

**HAND SANITIZER- alcohol liquid**  
**South Ridge Packing Company 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.

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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**

100 mL NDC: 75789-001-04



*Bath Springs*

**Hand & Surface Sanitizer**  
*Kills Harmful Bacteria and Germs*

**80%**  
 ETHYL ALCOHOL

**3.38 fl oz (100ml)**

WORLD HEALTH ORGANIZATION  
 APPROVED FORMULATION  
 NDC 75789-001-04

PACKED FOR: SOUTH RIDGE MAPLE CO. LIMITED  
 BY: SOUTH RIDGE PACKING CO. LTD., 99 CURTIS RD., FLORENCEVILLE-  
 BRISTOL, NB E7L 2H3. Made in Canada.  
 Visit [www.bathsprings.com](http://www.bathsprings.com)



<b>Drug Facts</b>	
<i>Active ingredient</i>	<i>Purpose</i>
Ethyl alcohol 80% v/v.....	Antimicrobial
<i>Use</i> • Hand sanitizer to help reduce bacteria on the skin	
<i>Warnings</i>	
Flammable. Keep away from open flame or other sources of heat.	
For external use only	
When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.	
Stop use and ask a doctor if irritation develops.	
Keep out of reach of children. If swallowed, call a poison control center or get medical help right away.	
<i>Directions</i>	
<ul style="list-style-type: none"> <li>• Adults and children over 2 years: For occasional and personal domestic use</li> <li>• Supervise children when they use this product</li> <li>• Rub thoroughly into hands for at least 30 seconds and allow to dry.</li> </ul>	
<i>Other information</i>	
<ul style="list-style-type: none"> <li>• Store at room temperature ( 59 - 86 °F (15 - 30 °C)).</li> <li>• May discolor certain fabrics or surfaces</li> </ul>	
<i>Inactive Ingredients</i>	
• Glycerine, Hydrogen Peroxide, Purified Water.	

2.825"

3.5"

240ml NDC:75789-001-01

<b>Drug Facts</b> <b>Active ingredient</b> Ethyl alcohol 80% v/v <b>Purpose</b> Antimicrobial		<b>Drug Facts (continued)</b> Stop use and ask a doctor if irritation develops. Keep out of reach of children. If swallowed, call a poison control center or get medical help right away.	 FOR POSITION ONLY	 <b>Hand &amp; Surface Sanitizer</b> Kills Harmful Bacteria and Germs <b>80% ETHYL ALCOHOL</b> 8.1 fl oz (240ml) <small>WORLD HEALTH ORGANIZATION APPROVED FORMULATION NDC:75789-01</small>
<b>Use</b> • Hand sanitizer to help reduce bacteria on the skin <b>Warnings</b> Flammable. Keep away from open flame or other sources of heat. For external use only When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.		<b>Drug Facts (continued)</b> • May discolor certain fabrics or surfaces <b>Inactive Ingredients</b> • Glycerine, Hydrogen Peroxide, Purified Water. <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>Other information</b> • Store at room temperature (59 - 86 °F (15 - 30 °C)).		

7.75"

1.5"



1litre NDC:75789-001-01



# Hand & Surface Sanitizer

Kills Harmful Bacteria and Germs

80% ETHYL ALCOHOL

33.8 fl oz (1L)

WORLD HEALTH ORGANIZATION APPROVED FORMULATION  
NDC 75789-001-02

### Drug Facts

Active ingredient	Purpose
Ethyl alcohol 80% v/v.....	Antimicrobial

**Use** • Hand sanitizer to help reduce bacteria on the skin

### Warnings

**Flammable. Keep away from open flame or other sources of heat.**

**For external use only**

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

**Stop use and ask a doctor if** irritation develops.

**Keep out of reach of children.** If swallowed, call a poison control center or get medical help right away.

**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.

### Drug Facts (continued)

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

**Inactive Ingredients** • Glycerine, Hydrogen Peroxide, Purified Water.

**PACKED FOR:** SOUTH RIDGE MAPLE CO. LIMITED  
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Made in Canada.

Visit [www.bathsprings.com](http://www.bathsprings.com)



FOR POSITION ONLY



3.5"

3.5"



CYAN



MAGENTA



YELLOW



BLACK

4litre NDC: 75789-001-03



# Hand & Surface Sanitizer

Kills Harmful Bacteria and Germs

80% ETHYL ALCOHOL

WORLD HEALTH ORGANIZATION APPROVED FORMULATION

NDC 75789-001-03

135.2 fl oz (4L)

### Drug Facts

**Active ingredient** Ethyl alcohol 80% v/v.....**Purpose** Antimicrobial

**Use** • Hand sanitizer to help reduce bacteria on the skin

### Warnings

**Flammable. Keep away from open flame or other sources of heat.**

**For external use only**

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

**Stop use and ask a doctor if** irritation develops.

**Keep out of reach of children.** If swallowed, call a poison control center or get medical help right away.

**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.

### Drug Facts (continued)

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

**Inactive Ingredients** • Glycerine, Hydrogen Peroxide, Purified Water.

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FOR POSITION ONLY



5"

5"



CYAN



MAGENTA



YELLOW



BLACK

## HAND SANITIZER

alcohol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75789-001
<b>Route of Administration</b>	TOPICAL		

<b>Active Ingredient/Active Moiety</b>				
		<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
		ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL
<b>Inactive Ingredients</b>				
		<b>Ingredient Name</b>	<b>Strength</b>	
		GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL	
		HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL	
		WATER (UNII: 059QF0K00R)		
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75789-001-01	240 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/20/2020	
2	NDC:75789-001-02	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/21/2020	
3	NDC:75789-001-03	4000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/21/2020	
4	NDC:75789-001-04	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/21/2020	
<b>Marketing Information</b>				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	03/03/2020	

**Labeler** - South Ridge Packing Company Ltd. (204128925)

**Registrant** - South Ridge Packing Company Ltd. (204128925)

### Establishment

Name	Address	ID/FEI	Business Operations
South Ridge Packing Company Ltd.		204128925	manufacture(75789-001)

Revised: 4/2020

South Ridge Packing Company Ltd.