

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



+

ALCOHOL GEL 70% v/v

**HANDS AND ARMS
SANITIZER ANTI-BACTERIAL**
SANITIZANTE ANTIBACTERIAL PARA MANOS Y BRAZOS

HOW TO USE:



Apply a dose of product



Extend on the hand surface



Rub both hands



Interwine fingers



Rub thumbs



Extend and rub arms

DRUG FACTS / INFORMACIÓN DEL MEDICAMENTO :

ACTIVE INGREDIENTS / Ingrediente activo: Ethyl alcohol / Alcohol Etilico 70% v/v **Purpose** / **Próposito:** Anti-bacterial / Antibacterial

USES: Sanitizer Anti-bacterial helps eliminate bacteria on hand and arms. This product is not a substitute of soap hand washing. Avoid contact with broken or damaged skin • **Usos:** Sanitizante antibacterial que ayuda a eliminar las bacterias de manos y brazos. Este producto no es un sustituto del lavado de manos con jabón. Evite el contacto con heridas abiertas o piel dañada.

WARNINGS: For external use only • Precauciones: Sólo para uso externo

Flammable: Keep away from heat and flame. Highly flammable liquid and vapor • **Inflamable:** Mantener alejado del calor y las llamas. Líquidos y vapores altamente inflamables.

When using this product avoid contact with eyes. In case of contact, flush with water for several minutes • **Cuando use este producto,** evite el contacto con los ojos. En caso de contacto, enjuague con agua durante varios minutos.

Keep out of reach of children, except under adult supervision. If swallowed, get medical help, or contact a Poison Control Center right away • **Mantener fuera del alcance de los niños,** excepto bajo supervisión de un adulto. En caso de ingestión, obtenga ayuda médica o comuníquese con un Centro de Control de Envenamamiento de inmediato

Stop use and ask Doctor: if skin irritation develops • **Deje de usar y pregunte al médico:** Si se desarrolla irritación de la piel

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 / **Instrucciones:** Coloque suficiente producto en la palma de la mano para cubrir bien manos y brazos • **Frote las manos** con fuerza hasta secar el producto • **Los niños menores de 6 años** deben ser supervisados cuando usen el producto

Do not Use: do not swallow • **No usar:** no ingerir

INACTIVE INGREDIENTS / **Ingredientes inactivos:** Aqua (Water), Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine.

Questions or comments? / **Preguntas o comentarios?** Phone / Teléfono: +1 (305)6700979
Monday to Friday / Lunes a Viernes: 9am to 5pm • **Address / Dirección:** 8950 SW 74 Court. Suite 1406. Miami, FL 33156

Marketed by: Plus Cosmética S.A. Av. Victor Andres Bataurdo No. 280 Zdo Piso - Lima - Perú. RUC: 20335315759. NSDC44962-20PE. Imported and distributed: Colombia: Starbrands Colombia S.A.S. www.starbrandsgroup.com Bogotá - Colombia. Made in Peru. Lat. VO1



Net Wt. 37.1 fl.oz (1100 mL)

IMMEDIATE ACTION • FAST ABSORPTION / Acción inmediata • Rápida absorción






PLUS COSMETICA S A

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78343-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	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 Date	Marketing End Date
1	NDC:78343-004-01	1100 mL in 1 BOTTLE, PUMP; 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(78343-004)

Establishment

Name	Address	ID/FEI	Business Operations
Plus Cosmetica S A		934891404	label(78343-004)

Revised: 6/2020

Plus Cosmetica S.A.