

RAINFOREST NATURAL HAND SANITIZER- ethanol 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 Sanitizer Spray WHO FORMULA

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 wipes

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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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, lemongrass essential oil, spearmint essential oil.

Package Label - Principal Display Panel

Drug Facts

Active Ingredient.

Ethyl alcohol.....80% v/v

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MADE IN CANADA



Hand Sanitizer Spray

250 ml/ 8.5 oz

Inactive ingredients:

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

Manufactured and Distributed by:

Splice Biotechnics Inc. 86 B Northline Road, Toronto, ON, M4B 3E5

Not tested on animals Triclosan and Paraben free



www.splicebiotechnics.com

WHO formula with lemongrass and Spearmint essential oils

250 ml NDC: 81619-117-01

RAINFOREST NATURAL HAND SANITIZER

ethanol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81619-117
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
EAST INDIAN LEMONGRASS OIL (UNII: UP0M8M3VZ W)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SPEARMINT OIL (UNII: C3M81465G5)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81619-117-01	250 mL in 1 CANISTER; Type 0: Not a Combination Product	08/28/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/28/2021	

Labeler - Splice Biotechnics Inc. (204252568)

Establishment

Name	Address	ID/FEI	Business Operations
Pame Eco Technology Inc.		204258441	manufacture(81619-117)

Revised: 9/2021

Splice Biotechnics Inc.