

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.

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

Drug Facts	
Active ingredient Ethyl Alcohol 70% v/v.....	PurposeAntiseptic
Use To help reduce bacteria on hands.	
Warnings Flammable. Keep away from heat or flame. For external use only.	
Do not use <ul style="list-style-type: none">• 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.	
Stop use and ask 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 <ul style="list-style-type: none">• Put enough product on to cover hands and rub hands together until dry.• Supervise children under 6 years when using the product to avoid swallowing.	
Other information <ul style="list-style-type: none">• 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 Chinensis (Jojoba) Seed Oil, Aminomethyl Propanol	
DIST. BY: North Coast Innovations, LLC 504 Malcolm Ave SE Suite 300 Minneapolis, MN 55414	
 60004 85920 8	
NORTH COAST	



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: 059QF0K00R)	
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: UP0M8M3VZW)					
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.