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



IMPACTA

HEALTH

HAND SANITIZER NON-STERILE SOLUTION

Isopropyl Alcohol Antiseptic 75% Topical Solution

16. 9 fl.oz. (500ml)

HAND SANITIZER NON-STERILE SOLUTION

Isopropyl Alcohol Antiseptic 75% Topical Solution

2 fl. oz. (60ml)

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

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MFG:05/2020

EXP: 05/2022

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IH-SAN-B1002

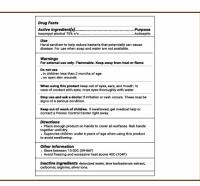


Other information • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)

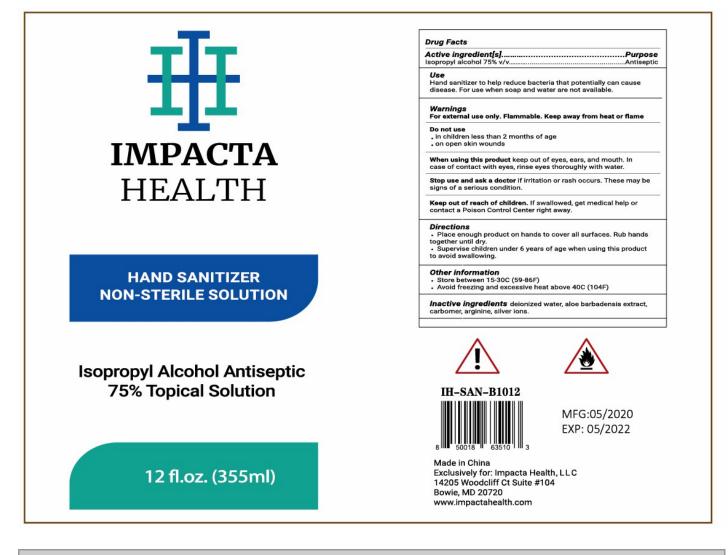
Inactive ingredients deionized water, aloe barbadensis extract, carbomer, arginine, silver ions.

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



HAND SANITIZER NON-STERILE

hand sanitizer non-sterile solution

| Product Information | | | | | | | | | |
|---|------------------------------|--------------------|----------------------|--------|--------------------|--|--|--|--|
| Product T ype | HUMAN OTC DRUG | Item Code (Source) | | NDC:75 | NDC:75605-008 | | | | |
| Route of Administration | TOPICAL | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| Active Ingredient/Active Moiety | | | | | | | | | |
| Ing | gredient Name | | Basis of Str | ength | 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 HOMOPOLYMER, UNS | PECIFIED TYPE (UNII: 0 A5MM3 | 07FC) | | | | | | | |
| ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 | X) | | | | | | | | |
| | 60AN9V) | | | | | | | | |

WATER (UNII: 059QF0KO0R)

| 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 | | y Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | | | | |
| 0 | TC monograph not fin | al 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