

HAND SANITIZER- alcohol gel

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.

Active Ingredient(s)

Alcohol 75% 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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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

Water (Aqua), Glycerin, Aloe Barbadensis Leaf Juice, Carbomer, Imidazolidinyl Urea, Triethanolamine.

Package Label - Principal Display Panel

500 mL NDC: 77877-002-01



CH₃ CH₂ OH[®]

*Hand Sanitizer**

ALCOHOL ANTISEPTIC 75%

WITH ALOE VERA

TOPICAL SOLUTION

GLOBAL TECHNOLOGY[®]

16.9 FL OZ
(500 ML)

+ Glycerin
Hand Rub



PANTONE Process Cyan C

Drug Facts

Active Ingredient [s]

Purpose

Ethyl alcohol 75% v/v Antiseptic

Use [s]

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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



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PANTONE Process Cyan C



CH₃ CH₂ OH[®]

*Hand Sanitizer**

ALCOHOL ANTISEPTIC 75%
WITH ALOE VERA
TOPICAL SOLUTION
GLOBAL TECHNOLOGY[®]

8.5 FL OZ | **+ Glycerin**
(250 ML) | **Hand Rub**



PANTONE Process Cyan C

Drug Facts

Active Ingredient [s]	Purpose
Ethyl alcohol 75% v/v	Antiseptic

Use [s]
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Warnings
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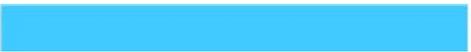
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PANTONE Process Cyan C

10 mL NDC: 77877-002-03





CH₃ CH₂ OH[®]

Hand Sanitizer, Topical Solution

ALCOHOL ANTISEPTIC 75% 34 FL OZ (10 ml)

Drug Facts

<i>Active Ingredient [s]</i>	<i>Purpose</i>
Ethyl alcohol 75% 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.

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Inactive ingredients: Water (Aqua), Glycerin, Aloe Barbadensis Leaf Juice, Carbomer, Imidazolidinyl Urea, Triethanolamine.

Warnings

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

Do not use

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CH₃ CH₂ OH[®]

*Hand Sanitizer**

ALCOHOL ANTISEPTIC 75%
WITH ALOE VERA
TOPICAL SOLUTION
GLOBAL TECHNOLOGY[®]

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



PANTONE Process Cyan C

Drug Facts

Active Ingredient [s]	Purpose
Ethyl alcohol 75% v/v	Antiseptic

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PANTONE Process Cyan C



CH₃ CH₂ OH[®]

*Hand Sanitizer**

ALCOHOL ANTISEPTIC 75%
WITH ALOE VERA
TOPICAL SOLUTION
GLOBAL TECHNOLOGY[®]

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



 **PANTONE Process Cyan C**

Drug Facts

Active Ingredient [s]

Purpose

Ethyl alcohol 75% v/vAntiseptic

Use [s]

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PANTONE Process Cyan C

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77877-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 940 (UNII: 4Q93RCW27E)	0.5 g in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.8 mL in 100 mL
TRIETHANOLAMINE HYDRIODIDE (UNII: DT98IT03JK)	0.3 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL
WATER (UNII: 059QF0K00R)	
N-(3,4-BIS(HYDROXYMETHYL)-2,5-DIOXO-4-IMIDAZOLIDINYL)-N,N'-BIS(HYDROXYMETHYL)UREA (UNII: 483JN0JNJA)	0.6 g in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77877-002-01	500 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77877-002-02	250 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
3	NDC:77877-002-03	10 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
4	NDC:77877-002-04	3785 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
5	NDC:77877-002-05	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
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Naturelab, S. de R.L. de C.V.	951577513	manufacture(77877-002) , pack(77877-002) , label(77877-002)
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Revised: 5/2020

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