## LINGRUI HAND ANTISEPTIC RINSE FREE- hand sanitizer gel Henan Lingrui Biopharmaceutical 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.

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## LingRui, Sanitizer, Ethanol 68%, Gel

## **Active Ingredient(s)**

Ethanol 68% v/v. Purpose: Antiseptic

## Purpose

For hygienic hand antisepsis.

#### Use

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

## **Warnings**

Flammable. For external use only. Keep away from heat or flame.

- 1. Only external use, oral administration is prohibited.
- 2. Keep out of reach of children.
- 3. Those who are allergic to this product (alcohol, ethanol) are contraindicated.

#### Do not use

- on children less than 2 months of age
- on open skin wounds
- in the eyes. in case of contact, rinse eyes thoroughly with water

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 and redness develop and persist for more than 72 hours.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

Apply appropriate amount of this product to wash both hands and scrub for 1-3mins.

#### Other information

Store in sealed, cool and dark condition.

### **Inactive ingredients**

## Package Label - Principal Display Panel





[Description]Lingrui Hand Antiseptic Rinse Free Gel

[Dosage Form] Gel

[Main Ingredients] Ethanol, Glycerin, Carbomer [Active Ingredient] Ethanol 65% - 75% (V/V) [Germicidal Spectrum] Escherichia coli, Staphylococcus aureus, Candida albicans, Pseudomonas aeruginosa.

[Purpose] For hygienic hand antisepsis.
[Directions] Apply appropriate amount of this product to wash both hands and scrub for 1-3mins.

#### [Cautions]

- Only external use, oral administration is prohibited.
- 2. Keep out of reach of children.
- 3. Those who are allergic to this product are contraindicated.
- 4. Store in sealed, cool and dark condition.

[Production License] License Number of Healthcare Sterilization Henan 20040023 [Executive Standards] Q/LRSW019-2020 [Net Content] 60ml [Expiring Date] 1 year Batch No. and Expiry date: see tube end [Manufacturer] Henan Lingrui Biopharmaceutical Co.,Ltd [Adress] Lingrui industrial park, Xinxian County, Henan Province, China [Tel] 0086-376-2980666 [Fax] 0086-376-2968888 [Postcode] 465550 Made in China



### LINGRUI HAND ANTISEPTIC RINSE FREE

hand sanitizer gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42217-0110
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	40.6 mL in 60 mL

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)		
TRICLOSAN (UNII: 4NM5039Y5X)		
TROLAMINE (UNII: 9O3K93S3TK)		
WATER (UNII: 059QF0KO0R)		
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)		

ı	Packaging			
	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
	1 NDC:42217-0110-	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/27/2020	

## LINGRUI HAND ANTISEPTIC RINSE FREE

hand sanitizer gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42217-0115
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	340 mL in 500 mL

Strength

Packaging				
# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
1 NDC:42217-0115-1	$500\ mL$ in $1\ BOTTLE;$ Type $0\colon Not\ a\ Combination\ Product$	04/27/2020		
Marketing In	formation			
Marketing In		Marketing Start Date	Marketing End Date	
	ory Application Number or Monograph Citation	Marketing Start Date 04/27/2020	Marketing End Date	

# Labeler - Henan Lingrui Biopharmaceutical Co., Ltd (528000440)

## **Registrant -** A03 Lab of BTS (548009541)

Establishment				
Name	Address		Business Operations	
Henan Lingrui Biopharmaceutical Co., Ltd		528000440	label(42217-0115, 42217-0110), manufacture(42217-0115, 42217-0110)	

Revised: 4/2020 Henan Lingrui Biopharmaceutical Co., Ltd