

HAND SANITIZER- ethyl alcohol gel
Round Bridge Inc

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.

Hand Sanitizer

Active Ingredient(s)

Ethyl Alcohol 75% 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. Keep away from heat or flame

Do not use

- in children less than 2 months of age

When using this product keep out of eyes, ears, and mouth.

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.
- Children under 6 years of age should be supervised when using this product.

Other information

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

Inactive ingredients

Aqua, Glycerin, Carbomer, Triethanolamine

Package Label - Principal Display Panel

59 ml NDC: 34839-002-01

Clean Panda 

Hand Sanitizer

Fragrance Free

Kills most common germs and bacteria while refreshing your hands

2 fl oz (59mL)

118 ml NDC: 34839-002-02

Clean Panda 

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4 fl oz (118mL)

236 ml NDC: 34839-002-03

Clean Panda 

Hand Sanitizer

Fragrance Free

Kills most common germs and bacteria while refreshing your hands

8 fl oz (236mL)

500 ml NDC: 34839-002-04

Drug Facts	Purpose
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Distributed by Round Bridge, Inc
Fountain Valley, CA 92708
Made In USA From Domestic
and Globally Sourced Ingredients



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HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:34839-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	0.25 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.25 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:34839-003-02	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2020	
2	NDC:34839-003-03	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2020	
3	NDC:34839-003-04	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2020	
4	NDC:34839-003-01	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2020	

Marketing Information

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

Labeler - Round Bridge Inc (103309063)

Registrant - Round Bridge Inc (103309063)

Establishment

Name	Address	ID/FEI	Business Operations
Round Bridge Inc		103309063	manufacture(34839-003) , label(34839-003) , pack(34839-003) , repack(34839-003)

Revised: 5/2020

Round Bridge Inc