

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 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 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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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 Isopropyl alcohol 75% v/v	Purpose Antiseptic
Uses 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 <ul style="list-style-type: none"> On 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 <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. 	
Other information <ul style="list-style-type: none"> Store between 15 - 30C (59 - 86F) Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients: glycerin, hydrogen peroxide, water	
Made in Canada by ADFAST 2685, Diab, Ville St-Laurent QUÉBEC, H4S 1E7 TEL: 1-800-567-2659 / www.adfastcorp.com	



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AD CLEAN
MEDICAL

ISOPROPYL ALCOHOL ANTISEPTIC 75%
TOPICAL SOLUTION

HAND SANITIZER
NON-STERILE SOLUTION

World Health Organization recommended hand sanitizer formulation

470 mL (15.9 FL OZ)

Read label carefully before using

NPN 80099945

Drug Facts	
Active ingredient Isopropyl alcohol 75% v/v	Purpose Antiseptic
Uses 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 <ul style="list-style-type: none"> On 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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AD CLEAN
MEDICAL

ISOPROPYL ALCOHOL ANTISEPTIC 75%
TOPICAL SOLUTION

HAND SANITIZER
NON-STERILE SOLUTION

World Health Organization recommended hand sanitizer formulation

10 L (2.6 GAL)

Read label carefully before using

NPN 80099945

ADCLEAN - MEDICAL

isopropyl alcohol aerosol

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:78335-001

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3COOX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KOOR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	M
1	NDC:78335-001-01	10000 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78335-001-02	470 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	M

OTC monograph not final | part333A | 03/30/2020

Labeler - Adfast Corp (203870543)

Registrant - Dan Garnett (079817668)

Establishment

Name	Address	ID/FEI	Business Operations
Adfast Corp		203870543	manufacture(78335-001)

Revised: 5/2020