

HAND SANITIZER- alcohol gel
Ningbo Roni Cosmetic Co., Ltd

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.

Roni, Hand Sanitizer, Ethyl Alcohol 67% w/w, Gel, 59mL

Active Ingredient(s)

Ethyl Alcohol 67% w/w. Purpose: Antimicrobial

Purpose

Antimicrobial.

Use

Uses for handwashing to decrease bacteria on the skin.

Warnings

For external use only.

Flammable, keep away from heat and flame.

Do not use

Do not use in the eyes. In case of contact, rinse eyes thoroughly with water.

When using this product, do not use in or near the eyes or wound.

Stop use and ask a doctor if irritation and redness develop and persist for more than 72 hours.

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Directions

- Dispense product evenly on palms or on material surface and rub your hands until dry.
- Children should be under adult supervision when using this product.
- No dilute required.

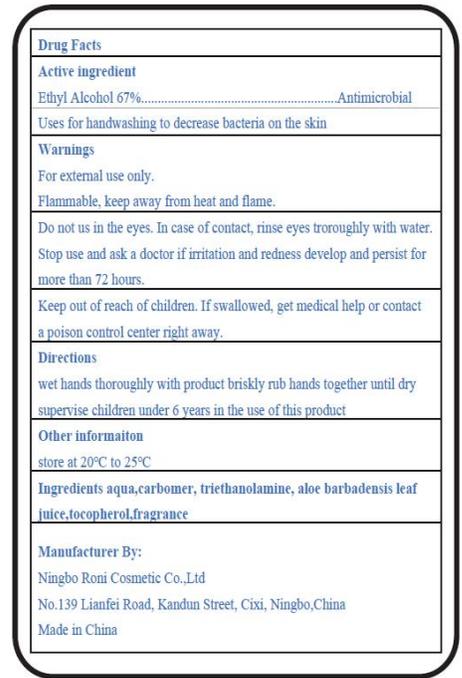
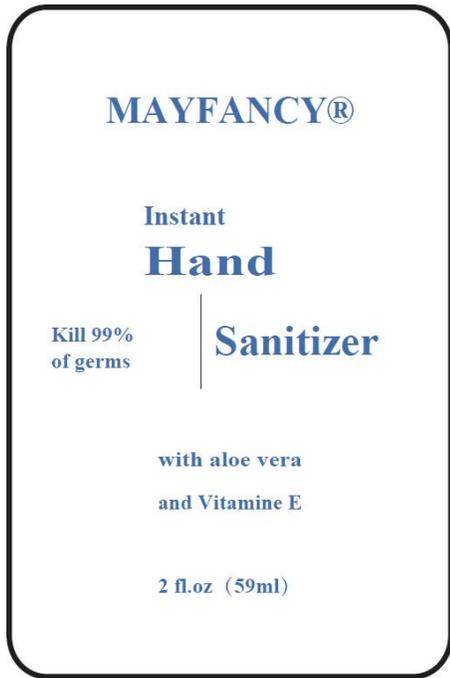
Other information

Store at 20° to 25°.

Inactive ingredients

Aqua, Carbomer, Triethanolamine, Aloe barbadensis leaf juice, Tocopherol, Fragrance.

Package Label - Principal Display Panel



HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77309-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	43.365 mL in 59 mL

Inactive Ingredients

Ingredient Name	Strength
.GAMMA.-TOCOPHEROL (UNII: 8EF1Z1238F)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
WATER (UNII: 059QF0K00R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TROLAMINE (UNII: 9O3K93S3TK)	
CLOVE (UNII: K48IKT5321)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77309-101-17	200 in 1 CARTON	05/12/2020	
1	NDC:77309-101-01	59 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/12/2020	

Labeler - Ningbo Roni Cosmetic Co., Ltd (411892769)

Registrant - A03 Lab of BTS (548009541)

Establishment

Name	Address	ID/FEI	Business Operations
Ningbo Roni Cosmetic Co., Ltd		411892769	manufacture(77309-101) , label(77309-101)

Revised: 5/2020

Ningbo Roni Cosmetic Co., Ltd