

**HAND SANITIZER- alcohol hand sanitizer gel**  
**Ningbo Lanzi Cosmetic Technology 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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**Lanzi, Hand Sanitizer, 68% Ethyl Alcohol, Gel, xx mL**

**Active Ingredient(s)**

Ethyl Alcohol 68% w/w. Purpose: Antiseptic

**Purpose**

Antiseptic

**Use**

For hand sanitizing to reduce bacteria on the skin.

**Warnings**

Flammable.

Keep away from fire or flame.

For external use only.

Do not inhale or ingest.

**Do not use**

Do not inhale or ingest.

When using this product Keep out of eyes.

In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears or lasts.

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

**Directions**

Squeeze out enough product in your palm to cover hands and rub hands together briskly until dry.

**Other information**

Store below 110°F (43°C).

**Inactive ingredients**

Ethyl Alcohol, Glycerin, Propylene Glycol, Triethanolamine, Carbomer, Fragrance, Disodium EDTA, Tocopheryl Acetate, Deionized Water.

**Package Label - Principal Display Panel**

The image shows the principal display panel of a hand sanitizer package. The label features a dark blue background with white and red text. At the top, it says 'COOL BREEZE' in a white oval. Below that, 'Hand Sanitizer' is written in large, bold, blue letters. Underneath, it says 'GEL Antibacterial' and includes an icon of hands being washed. A prominent red and black graphic states 'Kills 99.99% Of Germs!'. Below this, it says 'INSTANT SANITIZING' in a white box on a dark blue background, followed by '68% Alcohol Disinfectant'. At the bottom left, it says 'clean hands save lives!' and includes a red circular logo with a white cross. On the right side of the label, there is a white box containing product information: 'Kills 99.99% Of Germs!', 'Hand Sanitizer', 'Drug Facts', 'Active Ingredient' (Ethyl Alcohol 68%), 'Purpose' (Antiseptic), 'Uses' (For hand sanitizing to reduce bacteria on the skin), 'Warnings' (Flammable. Keep away from fire or flame. For external use only. When using this product Keep out of eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask doctor if irritation or rash appears and lasts. Do not inhale or ingest. Keep out of reach of children.), 'Directions' (Squeeze out enough product in your palm to cover hands and rub hands together briskly until dry.), 'Other information' (Store below 110 °F (43°C)), and 'Inactive ingredients' (Water(Aqua), Carbomer, Triethanolamine, Glycerin, Propylene glycol, Fragrance, Disodium EDTA, Tocopheryl Acetate).

<b>HAND SANITIZER</b>			
alcohol hand sanitizer gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75613-101
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	68 g in 100 mL
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## Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
CLOVE (UNII: K48IKT5321)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75613-101-21	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2022	
2	NDC:75613-101-22	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2022	
3	NDC:75613-101-30	15 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2022	
4	NDC:75613-101-31	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2022	
5	NDC:75613-101-32	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2022	
6	NDC:75613-101-33	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2022	
7	NDC:75613-101-71	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2022	
8	NDC:75613-101-72	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2022	
9	NDC:75613-101-75	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2022	
10	NDC:75613-101-76	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2022	
11	NDC:75613-101-77	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2022	
12	NDC:75613-101-79	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2022	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/03/2022	

**Labeler** - Ningbo Lanzi Cosmetic Technology Co., Ltd (554530929)

## Establishment

Name	Address	ID/FEI	Business Operations
Ningbo Lanzi Cosmetic Technology Co., Ltd		554530929	manufacture(75613-101) , label(75613-101)

Revised: 3/2022

Ningbo Lanzi Cosmetic Technology Co., Ltd