

HAND SANITIZER- alcohol liquid
CUNNINGHAM SPIRITS LLC dba OLD GLORY DISTILLING CO.

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.

HAND SANITIZER

Drug Facts

Active ingredient[s]

Alcohol 80% v/v

Purpose

Antiseptic

Use[s]

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

- on 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 thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious problem.

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, hydrogen peroxide, purified water USP

PRINCIPAL DISPLAY PANEL - 1892.7 ML Bottle Label

DISTILLED & BOTTLED BY
 Old
 GLORY
 DISTILLING • C^o
 CLARKSVILLE, TN

HAND
 SANITIZER
 ALCOHOL
 ANTISEPTIC 80%
 TOPICAL SOLUTION

NON-STERILE
 SOLUTION
 WHO-RECOMMENDED
 HANDRUB

1/2 GALLON | 1.89L (1892.7ML) | 64 OUNCES

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NDC: 76872-101-01

PRODUCED BY OLD GLORY
 DISTILLING CO, 451 ALFRED THUN RD.
 CLARKSVILLE, TN 37040

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HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76872-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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Alcohol (UNII: 3K9958V90M) (Alcohol - UNII:3K9958V90M)		Alcohol	80 mL in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
glycerin (UNII: PDC6A3C0OX)				
hydrogen peroxide (UNII: BBX060AN9V)				
water (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76872-101-01	1892.71 mL in 1 JUG; Type 0: Not a Combination Product	04/28/2020	
2	NDC:76872-101-02	3785.41 mL in 1 JUG; Type 0: Not a Combination Product	04/28/2020	
3	NDC:76872-101-03	18927.1 mL in 1 PAIL; Type 0: Not a Combination Product	04/28/2020	
4	NDC:76872-101-04	208198 mL in 1 DRUM; Type 0: Not a Combination Product	04/28/2020	
5	NDC:76872-101-05	1022061.2 mL in 1 CONTAINER; Type 0: Not a Combination Product	04/28/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part333A	04/28/2020		

Labeler - CUNNINGHAM SPIRITS LLC dba OLD GLORY DISTILLING CO. (092633844)

Establishment

Name	Address	ID/FEI	Business Operations
CUNNINGHAM SPIRITS LLC dba OLD GLORY DISTILLING CO.		092633844	MANUFACTURE(76872-101) , LABEL(76872-101) , PACK(76872-101)

Revised: 5/2020

CUNNINGHAM SPIRITS LLC dba OLD GLORY DISTILLING CO.