

HAND SANITIZER- isopropyl alcohol solution

Dr. Ginger's Health Care Products, 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.

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. Isopropyl Alcohol (75%, 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)

Isopropyl Alcohol 75% 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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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, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

414 ml NDC: 75423-414-01

The image shows the principal display panel of a Dr. Ginger's Hand Sanitizer Refill Bottle. The label is on a brown cardboard background and features a central logo with a coconut and lemons. Text on the label includes: 'MOISTURIZING & ENERGIZING', 'WITH ORGANIC COCONUT OIL', 'CRUELTY FREE', 'MADE IN USA', 'PLEASE RECYCLE', 'HARD ON THE GERMS EASY ON YOUR SKIN', '99% EFFECTIVE ON MOST COMMON GERMS', 'Hand sanitizer with organic coconut oil, orange peel oil, and lemon peel oil to keep your hands happy and clean.', 'Hand Sanitizer Refill Bottle', 'Essential Oils Soft On Skin', '14 Fl Oz. (414 ml)', 'Orange Twist', 'Refill Your Small Hand Sanitizer x7', 'Hands are a hot zone for germs. That's why at Dr. Ginger's we formulated our Hand Sanny to work extra hard to battle those germs while staying extra soft on your skin. Do a number on the germs, not on your hands.', 'www.drgingers.com', 'Made by: Dr. Ginger's Healthcare Products, Phoenix, AZ 85016, USA 844.688.2600', 'CONGRATS, YOU @ JUST WENT COCO.', and a barcode with the number 50013 42226 8.

MOISTURIZING & ENERGIZING **WITH ORGANIC COCONUT OIL** **CRUELTY FREE** **MADE IN USA**

Hand sanitizer with organic coconut oil, orange peel oil, and lemon peel oil to keep your hands happy and clean.

99% EFFECTIVE ON MOST COMMON GERMS

DRGINGER'S

DR

HARD ON THE GERMS EASY ON YOUR SKIN

Refill Your Small Hand Sanitizer x7

Hands are a hot zone for germs. That's why at Dr. Ginger's we formulated our Hand Sanny to work extra hard to battle those germs while staying extra soft on your skin. Do a number on the germs, not on your hands.

Hand Sanitizer Refill Bottle

Essential Oils Soft On Skin

14 Fl Oz. (414 ml)

Orange Twist

www.drgingers.com

Made by:
Dr. Ginger's
Healthcare Products
Phoenix, AZ 85016
USA 844.688.2600

CONGRATS, YOU @ JUST WENT COCO.

PLEASE RECYCLE

Active Ingredient[s]	Purpose
Isopropyl Alcohol 75% v/v.....	Antiseptic

Drug Facts

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Inactive ingredients

- glycerin, hydrogen peroxide, purified water USP, organic coco nucifera (coconut oil), organic citrus aurantium dulcis (orange peel oil), organic citrus medica limonum (lemon)

HAND SANITIZER

isopropyl alcohol solution

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75423-414	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)		ISOPROPYL ALCOHOL	75 mL in 100 mL	
Inactive Ingredients				
Ingredient Name		Strength		
GLYCERIN (UNII: PDC6A3C0OX)		1.45 mL in 100 mL		
HYDROGEN PEROXIDE (UNII: BBX060AN9V)		0.125 mL in 100 mL		
WATER (UNII: 059QF0KO0R)				
LEMON OIL (UNII: I9GRO824LL)		0.3 mL in 100 mL		
ORANGE OIL (UNII: AKN3KSD11B)		1.2 mL in 100 mL		
COCONUT OIL (UNII: Q9L0O73W7L)		1.5 mL in 100 mL		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75423-414-01	414 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/29/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	04/29/2020		

Labeler - Dr. Ginger's Health Care Products, LLC (120965206)

Registrant - Dr. Ginger's Health Care Products, LLC (095462377)

Establishment

Name	Address	ID/FEI	Business Operations
Dr. Ginger's Health Care Products, LLC		120965206	manufacture(75423-414) , label(75423-414) , pack(75423-414)

Revised: 4/2020

Dr. Ginger's Health Care Products, LLC