HAND SANITIZER- alcohol gel 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.

Hand Sanitizer

Drug Facts

Active ingredient(s)

Alcohol 70 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
- Superive children under 6 years of age when using this product to avoid swallowing

Other information

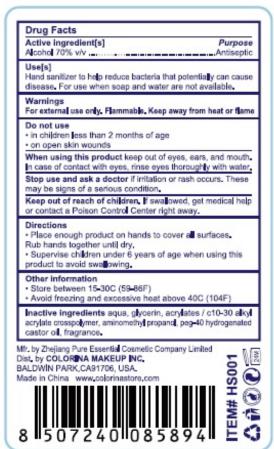
- Store between 15-30C(59-86F)
- Avoid freezing and excessive heat above 40C(104F)

Inactive ingredients

aqua, glycerin, acrylates / c10-30 alkyl acrylate crosspolymer, aminomethly propanol, peg-40 hydrogenated castor oil, fragrance

Package Labeling





HAND SANITIZER

alcohol gel

-		TC	. •
Pro	anct	Intor	mation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:77602-000

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients Ingredient Name Strength WATER (UNII: 059QF0KO0R) GLYCERIN (UNII: PDC6A3C0OX)

CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)

AMINOMETHYLPROPANOL (UNII: LU49E6626Q) POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)

l	Packaging				
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NI	DC:77602-000-60	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/06/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/06/2020	

Labeler - Colorina Makeup Inc (942265781)

Establishment			
Name	Address	ID/FEI	Business Operations
Zhejiang Pure Essential Cosmetic Co., Ltd.		543035759	manufacture(77602-000)

Revised: 5/2020 Colorina Makeup Inc