

TOPICAL HAND SANITIZER- alcohol solution
Colorina Makeup Inc.

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.

Topical Solution 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

- 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.

- Store between 15-30C (104F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, aqua(sterile distilled water)

Package Labeling:



TOPICAL HAND SANITIZER

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77602-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.8 mL in 1 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:77602-001-60	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/25/2020	

Labeler - Colorina Makeup Inc. (942265781)

Establishment			
Name	Address	ID/FEI	Business Operations
Zhejiang Pure Essential Cosmetic Co., Ltd.		543035759	manufacture(77602-001)

Revised: 5/2020

Colorina Makeup Inc.