NATEZONE HAND SANITIZER- alcohol gel Guangzhou Cluster Mapping Supply Chain Co., Ltd

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.

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. ethyl Alcohol (75%, 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)

Ethyl Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic

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

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

60ml NDC:90010-901-02

Alcohol Antiseptic 75% Topical Solution





236ml NDC:90010-901-08

Drug Facts

Active ingredient[s]

Purpose

Ethyl Alcohol 75% v/v

Antiseptic

Jse[s]

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Inactive ingredients

Purified Water, Glycerin, Carbomer, Thiethanolamine, Fragrance, Tocopheryl Acetate, Aloe Barbadensis Leaf

MPG: Guangzhcu Cluster Mapping Supply Chain Cc., Ltd
No.11 of Zhengxin Kuang Read, Nanling Center, Baiyun District
Guangzheu, Guangdeng 510540
Distributed by NateZone, Inc.
3830 Hickery Hill Rd, Memphis, TN 38115
Questions? Tel: 1-901-692-3273 | Made in PR.C
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MFG.DATE: 06/05/2020 EXP.DATE: 06/04/2023



Alcohol Antiseptic 75% Topical Solution





354ml NDC:90010-901-12

Drug Facts

Active ingredient[s]

Purpose

Ethyl Alcohol 75% v/v

.. Antiseptic

Use[s]

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Warnings

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Inactive ingredients

EXP.DATE: 06/04/2023

Purified Water, Glycerin, Carbomer, Thiethanolamine, Fragrance, Tocopheryl Acetate, Aloe Barbadensis Leaf

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MFG.DATE: 06/05/2020



Alcohol Antiseptic 75% Topical Solution





Aloe Gel

12 FL OZ (354 ml)

Drug Facts

Active ingredient[s]

Purpose

Ethyl Alcohol 75% v/v

.. Antiseptic

Use[s]

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Warnings

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MPG: Guangzheu Cluster Mapping Supply Chain Cc., Ltd NO.11 of Zhengxin Kuang Read, Nanling Center, Baiyun District, Guangzheu, Guangzheu, Guangzheu, Guangzheu, Guangzheu, Sidsal Bidsal Distributed by NateZene, Inc. 3830 Hickory Hill Rd, Memphis, TN 38115 Questions? Tei: 1-901-692-3273 | Made in PR.C @2020 All rights reserved.

MFG.DATE: 06/05/2020

EXP.DATE: 06/04/2023



NATEZONE HAND SANITIZER

alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:90010-901

Route of Administration TOPICAL

Active Ingredient/Active Moiety

<u> </u>			
Ingre	dient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (AI	COHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6 A3C0 OX)	1.45 mL in 100 mL		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL		
WATER (UNII: 059QF0KO0R)			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:90010-901- 02	48000 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/07/2020	
2	NDC:90010-901- 12	13680 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/07/2020	
3	NDC:90010-901- 08	10800 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/07/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	08/07/2020		

Labeler - Guangzhou Cluster Mapping Supply Chain Co., Ltd (554544021)

Establishment				
Name	Address	ID/FEI	Business Operations	
Guangzhou Cluster Mapping Supply Chain Co., Ltd		554544021	manufacture(90010-901)	

Revised: 9/2020 Guangzhou Cluster Mapping Supply Chain Co., Ltd