

## **HAND SANITISER- hand sanitiser 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 SANITISER**

#### **Active ingredient[s]**

Alcohol 75%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.

#### **Other information**

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

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

## Inactive ingredients

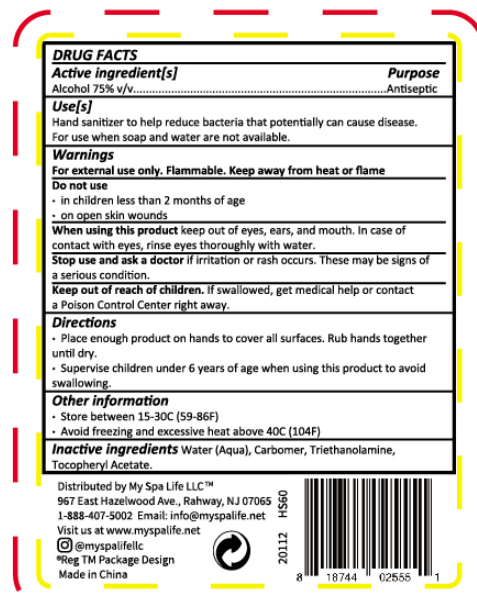
Water(Aqua) ,Carbomer,Triethanolamine,Tocopheryl Acetate.

## Package Label - Principal Display Panel

5-1.60ml label SIZE:36x46mm



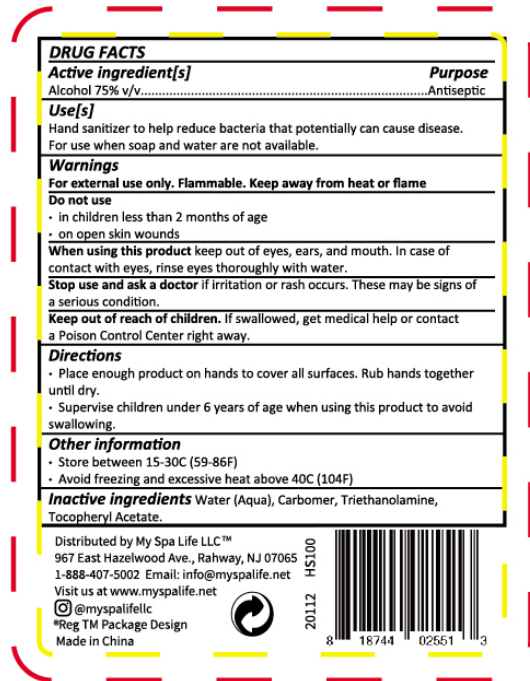
FRONT



BACK

CLEAR LABEL  
BLACK COPY

5-2.100ml label SIZE:40x52mm



5-3.250ml label SIZE:45x70mm



<b>DRUG FACTS</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Alcohol 75% v/v.....	Antiseptic
<b>Use[s]</b>	
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
<b>For external use only. Flammable. Keep away from heat or flame</b>	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>in children less than 2 months of age</li> <li>on open skin wounds</li> </ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>Store between 15-30C (59-86F)</li> <li>Avoid freezing and excessive heat above 40C (104F)</li> </ul>	
<b>Inactive ingredients</b> Water (Aqua), Carbomer, Triethanolamine, Tocopheryl Acetate.	

Distributed by My Spa Life LLC™  
 967 East Hazelwood Ave., Rahway, NJ 07065  
 1-888-407-5002 Email: info@myspalife.net  
 Visit us at www.myspalife.net  
 @myspalifelife  
 Reg TM Package Design  
 Made in China

HS250

20112


5-4.500ml label SIZE:55x85mm



<b>DRUG FACTS</b>	
<b>Active ingredient[s]</b> Alcohol 75% v/v.....	<b>Purpose</b> .....Antiseptic
<b>Use[s]</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> <b>For external use only. Flammable. Keep away from heat or flame</b> <b>Do not use</b> <ul style="list-style-type: none"><li>• in children less than 2 months of age</li><li>• on open skin wounds</li></ul> <b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. <b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> <ul style="list-style-type: none"><li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li><li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li></ul>	
<b>Other information</b> <ul style="list-style-type: none"><li>• Store between 15-30C (59-86F)</li><li>• Avoid freezing and excessive heat above 40C (104F)</li></ul>	
<b>Inactive ingredients</b> Water (Aqua), Carbomer, Triethanolamine, Tocopheryl Acetate.	

HS500

Distributed by My Spa Life LLC™  
967 East Hazelwood Ave., Rahway, NJ 07065  
1-888-407-5002 Email: info@myspallife.net  
Visit us at www.myspallife.net  
@myspallifellc  
Reg TM Package Design  
Made in China



20112 8 18744 02553 7

5-5.1000ml label SIZE:75x110mm



**DRUG FACTS**

<b>Active ingredient[s]</b> Alcohol 75% v/v.....	<b>Purpose</b> Antiseptic
<b>Use[s]</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> <b>For external use only. Flammable. Keep away from heat or flame</b> <b>Do not use</b> • in children less than 2 months of age • on open skin wounds <b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. <b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition. <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • 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.	
<b>Other information</b> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b> Water (Aqua), Carbomer, Triethanolamine, Tocopheryl Acetate.	

HS1000

Distributed by My Spa Life LLC™  
967 East Hazelwood Ave., Rahway, NJ 07065  
1-888-407-5002 Email: info@myspalife.net  
Visit us at www.myspalife.net  
@myspalifellc  
\*Reg TM Package Design  
Made in China

## HAND SANITISER

hand sanitiser gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74440-013
<b>Route of Administration</b>	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
CARBOMER HO M O P O L Y M E R, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)	
.ALPHA.-T O C O P H E R O L A C E T A T E (UNII: 9 E8 X80D2L0)	
T R O L A M I N E (UNII: 9 O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74440-013-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/07/2020	
2	NDC:74440-013-02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/07/2020	
3	NDC:74440-013-03	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/07/2020	
4	NDC:74440-013-04	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/07/2020	
5	NDC:74440-013-05	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/07/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/07/2020	

**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(74440-013)

Revised: 5/2020

Jiangxi Iris Chemical Co.,Ltd