

## **OZ NATURALS ANTISEPTIC GEL HANDSANITIZER- alcohol gel**

**OZ Naturals 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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### **OZ NATURALS Antiseptic Gel Handsanitizer**

#### **PURPOSE**

Antispetic Skin Cleanser

#### **Use**

Antiseptic skin cleanser to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

#### **DIRECTIONS FOR USE:**

Adults and children over 2 years

Supervise children when they use this product

For occasional and personal domestic use

Rub thoroughly into hands for at least 30 seconds. Allow to dry.

#### **ACTIVE INGREDIENT**

Ethyl Alcohol 70%p/p

#### **WARNINGS:**

For external use only

- When using this product, avoid contact with eyes. If contact occurs, rinse thoroughly with water
- Stop use and consult a health care professional if irritation develops
- Keep out of reach of children
- If swallowed, call a poison control center or get medical help right away
- Flammable
- Keep away from flames or heat source
- Avoid temperature over 43°C (110°F)

#### **Warnings**

Keep out of reach of children

## INACTIVE INGREDIENTS:

Aqua/Water/Eau, Glycerin, Tocopheryl Acetate, Aloe Barbadensis Leaf Juice, Citrus Paradisi (Grapefruit) Peel Oil, Carbomer, Triethanolamine

## Distributed by OZNaturals®

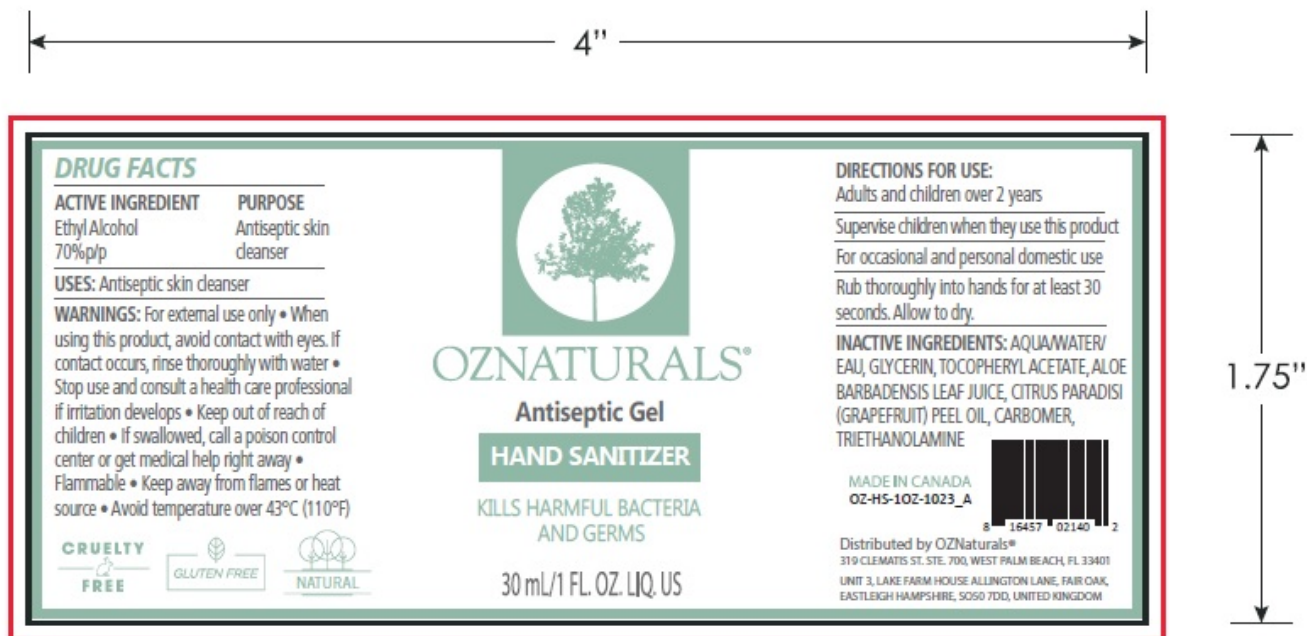
319 Clematis St. Ste. 700,  
West Palm Beach, FL 33401

MADE IN CANADA

## Principal Display Panel

OZNATURALS Antiseptic Gel Hand Sanitizer

KILLS HARMFUL BACTERIA AND GERMS



## OZ NATURALS ANTISEPTIC GEL HANDSANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75592-201
<b>Route of Administration</b>	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)			ALCOHOL	70 mL in 100 mL
Inactive Ingredients				
Ingredient Name				Strength
<b>CITRUS PARADISI FRUIT OIL</b> (UNII: 6A7N43E0OJ)				
<b>CARBOMER 940</b> (UNII: 4Q93RCW27E)				
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)				
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)				
<b>WATER</b> (UNII: 059QF0KO0R)				
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)				
<b>TRIETHANOLAMINE ISOSTEARATE</b> (UNII: T8OTU5ECY5)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75592-201-01	1 in 1 BOX	04/16/2020	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:75592-201-02	1 in 1 BOX	04/16/2020	
2		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:75592-201-03	1 in 1 BOX	04/16/2020	
3		475 mL in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	04/16/2020	

**Labeler** - OZ Naturals LLC (079726946)

**Registrant** - OZ Naturals LLC (079726946)

## Establishment

Name	Address	ID/FEI	Business Operations
OZ NATURALS LLC		079726946	manufacture(75592-201) , pack(75592-201) , label(75592-201)

