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 80% v/v. Purpose: Antiseptic

Benzalkonium chloride 0.13% w/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

Purified Water USP, Propylene Glycol, Glycerin, Chlorine Dioxide.

Package Label - Principal Display Panel



Hand Spray Sanitizer, Non-sterile Solution

ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION

GLOBAL TECHNOLOGY®

16.9 FL OZ + Glycerin (500 ML) Hand Rub





Active Ingredient [s]

Purpose

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







Hand Spray Sanitizer, Non-sterile Solution

ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION

GLOBAL TECHNOLOGY®

8.5 FL OZ + Glycerin (250 ML) Hand Rub





Active ingredient [s]

Purpose

Ethyl alcohol 80% v/v

Benzalkonium chloride 0.13%

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Drug Facts (continued)

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Hand Spray Sanitizer, Non-sterile Solution

ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION

GLOBAL TECHNOLOGY®

1 GAL + Glycerin (3.79 L) Hand Rub





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ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION

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Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77877-003	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
(BENZALKONIUM CHLORIDE	0.13 g in 100 mL	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
CHLO RINE DIO XIDE (UNII: 8061YMS4RM)	0.2 mL in 100 mL	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	7 mL in 100 mL	
GLYCERIN (UNII: PDC6A3C0OX)	0.6 mL in 100 mL	
WATER (UNII: 059QF0KO0R)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77877-003- 01	500 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77877-003- 02	250 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
3	NDC:77877-003- 03	10 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
4	NDC:77877-003- 04	3785 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
5	NDC:77877-003- 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. Revised: 5/2020