

HAND SANITIZER- ethyl alcohol gel
Exelencia Importers, Corp.

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.

HAND SANITIZER

Active Ingredient

Ethyl Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Uses

Decreases bacteria on skin that potentially can cause disease
Recommended for repeated use.

Warnings

For external use only.

Flammable. Keep away from heat or flame

When using this product, avoid contact with eyes, ears and mouth. In case of contact with eyes flush thoroughly with water.

Do not use

- In children less than 2 months of age.
- On open skin wounds.

When using this product, avoid contact with eyes, ears, and mouth. In case of contact with eyes flush thoroughly with water.

Stop use and ask a doctor if redness or irritation develops & persists for more than 72 hours.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Directions

- Wet hands thoroughly with product and allow to dry.
- Children under 6 years of age, use only under adult supervision.

Inactive ingredients

Water (Aqua), Carbomer, Triethanolamine, Fragrance (Parfum), Phospholipids, Polyquaternium-16, BHT, Panthenol, Niacinamide, Dimethicone, Bisabolol, Phenoxyethanol, Tocopheryl Acetate, CI 16035

Fromsoybean lecithin. FD&C RED 40.

Other Information

Do not store above 105F (43C).

May discolor some fabrics and surfaces.

EXEL

ALCOHOL EN GEL ANTIMICROBIANO

con liposomas humectantes y suavizantes

ALCOOL GEL ANTIMICROBIANO

com lipossomas de acao humectante e suavizante

HAND SANITIZER

with moisturizing and softening liposomes

BIOCOSMETICA PROFESIONAL

1.69 fl. Oz/50 ml e



Etiqueta: USA PM-0490-005-0720
Esta etiqueta se pega sobre el dorso del pomo

NOMBRE DE LA ETIQUETA A PEGAR: USA-PM-0490-005-0720
CÓDIGO DEL PRODUCTO: PM-0490-005-CP-0420

rev: 0 / 23-07-20
G-MIMEI-PM-0490-005

HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53863-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
POLYQUATERNIUM-16 (N-VINYLPYRROLIDINONE:3-METHYL-1-VINYLMIDAZOLIUM CHLORIDE (5:5)) (UNII: 1KX12A421J)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
PANTHENOL (UNII: WW9CM0067Z)	
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
NIACINAMIDE (UNII: 25X51I8RD4)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
LEVOMENOL (UNII: 24WE03BX2T)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53863-002-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	
2	NDC:53863-002-02	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	
3	NDC:53863-002-03	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	
4	NDC:53863-002-04	475 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	
5	NDC:53863-002-05	4000 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/03/2020	

Labeler - Exelencia Importers, Corp. (147644335)

Revised: 4/2023

Exelencia Importers, Corp.