

HAND SANITIZER- alcohol hand sanitizer gel
Shanghai Soap 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.

SSC, Sanitizer, 75% Alcohol, Gel; 500mL

Active Ingredient(s)

Ethyl alcohol 75% v/v. Purpose: Antiseptic

Purpose

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 on children less than 2 months of age
- Do not use on open skin wounds

When using this product keep out of eyes, ears, and mouth.

If 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.

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 59-86 °F (15-30 °C).

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

Inactive ingredients

Water (Aqua), Acrylates/C10-30 Alkyl/Acrylate Crosspolymer, Triethanolamine, Glycerin, Aloe Extract, Panthenol (pro-Vitamin B5)

Package Label - Principal Display Panel



ANTIBACTERIAL HAND SANITISER

Moisturising

with glycerin and pro- Vitamin B5



Manufacturer: Shanghai soap co., Ltd.
Add: 2310 Yangshupu Road, Yangpu Dist.,
Shanghai 200090

MADE IN CHINA



Expiry date see base of bottle.



ANTIBACTERIAL HAND SANITISER

Moisturising

with glycerin and pro- Vitamin B5



NO RINSE

KILLS
99.99% of
Most Common Germs

16.9 FL OZ (500 ml)



- Quick & convenient
- With added moisturisers
- Leaves hands soft, refreshed & hygienically clean

| | |
|--|----------------|
| Drug Facts | |
| Active ingredient(s) | Purpose |
| Ethyl alcohol 75% v/v..... | Antibiotic |
| 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 seek 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), Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Glycerin, Aloe Extract, Panthenol(Pro-Vitamin B5) | |

HAND SANITIZER

alcohol hand sanitizer gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76390-0108 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|------------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 375 mL in 500 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| WATER (UNII: 059QF0K00R) | |
| CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| DEXPANTHENOL (UNII: 1O6C93RI7Z) | |
| ALOE (UNII: V5VD430YW9) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:76390-0108-1 | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/11/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 06/11/2020 | |

Labeler - Shanghai Soap Co., Ltd. (545258233)

Registrant - A03 Lab of BTS (548009541)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---|
| Shanghai Soap Co., Ltd. | | 545258233 | label(76390-0108) , manufacture(76390-0108) |

Revised: 6/2020

Shanghai Soap Co., Ltd.