

## **NATURAL CARE ADVANCED- ethyl alcohol gel**

### **Dr. Natural**

*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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## **NATUAL CARE ADVNACED HAND SANITIZER**

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 (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)**

ETHYL ALCOHOL 62%

### **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**

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**

349 ML

NDC: 78261-003-01

<b>NATURAL CARE ADVANCED</b>			
ethyl alcohol gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78261-003
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 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)	

## Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78261-003-01	349 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	



Natural Care  
**ADVANCED**  
**HAND SANITIZER**  
ALCOHOL ANTISEPTIC

FRESH GEL  
MOISTURIZING FORMULA



Leaves hands feeling soft  
11.8 FL OZ (1 QT) 349 mL

Natural Care **FRESH GEL HAND SANITIZER**

**Drug Facts**

**Active Ingredients** .....**Purpose**  
Ethyl Alcohol 62% w/w.....Antibacterial

**Use** hand sanitizer to help reduce bacteria on the skin

**Warnings**  
**Flammable. Keep away from fire or flame.**

**For external use only**  
**When using this product** do not use in or near eyes. In case of contact, rinse eyes thoroughly with water.

**Stop use and ask a doctor** if irritation or redness develops.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Directions** ■ apply palmful to hands ■ rub hands together vigorously until dry ■ supervise children in the use of this product.

**Other information** ■ store below 110°F (43°C)  
■ may discolor certain fabrics or surfaces.

**Inactive ingredients** Water, Isopropyl Alcohol, Glycerin, Carbomer, Aminomethyl Propanol, Fragrance, Propylene Glycol, Isopropyl Myristate, Aloe Barbadensis Leaf Juice (Aloe Vera), Tocopheryl Acetate (Vitamin E), Yellow 5 (CI 19140), Blue 1 (CI 42090).



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CRUELTY FREE • NO ANIMAL TESTING  
Distributed by: Dr. Natural LLC  
New York, NY 10018 USA  
Made in USA

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/03/2020	

**Labeler** - Dr. Natural (080454165)

**Registrant** - Dr. Natural (080454165)

**Establishment**

Name	Address	ID/FEI	Business Operations
Dr. Natural		080454165	manufacture(78261-003)

Revised: 8/2020

Dr. Natural