

ADCLEAN MEDICAL GEL- isopropyl alcohol gel

Adfast Corp

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.

ADCLEAN Medical 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. Isopropyl Alcohol (70%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Purified water = 26.25 v%
- c. Rapidgel EZ1 = 3.00 v%
- d. Hydrogen peroxide 29% = 0.45 v%
- e. Fragrance = 0.30 v%

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 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

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

Warnings

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

Do not use

- 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.

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

Water

Polyethylene Glycol

Acrylate Polymer

Hydrogen Peroxide

Fragrance

Package Label - Principal Display Panel

78335-002

Drug Facts	
Active ingredient Isopropyl alcohol 70% v/v.....	Purpose Antiseptic
Uses To decrease bacteria on the skin that could cause disease. recommended for repeated use.	
Warnings For external use only. Flammable. Keep away from heat or flame. When using this product keep out of eyes. In case of contact with eyes flush thoroughly with water. Avoid contact with broken skin. Do not inhale or ingest. 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 15-30°C (59-86°F) Avoid freezing and excessive heat above 40°C (104°F) 	
Inactive ingredients: Water, Polyethylene glycol, Acrylate Polymer, Hydrogen Peroxide, Fragrance.	

Made in Canada by ADFAST
 2685, Diab, Ville St-Laurent QUÉBEC, H4S 1E7
 TEL. 1-800-567-2658 / www.adfastcorp.com
 UN1219 ISOPROPANOL



**ISOPROPYL ALCOHOL ANTISEPTIC 70%
 HAND SANITIZER GEL**



10 L (2.6 GAL)

Read label carefully before using

NDC: 78335-002-01

Drug Facts	
Active ingredient Isopropyl alcohol 70% v/v.....	Purpose Antiseptic
Uses To decrease bacteria on the skin that could cause disease. recommended for repeated use.	
Warnings For external use only. Flammable. Keep away from heat or flame. When using this product keep out of eyes. In case of contact with eyes flush thoroughly with water. Avoid contact with broken skin. Do not inhale or ingest. 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 15-30°C (59-86°F) Avoid freezing and excessive heat above 40°C (104°F) 	
Inactive ingredients: Water, Polyethylene glycol, Acrylate Polymer, Hydrogen Peroxide, Fragrance.	

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**ISOPROPYL ALCOHOL ANTISEPTIC 70%
 HAND SANITIZER GEL**



470 mL (15.9 FL oz)

Read label carefully before using

NDC: 78335-002-02

ADCLEAN MEDICAL GEL

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78335-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
RAPIDGEL EZ1 (UNII: 33JH4A7R2K)	3 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.45 mL in 100 mL
WATER (UNII: 059QF0KO0R)	26.25 mL in 100 mL
FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95)	0.3 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78335-002-01	10000 mL in 1 JUG; Type 0: Not a Combination Product	07/16/2020	
2	NDC:78335-002-02	470 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/16/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/30/2020	

Labeler - Adfast Corp (203870543)

Registrant - Dan Garnett (203870543)

Establishment

Name	Address	ID/FEI	Business Operations
Adfast Corp		203870543	manufacture(78335-002)

