

**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.*

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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, purified water USP

### Package Label - Principal Display Panel

240mL NDC: 77672-001-02

<b>Drug Facts</b>		<b>Drug Facts (continued)</b>	<b>Drug Facts (continued)</b>
<b>Active Ingredients</b> Ethyl alcohol 80% v/v	<b>Purpose</b> Antiseptic	Stop use and ask a doctor if irritation develops.	<b>Inactive Ingredients</b> Glycerine, Hydrogen Peroxide, Purified Water.
<b>Use</b> • Hand sanitizer to destroy (harmful) bacteria on the skin.		Keep out of reach of children. Do not consume. If swallowed, get medical help or contact a Poison Control Center immediately.	<b>Batch:</b> XXXX-XX <b>Exp:</b> 06/2022
<b>Warnings</b> Flammable. Keep away from flame and heat. For external use only.		<b>Directions</b> • 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.	<b>DISTRIBUTED BY:</b> Brennan Developments Ltd. 9079 Main Street Florenceville Bristol, New Brunswick E2L 2A5
<b>When using this product</b> do not use in or near the eyes. In case of contact, rinse eye thoroughly with water.		<b>Other Information</b> • Store at room temperature (59 - 86 °F (15-30 °C)) • May discolor certain fabrics or surfaces.	<b>BOTTLED BY:</b> South Ridge Packing Co. Ltd./ Bath Springs  MADE IN CANADA



330mL NDC: 77672-001-03

# Instant HAND SANITIZER

By b.d.

Kills 99.99% of most germs

WORLD HEALTH ORGANIZATION  
APPROVED FORMULATION



80% Alcohol-Based  
Fragrance Free

11.16 fl oz (330ml)  
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:

Canada 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



1L NDC: 77672-001-04

# Instant HAND SANITIZER

By b.d.



**Kills 99.99%**  
of most germs

33.8 fl. oz. (1L)



**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.

1L Pump NDC: 77672-001-05

# Instant HAND SANITIZER

By b.d.



**Kills 99.99%**  
of most germs

33.8 fl. oz. (1L)



**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
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**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: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77672-001-02	240 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2020	
2	NDC:77672-001-03	330 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2020	
3	NDC:77672-001-04	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2020	
4	NDC:77672-001-05	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/01/2020	

**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.