

SERV CLEAN SANITIZING WIPES- isopropyl alcohol cloth
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.

ServClean Sanitizing Wipes

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. Isopropyl Alcohol (75%, 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)

Isopropyl Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Personal hand sanitizing wipe to help reduce bacteria that potentially can cause disease.

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

Open the plastic tab at the front of the bottle. Pull up wipe and replace plastic cap. Always snap lid securely shut between uses to prevent moisture loss.

- Take one wipe and rub onto hands to cover all surfaces. Let hands air dry.
- NOT intended for intimate hygiene. Dispose of used wipes in trash.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Storage

Store at room temperature in a cool, dry place, avoid direct sunlight. Store below 110°F (43°C). Do not reuse empty canister.

Inactive ingredients

purified water

Package Label - Principal Display Panel

70 Count NDC: 64646-399-01

Drug Facts

Active Ingredient **Purpose**
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MADE IN CANADA

Charlotte Products Ltd.™
2060 Fisher Drive,
Peterborough, ON K9J 6X6 Canada
www.charlotteproducts.com • 1-877-745-2880

UPC CODE



70 wipes

DIE SIZE 5.875" x 8.375" - rewind #3

USA

180 Count NDC: 64646-399-02

PSL _____

19399-180

Drug Facts

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USA

SERV CLEAN SANITIZING WIPES

isopropyl alcohol cloth

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:64646-399 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302) | ISOPROPYL ALCOHOL | 70 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--------------------------|----------|
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:64646-399-01 | 343 mL in 1 CANISTER; Type 0: Not a Combination Product | 02/01/2021 | |
| 2 | NDC:64646-399-02 | 1000 mL in 1 CANISTER; Type 0: Not a Combination Product | 02/01/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 02/01/2021 | |

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

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|------------------------|
| Charlotte Products Ltd | | 248293359 | manufacture(64646-399) |

Revised: 2/2021

Charlotte Products Ltd.