# HAND SANITIZER- alcohol liquid North Coast Innovations, L.L.C.

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 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.

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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)

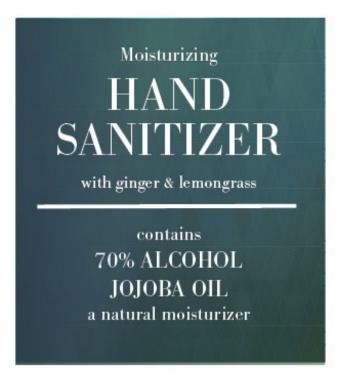
#### **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

## Package Label - Principal Display Panel

P	1
/ Lea To help reduce bacteria on hands.	Purpose Antiseptic
Warnings Flammable. Keep away from heat or flame. For external use only.	
Do not use On children under 2 months of age. On open skin wounds.	
When using this product keep out of eyes and mouth. In case of contact with eyes, rinse thoroughly with water.	
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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	enter right
<ul> <li>Directions</li> <li>Put enough product on to cover hands and rub hands together until dry.</li> <li>Supervise children under 6 years when using the product to avoid swallowing.</li> </ul>	ether to avoid
Other information Store between 59-86F (15-30C) Avoid freezing & excessive heat above 104F (40C)	
Inactive ingredients Water, Acrylates Copolymer, Glycerin, Ethyl Palmate, Cymbopogon Schoenanthus Oil, Zingiber Officinale (Ginger) Root Oil, Simmondsia Chinesis (Jojoba) Seed Oil, Aminomethyl Propanol	pogon mondsia
DIST. BY: North Coast Innovations, LLC 504 Malcolm Ave SE Suite 300 Minneapolis, MN 55414	028880





1/2 Gallon (64 fl oz) 1.89 L

## HAND SANITIZER

alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80218-104
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)		
WATER (UNII: 059QF0KO0R)		
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)		

GINGER OIL (UNII: SAS9Z1SVUK)	
JOJOBA OIL (UNII: 724GKU717M)	
ETHYL PALMATE (UNII: PY7890FR5M)	
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E)	
EAST INDIAN LEMONGRASS OIL (UNII: UP0 M8 M3 VZW)	

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:80218-104- 90	70 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/24/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/24/2020	

## Labeler - North Coast Innovations, L.L.C. (117625089)

Establishment				
Name	Address	ID/FEI	Business Operations	
Evergreen Innovations LLC		024394560	manufacture(80218-104)	

Revised: 9/2020 North Coast Innovations, L.L.C.