

HAND SANTIZER- alcohol liquid
Robert Mazza, Inc dba Five & 20 Spirits

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.

For topical use only

Alcohol - 80%ABV

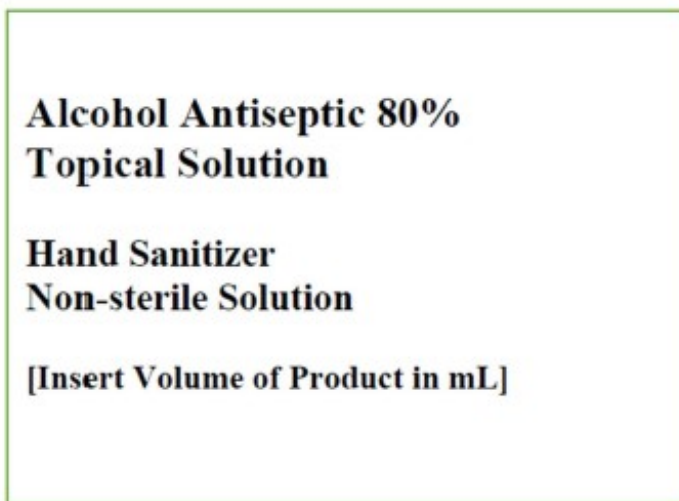
Glycerin, Hydrogen Peroxide, Water

For external use only

Keep out of reach of children

Sanitizer - for hands

For external use only, flammable, keep away from heat or flame.



DRUG FACTS LABEL

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 • 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.	
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	

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74054-100
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
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74054-100-01	287 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/26/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/26/2020	

Labeler - Robert Mazza, Inc dba Five & 20 Spirits (114974231)

Registrant - Robert Mazza, Inc. (114974231)

Establishment

Name	Address	ID/FEI	Business Operations
Robert Mazza, Inc.		114974231	manufacture(74054-100)

Revised: 3/2020

Robert Mazza, Inc dba Five & 20 Spirits