## ADVANCED LOCAL HEALTH HAND SANITIZER- alcohol gel Advanced Local Health LLC

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.

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### Advanced Local Health™ Hand Sanitizer

**Drug Facts** 

# **Active Ingredient**

Ethyl Alcohol 70% v/v

# Purpose

Antiseptic

#### Uses

To decrease bacteria on the skin when water, soap & towel are not available – Recommended for repeated use.

### **Warnings**

For external use only.

#### **Flammable**

Keep away from fire or flame.

*When using this product* keep out of eyes. In case of contact with eyes, rinse thoroughly with water. Do not use on broken or irritated skin.

**Stop use and ask a doctor if** irritation or redness develop and last more than 72 hours.

### Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

Apply enough product to wet hands. Rub hands together until dry. Supervise children in use of this product.

#### Other information

- Do not store above 105 °F (40 °C).
- May discolor certain wood surfaces.

## **Inactive Ingredients**

Water (Aqua) (EAU), Glycerin, Carbomer, Propylene Glycol, Phenoxyethanol / Iodopropynyl Butylcarbamate, Aminomethyl Propanol, Ext. Violet 2 (CI 60730), Tetrasodium EDTA, Aloe Barbadensis Leaf Juice.

# Questions?

Call +1 716-256-3240

Distributed by:

Advanced Local Health LLC, Doral, Florida, 33166

# PRINCIPAL DISPLAY PANEL - 200 ml Bottle Label

advanced local health<sup>TM</sup> hand sanitizer

U.S.A. sourced alcohol

TOPICAL SOLUTION contains 70% ethyl alcohol

WITH ALOE VERA

6.7 Fl. Oz. (200 ml)





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Made in México. Distributed by: Advanced Local Health LLC, Doral, Florida, 33166

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### ADVANCED LOCAL HEALTH HAND SANITIZER

alcohol gel

### **Product Information**

HUMAN OTC DRUG Product Type Item Code (Source) NDC:74264-002

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Alcohol (UNII: 3K9958 V90 M) (Alcohol - UNII: 3K9958 V90 M)	Alcohol	70 mL in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
water (UNII: 059QF0KO0R)		
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)		
GLYCERIN (UNII: PDC6A3C0OX)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)		
EXT. D&C VIOLET NO. 2 (UNII: G5UX3K0728)		
EDETATE SO DIUM (UNII: MP1J8420LU)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74264-002- 02	200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/04/2020	
2	NDC:74264-002- 04	415 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/04/2020	
3	NDC:74264-002- 01	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/04/2020	
4	NDC:74264-002- 03	240 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/04/2020	
5	NDC:74264-002- 05	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/04/2020	
6	NDC:74264-002- 06	$3785.41\mathrm{mL}$ in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/04/2020	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC MONOGRAPH NOT FINAL	part333A	08/04/2020			

# Labeler - Advanced Local Health LLC (117466501)

Establishment				
Name	Address	ID/FEI	Business Operations	
TECNOGLOBAL PH7		813006665	MANUFACTURE(74264-002)	

Revised: 8/2020 Advanced Local Health LLC