

CDC70HS HAND SANITIZER- ethanol liquid
Canadian Distribution Channel

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.

CDC70HS Liquid 76984-442

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) (70%, 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 70% 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

CDC70HS 100ml, 500ml, 1890ml, 2L and 3,79L, 300 ml, 60 ml

Label for 100ml 76984-442-01

Drug Facts:
Use[s]
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.

CDC BRANDS

Hand Sanitizer
CDC70HS

**Alcohol Antiseptic 70%
Topical Solution
Hand Sanitizer
Non-sterile Solution**

100 ml

Drug Facts (continued)
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

6 27314 59355 6 Recyclable container

76984-442-01

Made in Canada by
Canadian Distribution Channel o/a CDC Inc.
636 Queensway Cr1
Peterborough, Ontario K9J 7V6
Tel: 1-866-523-2462

Label for 500ml 76984-442-02

Drug Facts:

Use[s]

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.



Hand Sanitizer CDC70HS

Alcohol Antiseptic 70%

Topical Solution
Hand Sanitizer
Non-sterile Solution

500 ml

Drug Facts (continued)

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

HOW TO APPLY



76984-442-02

Made in Canada by
Canadian Distribution Channel o/a CDC Inc
636 Queensway Crt
Peterborough, Ontario K9J 7V6
Tel: 1-866-523-2462

Label for 1.89L 76984-442-03

Drug Facts

Active ingredient[s] **Purpose**
Alcohol 70% v/v.....Antiseptic

Use[s]

Health care personnel hand rub 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

- 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



Hand Sanitizer CDC70HS

Alcohol Antiseptic 70%
Topical Solution
Hand Sanitizer
Non-sterile Solution

NDC 76984-442-03

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- Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- Glycerol (1.45% v/v).
- Hydrogen peroxide (0.125% v/v).
- 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.



1.89L
(64 fl.oz)

Made in Canada by
Canadian Distribution Channel
Selwyn ON K9J 6X5 1-866-523-2462

Label for 2L 76984-442-04

Drug Facts

Active ingredient[s]	Purpose
Alcohol 70% v/v.....	Antiseptic

Use[s]

Health care personnel hand rub 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

- 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



Hand Sanitizer

CDC70HS

Alcohol Antiseptic 70%
Topical Solution
Hand Sanitizer
Non-sterile Solution

NDC 76984-442-04

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:

- Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- Glycerol (1.45% v/v).
- Hydrogen peroxide (0.125% v/v).
- 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.



2L
(67.6 fl.oz)

Made in Canada by
Canadian Distribution Channel
Selwyn ON K9J 6X5 1-866-523-2462

Label for 3.79L 76984-442-05

Drug Facts

Active ingredient[s]	Purpose
Alcohol 70% v/v.....	Antiseptic

Use[s]

Health care personnel hand rub 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

- 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



Hand Sanitizer

CDC70HS

Alcohol Antiseptic 70%
Topical Solution
Hand Sanitizer
Non-sterile Solution

NDC 76984-442-05

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:

- Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- Glycerol (1.45% v/v).
- Hydrogen peroxide (0.125% v/v).
- 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.



3.79 L
(128 fl.oz)

Made in Canada by
Canadian Distribution Channel
Selwyn ON K9J 6X5 1-866-523-2462

Label for CDC70HS 300 ml 76984-442-06

Drug Facts:**Use[s]**

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.



Hand Sanitizer

CDC70HS

Alcohol Antiseptic 70%
Topical Solution
Hand Sanitizer
Non-sterile Solution

300 ml

Drug Facts (continued)**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



Recyclable container

76984-442-06

Made in Canada by
Canadian Distribution Channel o/a CDC Inc
636 Queensway Crt
Peterborough, Ontario K9J 7V6
Tel: 1-866-523-2462

Label for CDC70HS 60ml 76984-442-07

Drug Facts:**Use[s]**

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.



Hand Sanitizer

CDC70HS

Alcohol Antiseptic 70%
Topical Solution
Hand Sanitizer
Non-sterile Solution

60 ml

Drug Facts (continued)**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



Recyclable container

76984-442-07

Made in Canada by
Canadian Distribution Channel o/a CDC Inc
636 Queensway Crt
Peterborough, Ontario K9J 7V6
Tel: 1-866-523-2462

CDC70HS HAND SANITIZER

ethanol liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:76984-442

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	70 mL in 100 mL	
Inactive Ingredients				
Ingredient Name		Strength		
WATER (UNII: 059QF0K00R)				
GLYCERIN (UNII: PDC6A3C0OX)		1.45 mL in 100 mL		
HYDROGEN PEROXIDE (UNII: BBX060AN9V)		0.125 mL in 100 mL		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76984-442-01	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/24/2020	
2	NDC:76984-442-02	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/24/2020	
3	NDC:76984-442-03	1890 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/24/2020	
4	NDC:76984-442-04	2000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/24/2020	
5	NDC:76984-442-05	3790 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/24/2020	
6	NDC:76984-442-06	300 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/24/2020	
7	NDC:76984-442-07	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/24/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	04/24/2020		

Labeler - Canadian Distribution Channel (242043508)

Registrant - Canadian Distribution Channel (242043508)

Establishment

Name	Address	ID/FEI	Business Operations
Canadian Distribution Channel		242043508	manufacture(76984-442)

Revised: 8/2020

Canadian Distribution Channel