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 10-40C (40-104F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

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

Package Label - Principal Display Panel

1000 mL NDC: 77976-001-10



INSTANT HAND SANITIZER

Drug Facts

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Inactive ingredients purified water USP, glycerin, carbomer, triethanolamine, fragrance Questions? 86-20-37966013

[Validity period] Two years [Production date] See Outer Packaging [Production Batch Number] See Outer Packaging Manufactured by: Whealth Lotmann Centralin (GZ) Co., Ltd. Address: No.8 Welye Road, Mingzhu Industrial District, Conghua, Guangshou (by, \$10931), Ohin.









INSTANT HAND SANITIZER

hand sanitizer gel

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Product TypeHUMAN OTC DRUGItem 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	660 mL in 1000 mL

Inactive Ingredients			
Ingredient Name	Strength		
TROLAMINE (UNII: 9O3K93S3TK)	1.7 mL in 1000 mL		

GLYCERIN (UNII: PDC6A3C0OX)	10 mL in 1000 mL
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	2.5 mL in 1000 mL
WATER (UNII: 059QF0KO0R)	325.6 mL in 1000 mL
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	0.2 mL in 1000 mL

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:77976-001- 10	1000 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.