

**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.*

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For topical use only

Alcohol - 80%ABV

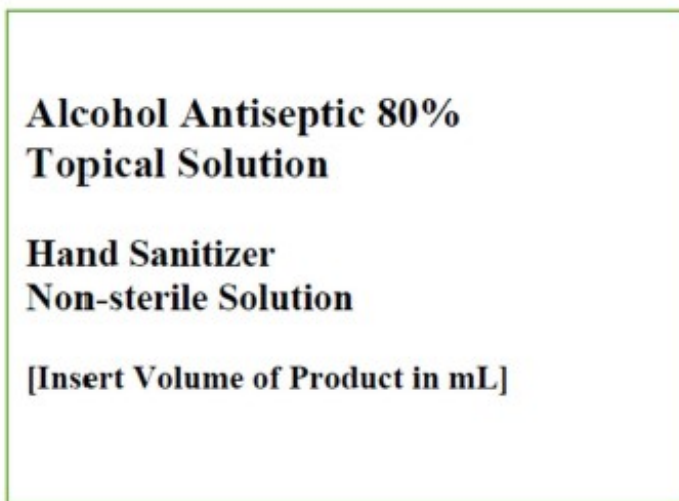
Glycerin, Hydrogen Peroxide, Water

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**

<b>Drug Facts</b>	
<b>Active Ingredient[s]</b> Alcohol 80% v/v.....	<b>Purpose</b> Antiseptic
<b>Use[s]</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> 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 <b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. <b>Stop use and ask a doctor</b> 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.	
<b>Directions</b> • 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.	
<b>Other information</b> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive Ingredients</b> glycerin, hydrogen peroxide, purified water USP	

alcohol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74054-100
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74054-100-02	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/26/2020	
2	NDC:74054-100-03	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/26/2020	
3	NDC:74054-100-04	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/26/2020	
4	NDC:74054-100-05	18927 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/26/2020	
5	NDC:74054-100-06	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/26/2020	
6	NDC:74054-100-07	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/26/2020	

### Marketing Information

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

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

**Registrant** - Robert Mazza, Inc. (114974231)

### Establishment

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

Revised: 4/2020

Robert Mazza, Inc dba Five & 20 Spirits