

HAND SANITIZER- alcohol liquid
Brennan Developments 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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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, purified water USP

Package Label - Principal Display Panel

60mL NDC: 77672-001-01

Instant
**HAND
SANITIZER**
By b.d.

Kills 99.99% of most germs

**WORLD HEALTH ORGANIZATION
APPROVED FORMULATION**

80% Alcohol-Based

Fragrance Free

2.03 fl oz (60ml)
NDC xxxxxxxxx

Drug Facts	
Active Ingredients	Purpose
Ethyl alcohol 80% v/v.....	Antiseptic
Use • Hand sanitizer to destroy (harmful) bacteria on the skin.	
Warnings Flammable. Keep away from flame and heat. For external use only.	
When using this product do not use in or near the eyes. In case of contact, rinse eye thoroughly with water.	
Stop use and ask a doctor if irritation develops.	
Keep out of reach of children. Do not consume. If swallowed, get medical help or contact a Poison Control Center immediately.	
Directions • Adults and children over 2 years: For occasional and personal domestic use • Supervise children when they use this product • Rub thoroughly into hands for at least 30 seconds and allow to dry.	
Other Information • Store at room temperature (59 - 86 °F (15 30 °C)) • May discolour certain fabrics or surfaces.	
Inactive Ingredients Glycerine, Hydrogen Peroxide, Purified Water.	

Batch: 052020-001 | EXP: 06/2022

MADE IN CANADA

Distributed by: 
 Brennan Developments Ltd.
 9079 Main Street
 Florenceville Bristol, New Brunswick
 E2L 2A5



FOR POSITION ONLY
628176074122

Bottled by:
 South Ridge Packing Co. Ltd./
 Bath Springs
 9 Divide Road
 Glassville, New Brunswick E7L 0B6



4 Liter NDC: 77672-001-06

Instant HAND SANITIZER

By b.d.



Kills 99.99% of most germs

1 Gallon (4L)



**World Health
Organization**
Approved Formula

Professional
80% Alcohol-Based

Batch: 052020-001
NDC XXXXXXXXXX

Exp:
06/22



Distributed by: 
Brennan Developments Ltd.
9079 Main Street
Florenceville Bristol, New Brunswick
E2L 2A5

Bottled by:
South Ridge Packing Co. Ltd./
Bath Springs
9 Divide Road
Glassville, New Brunswick E7L 0B6

FOR POSITION ONLY
628176074146



MADE IN CANADA

Drug Facts

Active Ingredients	Purpose
Ethyl alcohol 80% v/v,.....	Antiseptic

Use • Hand sanitizer to destroy (harmful) bacteria on the skin.

Warnings
Flammable.
Keep away from flame and heat.
For external use only.

When using this product do not use in or near the eyes. In case of contact, rinse eye thoroughly with water.

Stop use and ask a doctor if irritation develops.

Keep out of reach of children. Do not consume. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions • Adults and children over 2 years: For occasional and personal domestic use • Supervise children when they use this product • Rub thoroughly into hands for at least 30 seconds and allow to dry.

Other Information • Store at room temperature (59 - 86 °F (15 - 30 °C)) • May discolour certain fabrics or surfaces.

Inactive Ingredients
Glycerine, Hydrogen Peroxide, Purified Water.

HAND SANITIZER

alcohol liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:77672-001

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		
	GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL		
	HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL		
	WATER (UNII: 059QF0KO0R)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77672-001-01	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77672-001-06	4000 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
Marketing Information				
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
	OTC monograph not final	part333A	03/30/2020	

Labeler - Brennan Developments Ltd. (203151944)

Registrant - Brennan Developments Ltd. (203151944)

Establishment

Name	Address	ID/FEI	Business Operations
South Ridge Packing Company Ltd.		204128925	manufacture(77672-001)

Revised: 5/2020

Brennan Developments Ltd.