

HAND SANITIZER- alcohol gel
ACT Labs

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

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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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

AMINOMETHYL PROPANOL, CARBOMER, GLYCERIN, WATER (AQUA)

Package Label - Principal Display Panel

QuaranClean™
WITH 100% PURE ESSENTIAL OILS **+**

Hand Sanitizer Gel
70% Alcohol
8 fl. oz/ 236mL

Drug Facts

Active Ingredient	Purpose
Ethyl alcohol 70% v/v	Antimicrobial

Uses
Hand sanitizer to help reduce bacteria on the skin



Warnings
For external use only.
Flammable, keep away from heat and flame.
DO NOT USE in the eyes. In case of contact, rinse eyes thoroughly with water.
Stop use and seek a doctor if irritation and redness develop and persist for more than 72 hours.
Keep out of reach of children. If swallowed get a medical help or contact a Poison Control Center right away.

Directions
-Put enough product in your palm to cover hands and rub hands together UNTIL dry
-Children under 6 years of age should be supervised when using hand sanitizer

Other information
-Store below 110°F (43°C)
-May discolor certain fabrics or surfaces

Inactive ingredients
Water, glycerin, acetylglucosyl glucuronide, carbomer, ammonium l-propanol

Manufactured by JD Brands
Fountain Valley, CA

0 24291 15993 3

SDS-CA-16224

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236 mL NDC: 75664-1117-1; NDC: 75664-1117-2; NDC: 75664-1117-3

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75664-1117
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
EUCALYPTUS OIL (UNII: 2R04ONI662)	0.5 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.3 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.04 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75664-1117-1	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020	
2	NDC:75664-1117-2	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020	
3	NDC:75664-1117-3	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/14/2020	

Labeler - ACT Labs (078833578)

Registrant - ACT Labs (078833578)

Establishment

Name	Address	ID/FEI	Business Operations
ACT Labs		078833578	manufacture(75664-1117)

Revised: 7/2020

ACT Labs