

**ENVIROSOLUTIONS 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.*

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**ENVIROSolutions ES40 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.

**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.

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### **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: 64646-400-01

**Drug Facts**

**Active Ingredient**                      **Purpose**  
Isopropyl alcohol 70% v/v.....Antiseptic

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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

NDC 64646-400-01

UPC CODE



70 wipes

**DIE SIZE 5.875" x 8.375"- rewind #3**

**USA**

180 Count NDC: 64646-400-02

PSL \_\_\_\_\_

ES40-180

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**Sanitizing Wipes**

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**USA**

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isopropyl alcohol cloth

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:64646-400
<b>Route of Administration</b>	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:64646-400-01	343 mL in 1 CANISTER; Type 0: Not a Combination Product	02/01/2021	
2	NDC:64646-400-02	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(64646-400)

Revised: 2/2021

Charlotte Products Ltd.