

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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* 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

Hand Sanitizer Gel





ALCOHOL GEL 70% v/v

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

HOW TO USE:








DRUG FACTS / INFORMACIÓN DEL MEDICAMENTO:

ACTIVE INGREDIENTS / Ingrediente activo: Ethyl alcohol / Alcohol Etílico 70% v/v **Purpose / Propósito:** 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 flamas. 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 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: Agua (Water), Acrylates/CI 10-30 Alkyl Acrylate Copolymer, 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

Net Wt. 12.75 fl.oz (380 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:78343-002 |
| 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 Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:78343-002-01 | 380 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(78343-002) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------|---------|-----------|---------------------|
| Plus Cosmetica S A | | 934891404 | label(78343-002) |

Revised: 6/2020

Plus Cosmetica S.A.