

HAND SANITIZER GEL- alcohol gel

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.

CDC70HSG - Hand Sanitizer Gel

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.

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

100 mL NDC: 76984-434-01

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.

CDC BRANDS GEL Hand Sanitizer CDC70HSG

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

NDC 76984-434-01

**100ml
(3.38 fl.oz)**

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, carbomer 940, hydrogen peroxide, purified water

HOW TO APPLY

1. Dispense
2. Rub
3. Dry

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

6 27314 59355 6 Recyclable container

500 ml NDC 76984-434-02

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.



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

NDC 76984-434-02

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, carbomer 940, hydrogen peroxide, purified water

HOW TO APPLY



500ml
(16.9 fl.oz)

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

1.89L NDC76984-434-03

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.



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

NDC 76984-434-03

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, carbomer 940, hydrogen peroxide, purified water

HOW TO APPLY



1.89L
(64 fl.oz)

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

2L NDC 76984-434-04

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.



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

NDC 76984-434-04

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, carbomer 940, hydrogen peroxide, purified water

HOW TO APPLY



2L
(67.6 fl.oz)

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

3.79L NDC 76984-434-05

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.



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

NDC 76984-434-05

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, carbomer 940, hydrogen peroxide, purified water

HOW TO APPLY



3.79L
(128 fl.oz)

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

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.



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

NDC 76984-434-06

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, carbomer 940, hydrogen peroxide, purified water





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300ml
(10.1 fl.oz)

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

60ml NDC 76984-434-07

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.



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

NDC 76984-434-07

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, carbomer 940, hydrogen peroxide, purified water





6 27314 59355 6

60ml
(2.0 fl.oz)

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

HAND SANITIZER GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76984-434
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	70 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)				
CARBOMER 940 (UNII: 4Q93RCW27E)			0.5 mL in 100 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76984-434-06	300 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:76984-434-01	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:76984-434-02	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
4	NDC:76984-434-03	1890 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
5	NDC:76984-434-04	2000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
6	NDC:76984-434-05	3790 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
7	NDC:76984-434-07	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	03/30/2020		

Labeler - Canadian Distribution Channel (242043508)

Registrant - Canadian Distribution Channel (242043508)

Establishment

Name	Address	ID/FEI	Business Operations
Canadian Distribution Channel		242043508	manufacture(76984-434)