

## **PRACTICAL CARE HAND SANITIZER- ethyl alcohol liquid**

**Lindie Nzie Trading and Business Services**

*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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### **Hand Sanitizer**

#### **Active Ingredient(s)**

Alcohol 70% 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.

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.

#### **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**

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel and Information Panel 1 Liter



Antiseptic Hand Sanitizer  
Ethyl Alcohol 70%  
Non-sterile Solution

1000 mL NDC: 77682-001-02

**Drug Facts**

Active Ingredient[s]	Purpose
Ethyl alcohol 70%.....	Antiseptic

**Use** for hand sanitizing to decrease bacteria on the skin

**Warnings**

Flammable. Keep away from fire or flame.

For external use only.

**Do not use**

- on open skin wounds
- on children less than 2 months of age

**When using this product**

- avoid contact with eyes
- in case of eye contact, rinse eyes thoroughly with water.

**Stop use and ask a doctor if** irritation or redness develops and lasts 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**

- wet hands thoroughly with product
- allow to dry without wiping

**Other Information**

- store between 15-30°C (59-86°F)
- avoid freezing and excessive heat above 40°C (104°F)

**Inactive Ingredients**

Glycerin, hydrogen peroxide, purified water USP

Manufactured date:

Batch no:

Manufactured by - Linzie Nzie Trading, South Africa  
Imported and Distributed by BJM Products Inc. 6 Cedarhill  
Park Drive #13 Plymouth MA 02360 • 800-685-1859

**PRACTICAL CARE HAND SANITIZER**

ethyl alcohol liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77682-001
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77682-001-02	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/11/2020	
2	NDC:77682-001-03	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/11/2020	
3	NDC:77682-001-04	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/11/2020	
4	NDC:77682-001-05	5000 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** - Lindie Nzie Trading and Business Services (538995764)

**Registrant** - Lindie Nzie Trading and Business Services (538995764)

### Establishment

Name	Address	ID/FEI	Business Operations
Lindie Nzie Trading and Business Services		538995764	manufacture(77682-001)

Revised: 8/2020

Lindie Nzie Trading and Business Services