

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 75%

Purpose

Antiseptic

Use[s]

Hand Sanitizer to decrease bacteria on the skin that could cause disease.

Use anywhere, anytime; car, office, handbag, picnics, nappy change, camping, travel.

Warnings

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

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 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.

Other information

Store between 15-30C(59-86F)

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

Inactive ingredients

Water(Aqua) , Carbomer, Triethanolamine.

Package Label - Principal Display Panel

IR20Y0248

60ml hand sanitiser SIZE:36x46mm



front



back

IR20Y0249 500ml hand sanitiser SIZE:236x82mm



HAND SANITIZER

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74440-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74440-007-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/21/2020	
2	NDC:74440-007-02	500 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(74440-007)

Revised: 5/2020

Jiangxi Iris Chemical Co.,Ltd