

HAND SANITIZER NON-STERILE- hand sanitizer non-sterile solution
Guangzhou Shiruoni Cosmetics 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.

75605-008

HAND SANITIZER NON-STERILE SOLUTION

Active Ingredient(s)

Isopropyl alcohol 75% v/v

Purpose

Antiseptic

Use

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

WARNING

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

deionized water, aloe barbadensis extract, carbomer, arginine, silver ions

Package Label - Principal Display Panel

Made in China
Exclusively for: Impacta Health, LLC
14205 Woodcliff Ct Suite #104
Bowie, MD 20720
www.impactahealth.com

MFG: 05/2020
EXP: 05/2022



IH-SAN-B1008



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**IMPACTA
HEALTH**

**HAND SANITIZER
NON-STERILE SOLUTION**

Isopropyl Alcohol Antiseptic
75% Topical Solution

8.5 fl.oz. (252ml)

Drug Facts

Active ingredient[s].....**Purpose**
Isopropyl alcohol 75% v/v.....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.

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

Inactive ingredients deionized water, aloe barbadensis extract, carbomer, arginine, silver ions.



**IMPACTA
HEALTH**

**HAND SANITIZER
NON-STERILE SOLUTION**

Isopropyl Alcohol Antiseptic
75% Topical Solution

2 fl. oz. (60ml)

Drug Facts

Active ingredient[s].....**Purpose**
Isopropyl alcohol 75% v/v.....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.

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Directions
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• 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 deionized water, aloe barbadensis extract, carbomer, arginine, silver ions.



IH-SAN-B1002



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IH-SAN-B1016



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**IMPACTA
HEALTH**

**HAND SANITIZER
NON-STERILE SOLUTION**

Isopropyl Alcohol Antiseptic
75% Topical Solution

16.9 fl.oz. (500ml)

Drug Facts

Active ingredient[s].....**Purpose**
Isopropyl alcohol 75% v/v.....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.

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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.

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

Inactive ingredients deionized water, aloe barbadensis extract, carbomer, arginine, silver ions.



IMPACTA HEALTH

**HAND SANITIZER
NON-STERILE SOLUTION**

**Isopropyl Alcohol Antiseptic
75% Topical Solution**

12 fl.oz. (355ml)

Drug Facts

Active ingredient(s).....**Purpose**
Isopropyl alcohol 75% v/v.....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.

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 deionized water, aloe barbadensis extract, carbomer, arginine, silver ions.



IH-SAN-B1012



MFG:05/2020

EXP: 05/2022

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HAND SANITIZER NON-STERILE

hand sanitizer non-sterile solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75605-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ARGININE (UNII: 94ZLA3W45F)	
CARBOMER HO MO POL YMER, UNSPECIFIED TYPE (UNII: 0 A5MM30 7FC)	
ALOE VERA LEAF (UNII: ZY8 1Z83H0 X)	
HYDROGEN PERO XIDE (UNII: BBX060 AN9V)	
WATER (UNII: 059QF0 KO0R)	

SILVER CATION (UNII: 57N7B0K90A)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75605-008-03	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/21/2020	
2	NDC:75605-008-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/21/2020	
3	NDC:75605-008-02	252 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/21/2020	
4	NDC:75605-008-04	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/21/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/21/2020	

Labeler - Guangzhou Shiruoni Cosmetics Co.,Ltd (551125378)

Establishment

Name	Address	ID/FEI	Business Operations
Guangzhou Shiruoni Cosmetics Co.,Ltd		551125378	manufacture(75605-008)

Revised: 8/2020

Guangzhou Shiruoni Cosmetics Co.,Ltd