

## **PLUMERIA HAND SANITIZER- alcohol gel**

### **Intellectual AG 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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### **Active Ingredient(s)**

Alcohol 63% 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 vera, hydrogen peroxide, purified water USP, plumeria essential oil

**Package Label - Principal Display Panel**

100 mL NDC: 74190-100-01



<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Ethanol Alcohol 63% v/v.....	Antiseptic
<b>Use[s]</b>	
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>in children less than 2 months of age</li> <li>on open skin wounds</li> </ul>	
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.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>Store between 15-30C (59-86F)</li> <li>Avoid freezing and excessive heat above 40C (104F)</li> </ul>	
<b>Inactive ingredients</b> Boiled Water, Glycerine, Aloe Barbadensis Leaf Juice, Organic Plumeria Extract, Iodopropynyl Butylcarbamate, Diazolindinyl Urea	

Made by Intellectual AG LLC NDC: 74190-100-01 for:

Hemptuary Hawaii  
2113 Kalakaua Ave  
(808) 824-Hemp

PLUMERIA HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74190-100
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	74.13 mL in 100 mL
Inactive Ingredients			
Ingredient Name		Strength	
ALOE VERA LEAF (UNII: ZY81Z83H0X)		24.75 mL in 100 mL	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)		0.125 mL in 100 mL	
WATER (UNII: 059QF0KO0R)		1 mL in 100 mL	
PLUMERIA ALBA FLOWER (UNII: LGC8P2PC4H)		1 mL in 100 mL	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74190-100-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/30/2020	

**Labeler -** Intellectual AG LLC (084442238)

## Establishment

Name	Address	ID/FEI	Business Operations
Intellectual AG LLC		084442238	manufacture(74190-100)

Revised: 1/2022

Intellectual AG LLC