INSTANT HAND SANITIZER- hand sanitizer gel Whealth Lohmann Centralin (GZ) 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.

Active Ingredient(s)

Alcohol 66% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

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.

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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 15-40C (59-104F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

carbomer, fragrance, glycerin, purified water USP, triethanolamine.

Package Label - Principal Display Panel

520 mL NDC: 77976-001-95









INSTANT HAND SANITIZER

hand sanitizer gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:77976-001

Route of Administration TOPICAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|--------------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 343.2 mL in 520 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------------------|
| FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK) | 0.104 mL in 520 mL |
| TROLAMINE (UNII: 903K93S3TK) | 0.884 mL in 520 mL |
| GLYCERIN (UNII: PDC6A3C0OX) | 5.2 mL in 520 mL |
| CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208) | 1.3 mL in 520 mL |
| WATER (UNII: 059QF0KO0R) | 169.312 mL in 520 mL |

| P | ackaging | | | |
|---|----------------------|---|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | NDC:77976-001- 95 | 520 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 05/28/2020 | |

| Marketing Information | | | |
|-------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part333A | 05/28/2020 | |
| | | | |

Labeler - Whealth Lohmann Centralin (GZ) Co., Ltd (545350568)

Registrant - Whealth Lohmann Centralin (GZ) Co., Ltd. (545350568)

| Establishment | | | | |
|--|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Whealth Lohmann Centralin (GZ) Co., Ltd. | | 545350568 | manufacture(77976-001) | |

Revised: 7/2020 Whealth Lohmann Centralin (GZ) Co., Ltd