

HAND SANITIZER- hand sanitizer liquid
Manulele Distillers, 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.

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.

Use(s)

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Other information

Store between 15-30C (59-86F)

Avoid freezing and excessive heat above 40C (104F)

Active ingredients(s)

Alcohol 80% v/v

Purpose

Antiseptic

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.

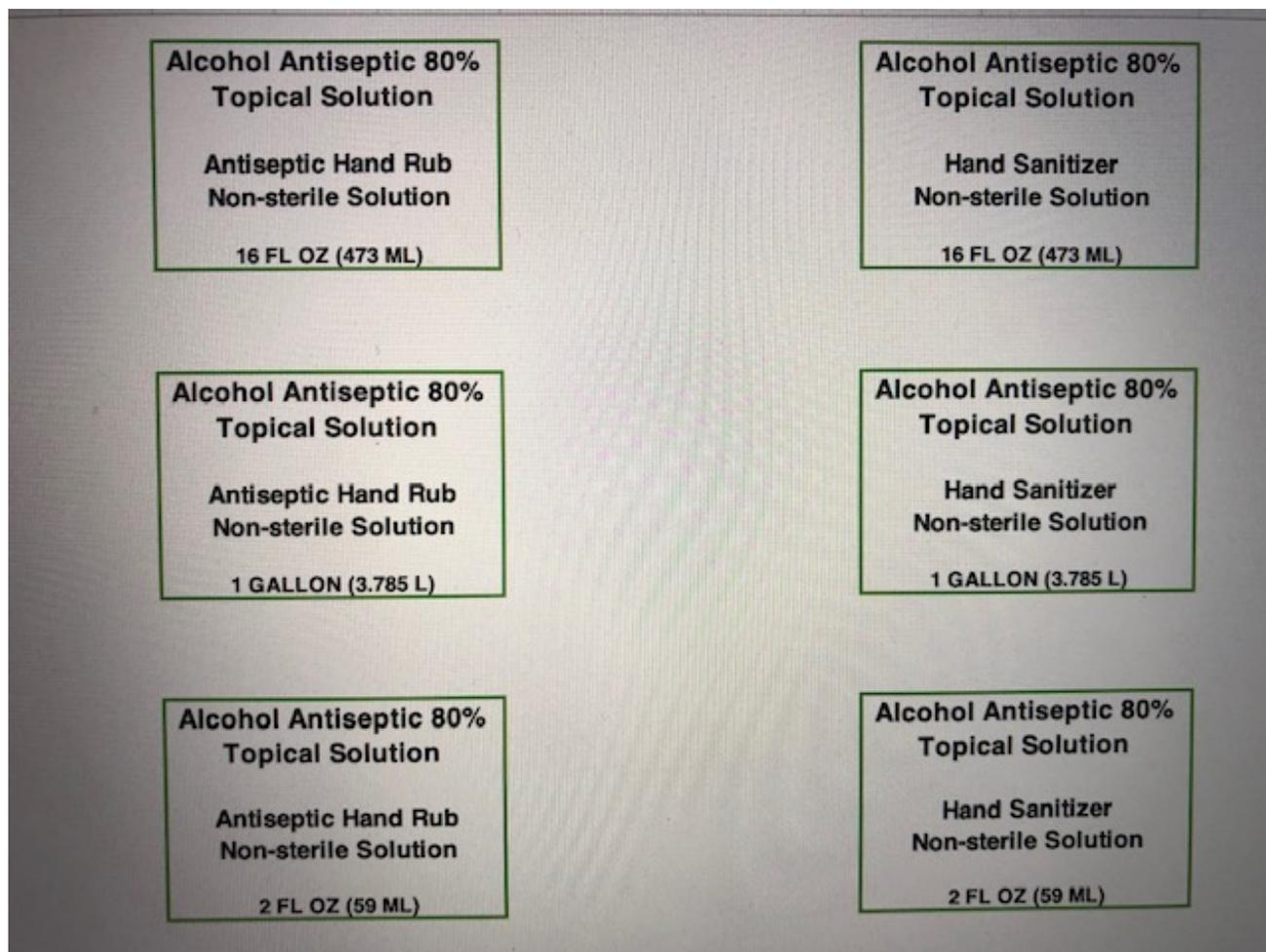
Inactive Ingredients

glycerin, hydrogen peroxide, purified water

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Carton Information



HAND SANITIZER

hand sanitizer liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:740 14-888
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
GLYCEROL FORMAL (UNII: 3L7GR2604E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74014-888-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/25/2020	
2	NDC:74014-888-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/25/2020	
3	NDC:74014-888-02	2 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/25/2020	
4	NDC:74014-888-64	1890 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/25/2020	
5	NDC:74014-888-59	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/25/2020	
6	NDC:74014-888-34	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/30/2020	
7	NDC:74014-888-55	208198 mL in 1 DRUM; Type 0: Not a Combination Product	05/04/2020	
8	NDC:74014-888-05	18927 mL in 1 JUG; Type 0: Not a Combination Product	05/04/2020	
9	NDC:74014-888-28	1040988 mL in 1 TANK; Type 0: Not a Combination Product	05/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/25/2020	

Labeler - Manulele Distillers, LLC (044450399)

Establishment

Name	Address	ID/FEI	Business Operations
Manulele Distillers, LLC		044450399	manufacture(74014-888)

Revised: 5/2020

Manulele Distillers, LLC