SERVCLEAN GEL HAND SANITIZER- alcohol gel 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.

Sanitizer Gel

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 70% 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

Gel Hand Sanitizer 500ml NDC 64646-328-12

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.

Warnings

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

Do not use

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Gel Hand Sanitizer

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

NDC 64646-328-12

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, carbomer 940, hydrogen peroxide, purified water USP



Made in Canada

Charlotte Products Ltd.

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



500 ml (16.9 fl.oz)

Gel Hand Sanitizer 2 Litres NDC 64646-328-02

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.

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.



Gel Hand Sanitizer

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

NDC 64646-328-02

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, carbomer 940, hydrogen peroxide, purified water USP



Made in Canada

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





(67.6 fl.oz)

Gel Hand Sanitizer 225 ML NDC 64646-328-25

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.

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.



Gel Hand Sanitizer

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

NDC 64646-328-25

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, carbomer 940, hydrogen peroxide, purified water USP



Made in Canada

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





225ml (7.6 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.



Gel Hand Sanitizer

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

NDC 64646-328-03

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, carbomer 940, hydrogen peroxide, purified water USP



Made in Canada

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





(121.7 fl.oz)

Gel Hand Sanitizer 3.78 Litres NDC 64646-328-04

Drug Facts

Active ingredient[s]

Purpose .Antiseptic

Alcohol 70% v/v.....

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.

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Gel Hand Sanitizer

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

NDC 64646-328-04

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, carbomer 940, hydrogen peroxide, purified water USP



Made in Canada

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





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.



Gel Hand Sanitizer

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

NDC 64646-328-07

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, carbomer 940, hydrogen peroxide, purified water USP



Made in Canada

8 82815 93289 5



700ml

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

Gel Hand Sanitizer 100 ML NDC 64646-328-70

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.



Gel Hand Sanitizer

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

NDC 64646-328-70

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, carbomer 940, hydrogen peroxide, purified water USP



Made in Canada

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





100ml

Gel Hand Sanitizer 60ml NDC 64646-328-60

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.



Gel Hand Sanitizer

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

NDC 64646-328-60

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, carbomer 940, hydrogen peroxide, purified water USP



Made in Canada





60 ml

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

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

Purpose .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.

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Gel Hand Sanitizer

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

NDC 64646-328-19

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, carbomer 940, hydrogen peroxide, purified water USP



Made in Canada

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





1.89L (63.9 fl.oz)

Gel Hand Sanitizer 750 ml NDC 64646-328-75

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.



Gel Hand Sanitizer

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

NDC 64646-328-75

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, carbomer 940, hydrogen peroxide, purified water USP



Made in Canada

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





750ml (63.9 fl.oz)

Gel 18.9L pail 64646-328-20

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.

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.

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Gel Hand Sanitizer

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

NDC 64646-328-20

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, carbomer 940, hydrogen peroxide, purified water USP



Made in Canada

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





18.9 L (5 gallon)

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.

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Gel Hand Sanitizer

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

NDC 64646-328-21

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

Inactive ingredients

glycerin, carbomer 940, 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)

Gel 1000L IBC 64646-328-22

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.

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Gel Hand Sanitizer

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

NDC 64646-328-22

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, carbomer 940, hydrogen peroxide, purified water USP



Made in Canada





1000 L (264.2 gallon) Charlotte Products Ltd. 2060 Fisher Dr Peterborough, Ontario K9J 6X6 Tel: 1-877-745-2880

SERVCLEAN GEL HAND SANITIZER

alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:64646-328

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64646- 328-75	750 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2020	
2	NDC:64646- 328-12	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2020	
3	NDC:64646- 328-02	2000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2020	
4	NDC:64646- 328-25	225 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2020	
5	NDC:64646- 328-03	3600 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2020	
6	NDC:64646- 328-04	3780 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2020	
7	NDC:64646- 328-07	700 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2020	
8	NDC:64646- 328-70	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2020	
9	NDC:64646- 328-60	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2020	
10	NDC:64646- 328-19	1890 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2020	
11	NDC:64646- 328-22	1000000 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	05/01/2020	
12	NDC:64646- 328-21	208000 mL in 1 DRUM; Type 0: Not a Combination Product	05/01/2020	
13	NDC:64646- 328-20	18900 mL in 1 PAIL; 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 - Charlotte Products Ltd (248293359)

Registrant - Charlotte Products Ltd (248293359)

Establishment						
Name	Address	ID/FEI	Business Operations			
Charlotte Products		248293359	manufacture(64646-328)			

Revised: 9/2020 Charlotte Products Ltd