

## **SERV CLEAN FOAMING HAND SANITIZER- alcohol solution** **Charlotte Products 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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### **ServClean Foaming Hand Sanitizer**

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) (75%, 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 (0.12% v/v).
- d. DI water
- e. Bis-PEG-12 dimethicone

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 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. 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, purified water USP

### **Package Label - Principal Display Panel**

575ml NDC 64646-082-12

19382-12

USA-NDC

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

**Inactive ingredients**  
water USP, bis-PEG-12 dimethicone, glycerin, hydrogen peroxide

**HOW TO APPLY**





## FOAMING HAND SANITIZER

ALCOHOL ANTISEPTIC 75%  
TOPICAL  
HAND SANITIZER  
NON-STERILE SOLUTION  
NDC 64646-082-12

Net Contents / Contenu Net:  
19.44 fl oz

**Drug Facts**

Active ingredient	Purpose
Alcohol 75% v/v.....	Antiseptic

**Use[s]**  
Antiseptic, Hand Sanitizer  
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

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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.

Manufactured by:  
Charlotte Products Ltd.  
2060 Fisher Drive, Peterborough  
Ontario, K9J 6X6 Canada  
1-877-745-2880  
www.charlotteproducts.com

**882815038214**

R457 Die - 3.5" x 9.25" - Rewind #4

PSL 1808A

1250 ml NDC 64646-082-04

19382-6

USA



**ServClean**

**FOAMING HAND SANITIZER**

ALCOHOL ANTISEPTIC 75%  
TOPICAL  
HAND SANITIZER  
NON-STERILE SOLUTION

NDC 64646-082-04

882815038207

Manufactured by:  
Charlotte Products Ltd.  
2060 Fisher Drive, Peterborough  
Ontario, K9J 6X6 Canada  
1-877-745-2880  
www.charlotteproducts.com

Net Contents:  
1250 mL (42 fl oz)

PSL1788B

FEEL HERE

**Drug Facts**

Active ingredient	Purpose
Alcohol 75% v/v.....	Antiseptic

**Use[s]**  
Antiseptic, Hand Sanitizer  
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

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Supervise children under 6 years of age when using this product to avoid swallowing.

**Other information**

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

**Inactive ingredients**  
water USP, bis-PEG-12 dimethicone, glycerin

**HOW TO APPLY**



GLUE AREA - NO INK

R368B Perflex Die - 5" x 2.5" - Rewind #3

PSL 1788B

## SERV CLEAN FOAMING HAND SANITIZER

alcohol solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:64646-082	
<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	75 mL in 100 mL	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
GLYCERIN (UNII: PDC6A3C0OX)			1.45 mL in 100 mL	
WATER (UNII: 059QF0KOOR)			20.55 mL in 100 mL	
BIS-PEG-12 DIMETHICONE (500 MPA.S) (UNII: 2CNS542YRT)			3 mL in 100 mL	
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:64646-082-04	1250 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	09/10/2021	
2	NDC:64646-082-01	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/10/2021	
3	NDC:64646-082-12	575 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/09/2022	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph not final	part333A	09/01/2021		

**Labeler** - Charlotte Products Ltd. (248293359)

## Establishment

Name	Address	ID/FEI	Business Operations
Charlotte Products Ltd.		248293359	manufacture(64646-082)

Revised: 12/2022

Charlotte Products Ltd.