

HAND SANITIZER- rainforest natural hand sanitizer spray who formula 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 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

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

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.

Inactive ingredients:

Water, Glycerin, Hydrogen Peroxide, Fragrance.

Not tested on animals

Triclosan and Paraben free

Manufactured and Distributed by:

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

Environmentally Friendly



www.splicebiotechnics.com



Hand Sanitizer Spray

WHO FORMULA

80% Alcohol

120 ml

Other information

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

MADE IN CANADA



120 ml NDC: 81619-112-11

HAND SANITIZER

rainforest natural hand sanitizer spray who formula spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81619-112
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
FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81619-112-11	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(81619-112)

Revised: 6/2021

Splice Biotechnics Inc.