

HAND SANITIZER- hand sanitizer gel**Jiangxi Iris Chemical 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[s]**

Alcohol(Ethanol)74%V/v.

Purpose

Antiseptic

Use[s]

To help sanitize hands

Warnings

Flammable. Keep away from fire or flame
For external use only.

Do not use

on 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 product on hands

Rub until dry.

Adult supervision required for children under 6 years old.

Other information

Store between 15-30°C(59-86°F)

Avoid freezing and excessive heat above 40°C(104°F)

Inactive ingredients

Water, Carbomer, Triethanolamine.

Package Label - Principal Display Panel

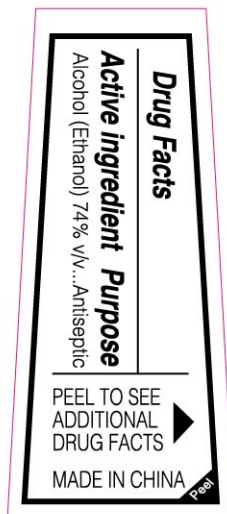
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0.78" x 1.77"

20x45mm



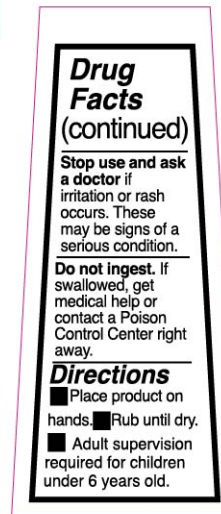
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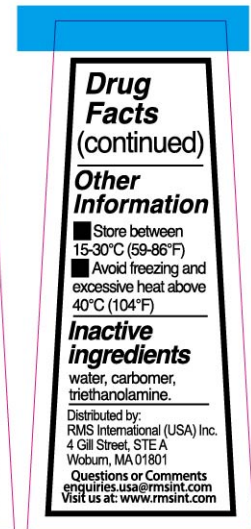
1 layer



2 layer



2 layer back



3 layer

label size:
1.37" x 1.18"
35x30mm



layer

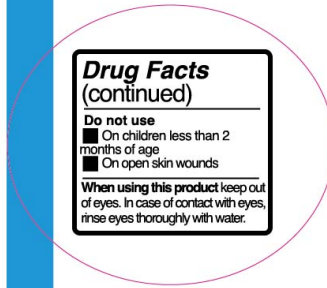


1 layer front



1 layer back

5mm

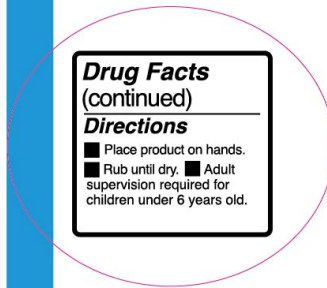


2 layer front



2 layer back

5mm



3 layer front



3 layer back

5mm



4 layer

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74440-009
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	74 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74440-009-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/21/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/21/2020	

Labeler - Jiangxi Iris Chemical Co.,Ltd (544366795)

Registrant - Jiangxi Iris Chemical Co.,Ltd (544366795)

Establishment

Name	Address	ID/FEI	Business Operations
Jiangxi Iris Chemical Co.,Ltd		544366795	manufacture(74440-009)

Revised: 7/2020

Jiangxi Iris Chemical Co.,Ltd