SERVCLEAN GEL HAND SANITIZER- alcohol gel Charlotte Products Ltd.

SC Gel 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) (71%, 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. Distilled water.
- e. 2,4-D diethylethanolamine
- f. acrylates crosspolymer

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 71% 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, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

USA Version 19380-6



GEL HAND SANITIZER

ALCOHOL ANTISEPTIC 71% **TOPICAL** HAND SANITIZER NON-STERILE GEL

NDC 64646-380-04

Net Contents: 1250 mL (42 fl oz)

Drug Facts

Active ingredient[s] Purpose Alcohol 71% 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

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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, glycerin, acrylates crosspolymer, 2,4-D diethylethanolamine, hydrogen peroxide.



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

882815038009

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

PSL 1789A

1250 mL NDC: 64646-380-04

Active ingredient[s] Purpose Alcohol 71% 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

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GEL HAND SANITIZER

ALCOHOL ANTISEPTIC 71% TOPICAL HAND SANITIZER NON-STERILE GEL

NDC 64646-380-12

Net Contents: 500 mL (16.9 fl oz)

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, glycerin, acrylates crosspolymer, 2,4-D
diethylethanolamine, hydrogen peroxide.



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500ml NDC:64646-380-12

Drug Facts

Active ingredient[s] Purpose Alcohol 71% 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 71% TOPICAL HAND SANITIZER NON-STERILE GEL

NDC 64646-380-02

Net Contents: 2 L (0.52 gallons)

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, glycerin, acrylates crosspolymer, 2,4-D diethylethanolamine, hydrogen peroxide.



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2L NDC:64646-380-02

Active ingredient[s] Purpose Alcohol 71% 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.

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GEL HAND SANITIZER

ALCOHOL ANTISEPTIC 71% TOPICAL HAND SANITIZER NON-STERILE GEL

NDC 64646-380-03

Net Contents: 3.78 L (1 gallon)

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, glycerin, acrylates crosspolymer, 2,4-D
diethylethanolamine, hydrogen peroxide.



882815038009

3.78 NDC:64646-380-03

Drug Facts

Active ingredient[s] Purpose Alcohol 71% 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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ServClean

GEL HAND SANITIZER

ALCOHOL ANTISEPTIC 71% TOPICAL HAND SANITIZER NON-STERILE GEL

NDC 64646-380-20

Net Contents: 18.9 L (5 gallons)

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, glycerin, acrylates crosspolymer, 2,4-D diethylethanolamine, hydrogen peroxide.



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18.9 L NDC:64646-380-20

Active ingredient[s] Purpose Alcohol 71% 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 71% TOPICAL HAND SANITIZER NON-STERILE GEL

NDC 64646-380-21

Net Contents: 55 L (14.5 gallon)

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, glycerin, acrylates crosspolymer, 2,4-D
diethylethanolamine, hydrogen peroxide.



882815038009

55L NDC:64646-380-21

Drug Facts

Active ingredient[s] Purpose Alcohol 71% 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

ServClean

GEL HAND SANITIZER

ALCOHOL ANTISEPTIC 71% TOPICAL HAND SANITIZER NON-STERILE GEL

NDC 64646-380-22

Net Contents:

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, glycerin, acrylates crosspolymer, 2,4-D diethylethanolamine, hydrogen peroxide.



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208 L (55 gallons)

208L NDC:64646-380-22

Drug Facts
Active ingredient[s] Purpose
Alcohol 71% 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.

ServClean

GEL HAND SANITIZER

ALCOHOL ANTISEPTIC 71% TOPICAL HAND SANITIZER NON-STERILE GEL

NDC 64646-380-23

Net Contents: 1000 L (264 gallons)

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, glycerin, acrylates crosspolymer, 2,4-D
diethylethanolamine, hydrogen peroxide.

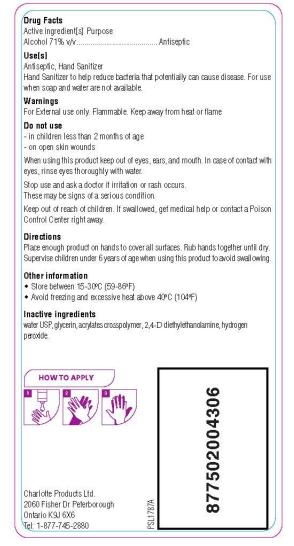


882815038009

1000L NDC:64646-380-23

ES43US-6 USA Version





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

PSL 1787A

1250 mL NDC: 64646-043-04



500 mL NDC:64646-043-12



2L NDC:64646-043-02



3.78L NDC:64646-043-03



18.9 L NDC: 64646-043-20



55 L NDC: 64646-043-21



208L NDC: 64646-043-22



1000L NDC: 64646-043-23

SERVCLEAN GEL HAND SANITIZER

alcohol gel

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:64646-380 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | |
|--|--------------------------|-----------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 71 mL in 100 mL | |

| Inactive Ingredients | | | |
|--|----------------------|--|--|
| Ingredient Name | Strength | | |
| ACRYLATES/VINYL ISODECANOATE CROSSPOLYMER (10000 MPA.S NEUTRALIZED AT 0.5%) (UNII: 2N8MDB79NA) | 0.3 mL in 100 mL | | |
| 2,4-D DIETHYLETHANOLAMINE (UNII: S07027211T) | 0.21 mL in 100 mL | | |
| GLYCERIN (UNII: PDC6A3C0OX) | 1.45 mL in 100 mL | | |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) | 0.12 mL in 100 mL | | |
| WATER (UNII: 059QF0KO0R) | | | |

| Packaging | | | |
|-------------|---------------------|-------------------------|-----------------------|
| # Item Code | Package Description | Marketing Start Date | Marketing End Date |

| 1 | NDC:64646- 380-04 | 1250 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 09/10/2021 | |
|---|----------------------|--|------------|--|
| 2 | NDC:64646- 380-12 | 500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 09/10/2021 | |
| 3 | NDC:64646- 380-02 | 2000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 09/10/2021 | |
| 4 | NDC:64646- 380-03 | 3780 mL in 1 BOTTLE; Type 0: Not a Combination Product | 09/10/2021 | |
| 5 | NDC:64646- 380-20 | 18900 mL in 1 PAIL; Type 0: Not a Combination Product | 09/10/2021 | |
| 6 | NDC:64646- 380-21 | 55000 mL in 1 DRUM; Type 0: Not a Combination Product | 09/10/2021 | |
| 7 | NDC:64646- 380-22 | 208000 mL in 1 DRUM; Type 0: Not a Combination Product | 09/10/2021 | |
| 8 | NDC:64646- 380-23 | 1000000 mL in 1 DRUM; Type 0: Not a Combination Product | 09/10/2021 | |

| Marketing Information | | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug | M016 | 09/10/2021 | |
| | | | |

Labeler - Charlotte Products Ltd. (248293359)

| Establishment | | | | |
|-------------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Charlotte Products Ltd. | | 248293359 | manufacture(64646-380) | |

Revised: 7/2024 Charlotte Products Ltd.