PRIMEAUTY SQUEEZE TUBE- 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 (Squeeze Tube w/screw cap)

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 SQUEEZE TUBE ethyl alcohol liquid									
Product Informat	tion								
Product Type		HUMAN OTC DRUG	Item Code (Source)		NDC:75150-002				
Route of Administra	tion	TOPICAL							
Active Ingredient/Active Moiety									
Ingredient Name				Basis of Strength		Strength			
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOH				ALCOHOL	75 mL in 100 mL				
Inactive Ingredie	nts								
		Ingredient Name				Strength			
GLYCERIN (UNII: PDC6A3C0OX)									
WATER (UNII: 059QF0KO0R)									
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)									
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)									
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)									
Packaging									
# Item Code		Package Description	Ma	arketing Start Date	Marke	ting End Date			
1 NDC:75150-002-01	10 mL in 1 TUB	E; Type 0: Not a Combination Pro	oduct 04/	/22/2020					
2 NDC:75150-002-02	20 mL in 1 TUB	E; Type 0: Not a Combination Pro	oduct 04/	/22/2020					
3 NDC:75150-002-03	30 mL in 1 TUB	E; Type 0: Not a Combination Pro	oduct 04/	/22/2020					

04/22/2020

4 NDC:75150-002-04 50 mL in 1 TUBE; Type 0: Not a Combination Product

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:75150-002-09	200 mL in 1 TUBE; Type 0: Not a Combination Product	04/22/2020					
8 NDC:75150-002-08	150 mL in 1 TUBE; Type 0: Not a Combination Product	04/22/2020					
7 NDC:75150-002-07	100 mL in 1 TUBE; Type 0: Not a Combination Product	04/22/2020					
6 NDC:75150-002-06	80 mL in 1 TUBE; Type 0: Not a Combination Product	04/22/2020					
5 NDC:75150-002-05	60 mL in 1 TUBE; 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(75150-002)

Revised: 4/2020

Huizhou New Road Cosmetics Company Limited