

**HAND SANITIZER- isopropyl alcohol solution, gel forming / drops**  
**C&C SECURITY INC**

*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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**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. 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 75% 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**

30 ml NDC: 77746-002-01



**Drug Facts**

**Active Ingredient(s)**

Isopropyl alcohol 75%..... Antiseptic

**Use**

Hand Sanitizer to help reduce bacteria that potentially can cause disease.

**Warning**

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

**Package Label - Principal Display Panel**

60 mL label 77746-002-02



<b>Drug Facts</b>	
<b>Active Ingredient(s)</b>	<b>Purpose</b>
Isopropyl alcohol 75%.....	Antiseptic
<b>Use</b>	
Hand Sanitizer to help reduce bacteria that potentially can cause disease.	
<b>Warning</b>	
For external use only. Flammable. Keep away from heat or flame	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>• in children less than 2 months of age</li> <li>• on open skin wounds</li> </ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	

**Package Label - Principal Display Panel**

100 mL lable 77746-002-03

ZELOP

# ANTISEPTIC HAND RUB

Isopropyl Alcohol Antiseptic 75%

Non-sterile Solution  
Topical Solution



100mL (3.3Oz)

## Drug Facts

Active Ingredient(s)	Purpose
Isopropyl alcohol 75%.....	Antiseptic

## Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease.

## Warning

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

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

## 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

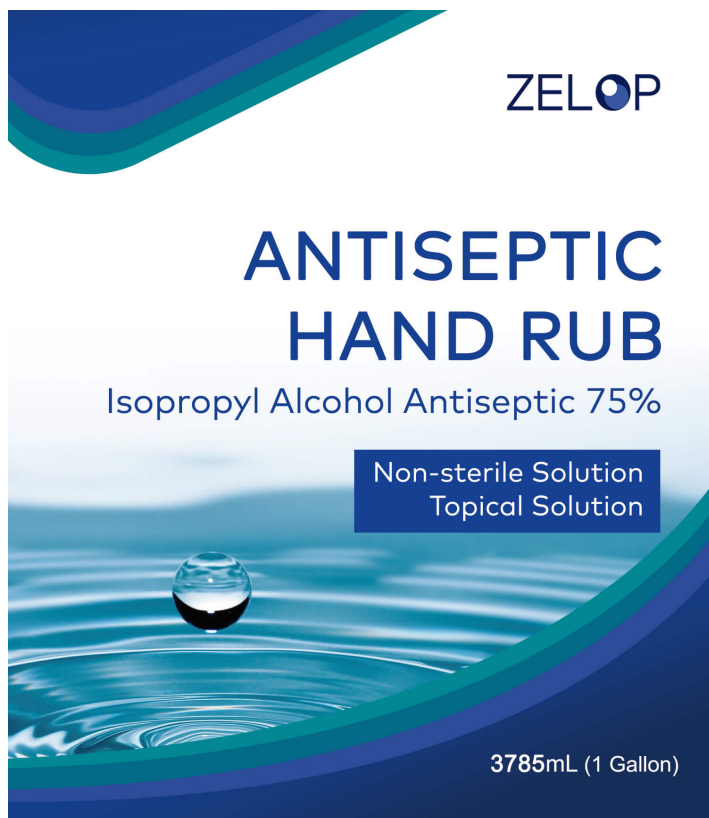
250 mL label 77746-002-04



<b>Drug Facts</b>	
<b>Active Ingredient(s)</b> Isopropyl alcohol 75% v/v.....	<b>Purpose</b> Antiseptic
<b>Use</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease.	
<b>Warning</b> For external use only. Flammable. Keep away from heat or flame	
<b>Do not use</b> <ul style="list-style-type: none"> <li>in children less than 2 months of age</li> <li>on open skin wounds</li> </ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> <ul style="list-style-type: none"> <li>Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
<b>Other information</b> <ul style="list-style-type: none"> <li>Store between 15-30C (59-86F)</li> <li>Avoid freezing and excessive heat above 40C (104F)</li> </ul>	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	

**Package Label - Principal Display Panel**

3785 mL label 77746-002-05



<b>Drug Facts</b>	<b>Datos Farmacologicos</b>
<b>Active Ingredient(s)</b> Isopropyl alcohol 75% v/v.....	<b>Purpose</b> Antiseptic
<b>Use</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease.	<b>Propósito</b> Alcohol isopropilico 75% v/v..... Antiséptico
<b>Warning</b> For external use only. Flammable. Keep away from heat or flame	<b>Uso(s)</b> Desinfectante de manos para ayudar a reducir las bacterias que pueden causar enfermedades potencialmente.
<b>Do not use</b> <ul style="list-style-type: none"> <li>in children less than 2 months of age</li> <li>on open skin wounds</li> </ul>	<b>Advertencias</b> Solo para uso externo
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	<b>No se utilice:</b> <ul style="list-style-type: none"> <li>niños menos de 2 meses de edad</li> <li>en heridas abiertas en la piel</li> </ul>
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	<b>Quando use este producto,</b> manténgalo lejos de ojos, oídos y boca, en caso de contacto con los ojos enjuague completamente con agua abundante.
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	<b>Suspenda su uso y consulte a su médico</b> si se produce irritación o sarpullido, estos pueden ser signos de una afección grave.
<b>Directions</b> <ul style="list-style-type: none"> <li>Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	<b>Manténgase fuera del alcance de los niños.</b> en caso de ingestión obtenga ayuda médica o póngase en contacto con un centro de control de envenenamiento.
<b>Other information</b> <ul style="list-style-type: none"> <li>Store between 15-30C (59-86F)</li> <li>Avoid freezing and excessive heat above 40C (104F)</li> </ul>	<b>Instrucciones</b> <ul style="list-style-type: none"> <li>Coloque suficiente producto en las manos para cubrir toda la superficie, frote las manos juntas hasta que se sequen.</li> <li>Supervise a los niños menores de 6 años cuando usen este producto para evitar que lo traguen.</li> </ul>
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	<b>Información Adicional</b> <ul style="list-style-type: none"> <li>Guardar en temperaturas de 15-30C (59 - 86 F)</li> <li>Evite la congelación del producto y el calor excesivo por encima de 40C (104F)</li> </ul>
	<b>Ingredientes Inactivos</b> glicerina, peróxido de hidrógeno, agua purificada USP

ZELOP



**HAND SANITIZER**

isopropyl alcohol solution, gel forming / drops

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77746-002	
Route of Administration	TOPICAL, CUTANEOUS			
Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL		
Inactive Ingredients				
Ingredient Name	Strength			
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL			
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL			
WATER (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77746-002-01	30 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/13/2020	
2	NDC:77746-002-02	60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/13/2020	
3	NDC:77746-002-03	100 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/13/2020	
4	NDC:77746-002-04	250 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/13/2020	
5	NDC:77746-002-05	3785 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/13/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	05/13/2020		

**Labeler** - C&C SECURITY INC (613331110)

**Registrant** - C&C SECURITY INC (613331110)

### Establishment

Name	Address	ID/FEI	Business Operations
C&C SECURITY INC		613331110	manufacture(77746-002) , pack(77746-002) , label(77746-002) , repack(77746-002) , relabel(77746-002)