SERVCLEAN LIQUID HAND SANITIZER- alcohol liquid 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.

Liquid 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) (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

Liquid Hand Sanitizer 500 ML NDC 64646-329-12

Drug Facts

Active ingredient[s]

Purpose Alcohol 70% v/v.....Antiseptic

Antiseptic, Hand Sanitizer

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

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.

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Liquid Hand Sanitizer

Alcohol Antiseptic 70% Topical Solution Hand Sanitizer Non-sterile Solution

NDC 64646-329-12

Drug Facts continued...

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

glycerin, hydrogen peroxide, purified water USP



Made in Canada





500 ml (16.9 fl.oz)

Active ingredient[s]

Purpose

Alcohol 70% v/v.....Antiseptic

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

For external use only. Flammable. Keep away from heat or flame

- · 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.



Liquid Hand Sanitizer

Alcohol Antiseptic 70% **Topical Solution Hand Sanitizer** Non-sterile Solution

NDC 64646-329-04

Drug Facts continued...

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

glycerin, hydrogen peroxide, purified water USP



Made in Canada

Charlotte Products Ltd. 2060 Fisher Dr Peterborough, Ontario K9J 6X6 Tel: 1-877-745-2880





3.78 L (133.2 fl.oz)

Liquid Hand Sanitizer 100 ML NDC 64646-329-70

Drug Facts

Active ingredient[s]

Purpose

Alcohol 70% v/v.....Antiseptic

Antiseptic, Hand Sanitizer 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.



Liquid Hand Sanitizer

Alcohol Antiseptic 70% **Topical Solution Hand Sanitizer** Non-sterile Solution

NDC 64646-329-70

Drug Facts continued...

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

glycerin, hydrogen peroxide, purified water USP



Made in Canada

Charlotte Products Ltd. 2060 Fisher Dr Peterborough, Ontario K9J 6X6 Tel: 1-877-745-2880





100ml

Active ingredient[s] Alcohol 70% v/v.....Antiseptic

Purpose

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.

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.



Liquid Hand Sanitizer

Alcohol Antiseptic 70% **Topical Solution Hand Sanitizer** Non-sterile Solution

NDC 64646-329-96

Drug Facts continued...

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

glycerin, hydrogen peroxide, purified water USP





Made in Canada

Charlotte Products Ltd. 2060 Fisher Dr Peterborough, Ontario K9J 6X6 Tel: 1-877-745-2880





100ml (3.4 fl.oz)

Liquid Hand Sanitizer 60ml NDC 64646-329-60

Drug Facts

Active ingredient[s] Alcohol 70% v/v.....Antiseptic

Antiseptic, Hand Sanitizer 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.



Liquid Hand Sanitizer

Alcohol Antiseptic 70% **Topical Solution Hand Sanitizer** Non-sterile Solution

NDC 64646-329-60

Drug Facts continued...

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

glycerin, hydrogen peroxide, purified water USP



Made in Canada





60 ml (2 fl.oz)

Active ingredient[s]

Purpose

Alcohol 70% v/v.....Antiseptic

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

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.



Liquid Hand Sanitizer

Alcohol Antiseptic 70% **Topical Solution Hand Sanitizer Non-sterile Solution**

NDC 64646-329-19

Drug Facts continued...

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

glycerin, hydrogen peroxide, purified water USP



Made in Canada



(63.9 fl.oz)

Charlotte Products Ltd. 2060 Fisher Dr Peterborough, Ontario K9J 6X6 Tel: 1-877-745-2880

Liquid Hand Sanitizer 750 ml NDC 64646-329-75

Drug Facts Active ingredient[s]

Alcohol 70% v/v.....Antiseptic

Purpose

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.

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.



Liquid Hand Sanitizer

Alcohol Antiseptic 70% **Topical Solution Hand Sanitizer** Non-sterile Solution

NDC 64646-329-75

Drug Facts continued...

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

glycerin, hydrogen peroxide, purified water USP



Made in Canada

Charlotte Products Ltd. 2060 Fisher Dr Peterborough, Ontario K9J 6X6 Tel: 1-877-745-2880





750ml (63.9 fl.oz)

Liquid Hand Sanitizer 2 Litres NDC 64646-329-02

Drug Facts

Active ingredient[s] Alcohol 70% v/v.....Antiseptic

Purpose

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.

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.



Liquid Hand Sanitizer

Alcohol Antiseptic 70% Topical Solution Hand Sanitizer Non-sterile Solution

NDC 64646-329-02

Drug Facts continued...

Directions

- · Place enough product on hands to cover all surfaces. Rub hands together until drv.
- 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

glycerin, hydrogen peroxide, purified water USP



Made in Canada



(67.6 fl.oz)

Active ingredient[s] Purpose
Alcohol 70% 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.

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.



Liquid Hand Sanitizer

Alcohol Antiseptic 70%
Topical Solution
Hand Sanitizer
Non-sterile Solution

NDC 64646-329-25

Drug Facts continued...

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

glycerin, hydrogen peroxide, purified water USP



Made in Canada

Charlotte Products Ltd. 2060 Fisher Dr Peterborough, Ontario K9J 6X6 Tel: 1-877-745-2880







Liquid Hand Sanitizer 3.6 Litres NDC 64646-329-03

Active ingredient[s]

Purpose

Alcohol 70% 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.

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.



Liquid Hand Sanitizer

Alcohol Antiseptic 70%
Topical Solution
Hand Sanitizer
Non-sterile Solution

NDC 64646-329-03

Drug Facts continued...

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

glycerin, hydrogen peroxide, purified water USP



Made in Canada

Charlotte Products Ltd. 2060 Fisher Dr Peterborough, Ontario K9J 6X6 Tel: 1-877-745-2880



3.6 L

Liquid Hand Sanitizer 700 ML NDC 64646-329-07

Drug Facts

Active ingredient[s]

Purpose

Alcohol 70% v/v......Antiseptic

Useſs

Antiseptic, Hand Sanitizer
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.



Liquid Hand Sanitizer

Alcohol Antiseptic 70%
Topical Solution
Hand Sanitizer
Non-sterile Solution

NDC 64646-329-07

Drug Facts continued...

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

glycerin, hydrogen peroxide, purified water USP



Made in Canada







Active ingredient[s] Alcohol 70% v/v.....Antiseptic

Purpose

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.

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.



Liquid Hand Sanitizer

Alcohol Antiseptic 70% Topical Solution Hand Sanitizer Non-sterile Solution

NDC 64646-329-20

Drug Facts continued...

- 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

glycerin, hydrogen peroxide, purified water USP



Made in Canada

Charlotte Products Ltd. 2060 Fisher Dr Peterborough, Ontario K9J 6X6 Tel: 1-877-745-2880





Liquid Hand Sanitizer Drum 64646-329-21

Active ingredient[s]

Purpose

Alcohol 70% v/v.....Antiseptic

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

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.



Liquid Hand Sanitizer

Alcohol Antiseptic 70% Topical Solution Hand Sanitizer Non-sterile Solution

NDC 64646-329-21

Drug Facts continued...

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

glycerin, hydrogen peroxide, purified water USP



Made in Canada

Charlotte Products Ltd. 2060 Fisher Dr Peterborough, Ontario K9J 6X6 Tel: 1-877-745-2880





208 L (55 gallon)

Liquid Hand Sanitizer IBC 64646-329-22

Drug Facts

Active ingredient[s]

Purpose

Alcohol 70% 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.

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.



Liquid Hand Sanitizer

Alcohol Antiseptic 70% Topical Solution Hand Sanitizer Non-sterile Solution

NDC 64646-329-22

Drug Facts continued...

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

glycerin, hydrogen peroxide, purified water USP



Made in Canada

Charlotte Products Ltd. 2060 Fisher Dr Peterborough, Ontario K9J 6X6 Tel: 1-877-745-2880





1000 L (264.2 gallon)

SERVCLEAN LIQUID HAND SANITIZER

alcohol liquid

Product Type HUMAN OTC DRUG Item Code (Source) NDC:64646-329

Route of Administration TOPICAL

Active Ingredient/Active Moiety

ı	Ingredient Name	Basis of Strength	Strength
ı	ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII: 3K9958 V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name
Strength
GLYCERIN (UNII: PDC6A3C0OX)
1.45 mL in 100 mL
HYDROGEN PERO XIDE (UNII: BBX060AN9 V)
0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:64646- 329-70	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020			
2	NDC:64646- 329-12	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020			
3	NDC:64646- 329-04	3780 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020			
4	NDC:64646- 329-96	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020			
5	NDC:64646- 329-60	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020			
6	NDC:64646- 329-19	1890 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020			
7	NDC:64646- 329-75	750 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020			
8	NDC:64646- 329-02	2000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020			
9	NDC:64646- 329-25	225 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020			
10	NDC:64646- 329-03	3600 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020			
11	NDC:64646- 329-07	700 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020			
12	NDC:64646- 329-20	18900 mL in 1 PAIL; Type 0: Not a Combination Product	03/30/2020			
13	NDC:64646- 329-22	1000000 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020			
14	NDC:64646- 329-21	208000 mL in 1 DRUM; 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 - Charlotte Products Ltd (248293359)

Registrant - Charlotte Products Ltd (248293359)

Establishment								
Name	Address	ID/FEI	Business Operations					
Charlotte Products Ltd		248293359	manufacture(64646-329)					

Revised: 9/2020 Charlotte Products Ltd