

HAND SANITIZER - ETHANOL- alcohol liquid

Benet Incorporated

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.

WHO Recommended Hand Sanitizer Formulation - Ethanol

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, purified water USP

Hand Sanitizer - Topical Antiseptic

Hand Sanitizer Label 1 Gallon

GoKlean
— Professional Cleaning Products™

HAND SANITIZER

1 Gallon

Ethanol 80%, Glycerol 1.45%, Hydrogen peroxide 0.125%

World Health Organization - recommended handrub formulation



For external use only.

Keep out of the reach of children.

If swallowed seek medical attention or contact poison control center.

Avoid contact with eyes.

Flammable: Keep away from flame and heat.

Use: Apply a palmful of alcohol-based handrub and cover all surfaces of the hands. Rub hands until dry.



Made in USA

GoKlean Products
www.goklean.com
386-943-4171

1220 Biscayne Blvd.,
DeLand, FL 32724

GoKlean
— Professional Cleaning Products™

HAND SANITIZER

1 Quart

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386-943-4171

1220 Biscayne Blvd.,
DeLand, FL 32724

3785 mL NDC: 76779-0001-1

Hand Sanitizer 1 Gallon.jpg

946 mL NDC: 76779-0001-2

Hand Sanitizer 1 Quart.jpg

HAND SANITIZER - ETHANOL

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76779-0001(NDC:65353-4934)
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
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL

HYDROGEN PEROXIDE (UNII: BBX060AN9V)

0.125 mL in 100 mL

WATER (UNII: 059QF0K00R)

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76779-0001-1	3785.4 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/01/2020	
2	NDC:76779-0001-2	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/01/2020	
3	NDC:76779-0001-3	473.2 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/01/2020	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Benet Incorporated (104989944)

Registrant - Benet Incorporated (104989944)

Establishment

Name	Address	ID/FEI	Business Operations
Benet Incorporated		104989944	repack(76779-0001)

Revised: 4/2020

Benet Incorporated