

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.

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.

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



The package label features a green circular logo with the text "TRUE Hygiene" and a registered trademark symbol. To the right, the words "HAND SANITIZER" are printed in large, bold, black letters, with "WHO Recommended Formation" written below in a smaller font. An image of three orange slices is centered on the label, with the text "Enriched with Orange Essential Oil" underneath. On the left side, the text "80% ALCOHOL" is written in large purple letters, followed by "KILLS 99.99% OF GERMS" in black. At the bottom left, the volume "3.3 FL OZ e (100ml)" is displayed.

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	
Do not use <ul style="list-style-type: none">• 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 at 1-800-222-1222	
Directions <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• 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	



Vertical text and logos on the right side of the label include: a recycling symbol, the text "Distributed by Indo American Holding Inc. New York USA. info@bbmaxim.com", a "back to nature" logo with a leaf, a barcode with the number "8 908016 4486028", a QR code, and the text "MADE IN INDIA".

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 OZ e (200ml)

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	
Do not use <ul style="list-style-type: none"> • 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 at 1-800-222-1222	
Directions <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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	



back to nature
100% PLASTIC FREE

Distributed by
Indo American Holding Inc.
New York, USA.
info@bamexam.com

Manufactured by
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MADE IN INDIA

Package Label - Principal Display Panel

500 mL NDC: 82068-001-04



HAND SANITIZER

WHO Recommended Formation



Enriched with
Orange Essential Oil

80%
ALCOHOL

KILLS 99.99%
OF GERMS

16.9 FL OZ e (500ml)

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	
Do not use <ul style="list-style-type: none"> • 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 at 1-800-222-1222	
Directions <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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	



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Distributed by
Indo American Holding Inc.
New York, USA.
info@bamexam.com

Manufactured by
back to nature



MADE IN INDIA

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: GX5J17UXQ7)			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				
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)

