PRIMEAUTY HDPE BARREL W/ PUMP- ethyl 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 (HDPE Barrel 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 HDPE BARREL W/ PUMP ethyl alcohol liquid												
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Product Information												
Product T ype			HUMAN OTC DRUG	Item Code (Source)		NDC:75150-003						
Route of Administration			TOPICAL									
Active Ingredient/Active Moiety												
Ingredient Name					Basis of Strengtl		Strength					
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V9					ALCOHOL		75 L in 100 L					
Inactive Ingredients												
Ingredient Name												
G	LYCERIN (UNII: PDC	6A3C0OX)										
WATER (UNII: 059QF0K00R)												
	LOE VERA LEAF (UI		,									
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)												
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)												
Packaging												
#	Item Code		Package Description	Mark	eting Start Date	Mark	eting End Date					
1	NDC:75150-003-01	1 L in 1 DRUM;	Type 0: Not a Combination Prod	uct 04/22/2	020							
2	NDC:75150-003-02	2 L in 1 DRUM;	Type 0: Not a Combination Prod	uct 04/22/2	020							
3	NDC:75150-003-03	4 L in 1 DRUM;	Type 0: Not a Combination Prod	uct 04/22/2	020							

04/22/2020

4 NDC:75150-003-04 5 L in 1 DRUM; Type 0: Not a Combination Product

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OTC monograph not fin	al part333A	04/22/2020								
Marketing Categor	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date							
Marketing Information										
9 NDC:75150-003-08	20 L in 1 DRUM; Type 0: Not a Combination Product	04/22/2020								
	· • • •									
8 NDC:75150-003-09	50 L in 1 DRUM; Type 0: Not a Combination Product	04/22/2020								
7 NDC:75150-003-07	25 L in 1 DRUM; Type 0: Not a Combination Product	04/22/2020								
6 NDC:75150-003-06	15 L in 1 DRUM; Type 0: Not a Combination Product	04/22/2020								
5 NDC:75150-003-05	10 L in 1 DRUM; Type 0: Not a Combination Product	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(75150-003)

Revised: 8/2020

Huizhou New Road Cosmetics Company Limited