PLUS COSMETICA S A- alcohol gel Plus Cosmetica S.A.

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.

Alcohol Gel 70%

Active Ingredient

Active Ingredient Purpose

Ethyl Alcohol 70%..... Antibacterial

Uses

Uses

* Sanitizer antibacterial helps eliminate bacteria on hands and arms. This product is not a substitute of hands and soap hand washing. Avoid contact with broken or damaged skin

Warnings

- For external use only
- **Flammable: Keep away from heat and flame.** Highly flammable liquid and vapor.
- When using this products avoid contact with eyes. In case of contact flush with water for several minutes.
- Keep out of reach of children except under adult supervision. If swallowed, get medical help, or contact a Poison Control

Center right away.

- **Stop use and ask Doctor:** if skin irritation develops when using this product.
- Do not use: do not swallow

Stop use and ask a doctor if

Stop use and ask a doctor if

* Irritation develops while using this product

Keep out of reach of children

Keep out of reach of children except under adult supervision. If swallow, get medical help or contact a Poison Center right away

Directions

• **Directions:** Place enough product in your palm to thoroughly cover your hands and arms. Rub hands together briskly until dry. Children under 6 years of age should be supervised when using this product.

Inactive Ingredients

water, acrylates/C10-30 Alkyl Acrylate Crosspolymer, triethanolamine

Questions?

QUESTIONS OR COMMENTS: (305) 670 0979. Monday to Friday/ Address: 8950 SW 74 Court. Suite 1406. Miami, Florida 33156

Uses

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Hand Sanitizer Gel



PLUS COSMETICA S A

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78343-003	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mg in 1 mL		

Inactive Ingredients	
Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	

Packaging				
# Item Code Package Description		Marketing Start Marketing End Date Date		
	NDC:78343-003- 02	1100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	06/01/2020		

Labeler - Plus Cosmetica S.A. (934891404)

Registrant - Plus Cosmetica S.A. (934891404)

Establishment				
Name	Address	ID/FEI	Business Operations	
YOBEL SUPPLY CHAIN MANAGEMENT S.A.		934116930	manufacture(78343-003)	

Establishment					
Name	Address	ID/FEI	Business Operations		
Plus Cosmetica S A		934891404	label(78343-003)		

Revised: 6/2020 Plus Cosmetica S.A.