HAND SANITIZER- alcohol liquid Back To Nature Exim Pvt 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. 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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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)

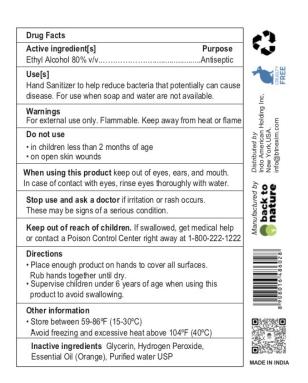
Inactive ingredients

glycerin, hydrogen peroxide, fragrance(Orange), purified water USP

Package Label - Principal Display Panel

100 mL NDC: 82068-001-01





Package Label - Principal Display Panel

200 mL NDC: 82068-001-02



HAND SANITIZER

WHO Recommended Formation



Enriched with Orange Essential Oil

80% **ALCOHOL**

KILLS 99.99% OF GERMS

6.7 FL 0Ze (200ml)

Drug Facts

Active ingredient[s]

Purpose Ethyl Alcohol 80% v/v. .Antiseptic

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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away at 1-800-222-1222

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

Inactive ingredients Glycerin, Hydrogen Peroxide, Essential Oil (Orange), Purified water USP



Distributed by Indo American H New York, USA. info@btnexim.cc







Package Label - Principal Display Panel

500 mL NDC: 82068-001-04



HAND SANITIZER

WHO Recommended Formation



KILLS 99.99% OF GERMS

80%

16.9 FL 0Ze (500ml)



Enriched with Orange Essential Oil

Drug Facts

Active ingredient[s] Ethyl Alcohol 80% v/v.





Distributed by Indo American He New York, USA. info@btnexim.co

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Warnings

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- product to avoid swallowing

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- Store between 59-86°F (15-30°C)
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Inactive ingredients Glycerin, Hydrogen Peroxide, Essential Oil (Orange), Purified water USP





HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82068-001
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			
FRAGRANCE ORANGE ORC2000765 (UNII: GX5JI7UXQ7)	0.2 mL in 100 mL			
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL			
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL			
WATER (UNII: 059QF0KO0R)				

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	ORANGE	Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82068- 001-01	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/19/2021	
2	NDC:82068- 001-02	200 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/19/2021	
3	NDC:82068- 001-04	500 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/19/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/19/2021	

Labeler - Back To Nature Exim Pvt Ltd (872093123)

Establishment				
Name	Address	ID/FEI	Business Operations	
Back To Nature Exim Pvt Ltd		872093123	manufacture(82068-001)	

Revised: 9/2021 Back To Nature Exim Pvt Ltd