLOGY\*

33.8 FL OZ  
(1 QT 1 FL OZ)  
(1 L) + Glycerin  
Hand Rub



### Drug Facts

**Active Ingredient [s]** Ethyl alcohol 80% v/v  
**Purpose** Antiseptic

**Use [s]**  
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.

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**Inactive ingredients:** Purified Water USP, Glycerin, Hydrogen Peroxide.

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CARRILLO DELARRE 144 COL. ROMERO DETERMINOS,  
ALCALÁ DE COTACÁN C.A. 84710 COAH. MADE IN MEXICO

[www.defend-x1.com](http://www.defend-x1.com)



PANTONE Process Cyan C



PANTONE Process Cyan C

## HAND SANITIZER

alcohol liquid

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:77877-001 |
| Route of Administration | 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)          | 1.45 mL in 100 mL  |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) | 0.125 mL in 100 mL |
| WATER (UNII: 059QF0K00R)             |                    |

### Packaging

| # | Item Code        | Package Description  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:77877-001-01 | 500 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 03/30/2020           |                    |

|   |                  |  |            |  |
|---|------------------|--|------------|--|
| 2 | NDC:77877-001-02 | 250 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 03/30/2020 |  |
| 3 | NDC:77877-001-03 | 10 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product  | 03/30/2020 |  |
| 4 | NDC:77877-001-04 | 3785 mL in 1 CONTAINER; Type 0: Not a Combination Product    | 03/30/2020 |  |
| 5 | NDC:77877-001-05 | 1000 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** - Naturelab, S. de R.L. de C.V. (951577513)

**Registrant** - Naturelab, S. de R.L. de C.V. (951577513)

## Establishment

| Name                          | Address | ID/FEI    | Business Operations   |
|-------------------------------|---------|-----------|---|
| Naturelab, S. de R.L. de C.V. |         | 951577513 | manufacture(77877-001) , pack(77877-001) , label(77877-001) |

Revised: 5/2020

Naturelab, S. de R.L. de C.V.