

## **HAND SANITIZER- rainforest natural hand sanitizer spray spray Splice Biotechnics Inc.**

*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.*

-----

### **Rainforest Natural Hand Sanitizing 80 vv ethanol**

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) (80%, 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. 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)**

Alcohol 80% 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.

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, water, hydrogen peroxide, Lemon fragrance.

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

**Drug Facts**  
**Active Ingredients:**  
 Ethyl alcohol.....80% v/v

**Use/Purpose**

Antiseptic skin cleanser.

**Cautions and Warnings:**

Flammable warning. Keep away from open flame and sources of heat. For external use only. Keep out of reach of children. If swallowed, call poison control center or get help immediately. Stop use and ask/consult a doctor/physician/healthcare practitioner/health care provider/health care professional if irritation develops. When using this product, avoid contact with eyes. If contact occurs, rinse thoroughly with water.

**Directions:**

Adults and children over 2 years of age. 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.

**Contraindications**

Do not use on children/infants less than 2 years of age. Do not use on open skin wounds.

**Inactive ingredients:**

Water, Glycerin, Cymbopogon Schoenanthus (Lemongrass) Essential Oil, Mentha viridis (Spearmint) Leaf Oil.

**Storage and handling:**

Store between 15-30C (59-86F)  
 Avoid freezing and excessive heat above 40C (104F)

MADE IN CANADA



[www.splicebiotechnics.com](http://www.splicebiotechnics.com)



# Hand Sanitizer

Lemongrass and Spearmint essential oils

80% Alcohol

250 ml

**Manufactured and Distributed by:**  
 Splice Biotechnics Inc.  
 86 B Northline Road, Toronto,  
 ON, M4B 3E5

Not tested on animals  
 Triclosan and Paraben free



120 ml NDC: 81619-115-15

## HAND SANITIZER

rainforest natural hand sanitizer spray spray

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:81619-115 |
| <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           | 80 mL in 100 mL |

### Inactive Ingredients

| Ingredient Name                                      | Strength |
|--|----------|
| <b>SPEARMINT OIL</b> (UNII: C3M81465G5)              |          |
| <b>EAST INDIAN LEMONGRASS OIL</b> (UNII: UP0M8M3VZW) |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                      |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                   |          |

## Packaging

| # | Item Code        | Package Description  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:81619-115-15 | 120 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 06/24/2021           |                    |

## Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A                                 | 06/24/2021           |                    |

**Labeler** - Splice Biotechnics Inc. (204252568)

## Establishment

| Name                     | Address | ID/FEI    | Business Operations    |
|--------------------------|---------|-----------|------------------------|
| Pame Eco Technology Inc. |         | 204258441 | manufacture(81619-115) |

Revised: 6/2021

Splice Biotechnics Inc.