

PRIMEAUTY BOTTLE (PUMP)- alcohol liquid
Huizhou New Road Cosmetics Company Limited

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.

Primeauty (PET Bottle w/ pump)

Active Ingredient(s)

Ethyl Alcohol 75% Purpose: Antimicrobial

Purpose

Antimicrobial

Uses

- For hand washing to decrease bacteria on the skin
- Recommended for repeated use

Warnings

- **Do not use** in the eyes. In case of contact, rinse eyes thoroughly with water.
- **for external use only.**
- **Flammable, keep away from heat and flame**

- **Stop use and ask a doctor if**
- irritation and redness develop and persist for more than 72 hours
- Swallowed, get medical help or contact a poison control center right away.

Keep out of reach of children. Children must be supervised in use of this product.

Directions

- Put enough product on hands to cover all surfaces. Rub hands together until dry.
- Children under 6 years of age should be supervised when using this product.

Other information

- Store below 110F (43C)
- May discolor certain fabrics or surfaces

Inactive ingredients

Water, Glycerin, Carbomer, Triethanolamine, Tocopheryl Acetate, Aloe

Package Label - Principal Display Panel

Primeauty
Instant Hand Sanitizer GEL
 Kills 99.999% of GERMS
 With Moisturizer Aloe & Vitamin E
 Leaves Hands Feeling Soft & Refreshed
 16.9 FL OZ (500ml)

Drug Facts	
Active ingredient (in each dosage unit)	Purpose
Ethyl Alcohol 75%	Antimicrobial
Uses	
<ul style="list-style-type: none"> For hand washing to decrease bacteria on the skin Recommended for repeated use 	
Warnings	
<ul style="list-style-type: none"> Do not use in the eyes. In case of contact, rinse eyes thoroughly with water. for external use only Flammable, keep away from heat and flame. Stop use and ask a doctor if Irritation and redness develop and persist for more than 72 hours. Swallowed, get medical help or contact a poison control center right away. 	
Keep out of reach of children. Children must be supervised in use of this product.	
Directions:	
Put enough product in your palm to cover hands and rub hands together until dry. Children under 6 years of age should be supervised when using this product	
Other information:	
<ul style="list-style-type: none"> Store below 110°F (43°C) May discolor certain fabrics or surfaces 	

Validity Date: 2 years
 Lot No./Exp Date: Shown in the bottle
 Production Location: Huizhou, Guangdong
 Production Company: Huizhou New Road Cosmetics Company Limited
 Address:
 Room 1902-1903, No. 2 Building, West Area, Ganghui No. 7 Yanda Road, Huizhou City, Guangdong Province, China
 Tel: 0752-7385616
 Fax: 0752-7385616
 Postcode: 516006
 Web: <https://mcosmetic.en.alibaba.com>

CE, No flame, No children
 16.9 FL OZ (500ml)
 Made in China
 6 973115 730008

PRIMEAUTY BOTTLE (PUMP)

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75150-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75150-001-01	240 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/22/2020	
2	NDC:75150-001-02	250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/22/2020	

3	NDC:75150-001-03	300 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/22/2020	
4	NDC:75150-001-04	350 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/22/2020	
5	NDC:75150-001-05	400 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/22/2020	
6	NDC:75150-001-06	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/22/2020	
7	NDC:75150-001-07	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/22/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/22/2020	

Labeler - Huizhou New Road Cosmetics Company Limited (554530156)

Establishment

Name	Address	ID/FEI	Business Operations
Huizhou Duomei Daily Necessities Co., Ltd.		554530153	manufacture(75150-001)

Revised: 4/2020

Huizhou New Road Cosmetics Company Limited