

HAND SANITIZER- alcohol liquid
HANGZHOU AROMA ELECTRONIC COMMERCE 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.

HAND SANITIZER

Active Ingredient

Alcohol 68% Purpose: Antiseptic

Purpose

Antiseptic

Use

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.

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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.

Inactive ingredients

Deionized water, Aloe Barbadensis Gel, Fragrance, Glycerin, Propylene Glycol, Carbomer, Trolamine, FD&C Red 4#, FD&C Yellow 5#, FD&C Blue 1#.

Package Label - Principal Display Panel

Drug Facts

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Alcohol 68%.....	Antiseptic

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Kills 99.99% of Most Common Germs That May Cause Illness

Distributed by
Company Name Co. Inc.
xxxxxxxxxx, Country

MADE IN CHINA



HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78881-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	68 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	

TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA WHOLE (UNII: KIZ4X2EHYX)	
DIHYDRO PENTAMETHYLINDANONE (UNII: BZR4438MY4)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78881-001-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/09/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/09/2020	

Labeler - HANGZHOU AROMA ELECTRONIC COMMERCE CO.,LTD (547703131)

Establishment			
Name	Address	ID/FEI	Business Operations
HANGZHOU AROMA ELECTRONIC COMMERCE CO.,LTD		547703131	manufacture(78881-001)

Revised: 6/2020

HANGZHOU AROMA ELECTRONIC COMMERCE CO.,LTD