

**HOSP CLEAN- alcohol gel**  
**INTERBRILHO HIGIENE E LIMPEZA LTDA**

*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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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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (77%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Aloe Barbadensis Leaf Extract
- c. Carbomer
- d. Denatonium Benzoate
- e. Glycerin
- f. Triethanolamine
- g. 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)**

Alcohol 77% 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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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**

Aloe Barbadensis Leaf Extract, Carbomer, Denatonium Benzoate, Glycerin, Triethanolamine, water

### **Package Label - Principal Display Panel**

4831 mL NDC: 79868-300-01

# HAND SANITIZER

WITH ALOE



ALOE VERA  
EXTRACT



MOISTURIZING ACTION  
DOESN'T DRY THE SKIN  
ANTISEPTIC GEL



**4,831 mL**  
**( 163.3 FL OZ )**



494 mL NDC: 79868-300-02



# HAND SANITIZER

WITH ALOE

MOISTURIZING ACTION  
DOESN'T DRY THE SKIN  
ANTISEPTIC GEL





483 mL NDC: 79868-300-03





# HAND SANITIZER WITH ALOE

MOISTURIZING ACTION  
DOESN'T DRY THE SKIN  
ANTISEPTIC GEL



ALOE VERA  
EXTRACT



**483mL**  
**(16.3 FL OZ)**



191 mL NDC: 79868-300-04



# HAND SANITIZER WITH ALOE

ANTISEPTIC GEL

MOISTURIZING ACTION

DOESN'T DRY THE SKIN



ALOE VERA  
EXTRACT



**191mL**  
**(6.4 FL OZ)**



101 mL NDC: 79868-300-05



## HOSP CLEAN

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79868-300
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>ALCOHOL</b> (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	77 mL in 100 mL
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### Inactive Ingredients

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>WATER</b> (UNII: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79868-300-01	4831 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:79868-300-02	494 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:79868-300-03	483 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
4	NDC:79868-300-04	191 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
5	NDC:79868-300-05	101 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

**Labeler** - INTERBRILHO HIGIENE E LIMPEZA LTDA (899673646)

**Registrant** - AY CONSULTING SERVICES, LLC (078311971)

### Establishment

Name	Address	ID/FEI	Business Operations
INTERBRILHO HIGIENE E LIMPEZA LTDA		899673646	manufacture(79868-300)

Revised: 1/2022

INTERBRILHO HIGIENE E LIMPEZA LTDA