

HAND SANITIZER- 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.

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) (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 80% 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.

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.
- 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



Drug Facts

Active Ingredient(s)

Alcohol 80% v/v..... Antiseptic

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warning

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

30 mL NDC: 77746-01-01

Package Label -Principal Display Panel

ZELOP

HAND SANITIZER

Alcohol Antiseptic 80%

Non-sterile Solution
Topical Solution



A1234567890A

60mL (2.2Oz)

Drug Facts

Active Ingredient(s)

Alcohol 80% v/v.....

Purpose

Antiseptic

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

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.

60 mL NDC: 77746-01-02

Package Label - Principal Display Panel

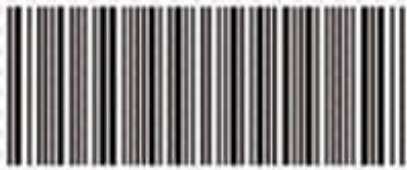
100 mL NDC: 77746-01-03

The logo for ZELOP, featuring the brand name in a bold, sans-serif font. The letter 'O' is stylized as a blue circle with a white dot in the center, resembling an eye or a lens.

HAND SANITIZER

Alcohol Antiseptic 80%

Non-sterile Solution
Topical Solution



A1234567890A

100mL (3.3Oz)

Drug Facts

Active Ingredient(s)	Purpose
Alcohol 80% v/v.....	Antiseptic

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

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 - Princepal Display Panel

250 mL NDC: 77746-01-04

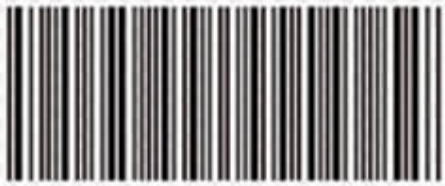


ZELOP

HAND SANITIZER

Alcohol Antiseptic 80%

Non-sterile Solution
Topical Solution



A1234567890A

250mL (8.4Oz)

Drug Facts

Active Ingredient(s)

Alcohol 80% v/v.....

Purpose

Antiseptic

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

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.
- 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



ZELOP

HAND SANITIZER

Alcohol Antiseptic 80%

Non-sterile Solution
Topical Solution



3785mL (1 Gallon)



Drug Facts	Datos Farmacologicos
Active Ingredient(s) Alcohol 80% v/v..... Antiseptic	Ingrediente(s) Activo(s) Alcohol 80% v/v..... Anticéptico
Use Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	Uso(s) Desinfectante de manos para ayudar a reducir las bacterias que pueden causar enfermedades potencialmente. Para uso cuando no hay jabón y agua disponible.
Warning For external use only. Flammable. Keep away from heat or flame	Advertencias Solo para uso externo
Do not use <ul style="list-style-type: none"> in children less than 2 months of age on open skin wounds 	No se utilice: <ul style="list-style-type: none"> niños menos de 2 meses de edad en heridas abiertas en la piel
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	Cuando use este producto, manténgalo lejos de ojos, oídos y boca, en caso de contacto con los ojos enjuague completamente con agua abundante.
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.	Suspenda su uso y consulte a su médico si se produce irritación o sarpullido, estos pueden ser signos de una afección grave.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	Manténgase fuera del alcance de los niños. en caso de ingestión obtenga ayuda médica o póngase en contacto con un centro de control de envenenamiento.
Directions <ul style="list-style-type: none"> 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. 	Instrucciones <ul style="list-style-type: none"> Coloque suficiente producto en las manos para cubrir toda la superficie, frote las manos juntas hasta que se sequen. Supervise a los niños menores de 6 años cuando usen este producto para evitar que lo ingieran.
Other information <ul style="list-style-type: none"> Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F) 	Información Adicional <ul style="list-style-type: none"> Guardar en temperaturas de 15-30C (59 - 86 F) Evite la congelación del producto y el calor excesivo por
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	Ingredientes Inactivos glicerina, peróxido de hidrógeno, agua purificada USP

ZELOP



A 1 2 3 4 5 6 7 8 9 0 A

3785 mL NDC: 77746-01-05

HAND SANITIZER

alcohol solution, gel forming / drops

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:77746-001

Route of Administration TOPICAL, CUTANEOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 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: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77746-001-01	30 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/13/2020	
2	NDC:77746-001-02	60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/13/2020	
3	NDC:77746-001-03	100 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/13/2020	
4	NDC:77746-001-04	250 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/13/2020	
5	NDC:77746-001-05	3785 mL in 1 BOTTLE, DISPENSING; 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	03/30/2020	

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(77746-001) , pack(77746-001) , label(77746-001) , repack(77746-001) , relabel(77746-001)

Revised: 5/2020

C&C SECURITY INC