

MEDIFENSE CLEAN HAND SERUM TROPICAL FRUIT- alcohol liquid
L&P Cosmetic Co., Ltd.

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.

Active Ingredient(s)

ALCOHOL 62.0% v/v

Purpose

ANTISEPTIC

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children

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

Uses

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Directions

- For optimal results, place enough product on hands and rub hands together for 30 seconds.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

1,2-Hexanediol, 3-O-Ethyl Ascorbic Acid, Acrylates Copolymer, Aminomethyl Propanol, Caprylic/Capric Triglyceride, Carbomer, Cetyl Alcohol, Citric acid, Citrus Limon (Lemon) Fruit

Extract, Citrus Paradisi (Grapefruit) Fruit Extract, Fragrance, Glycerin, Olea Europaea (Olive) Fruit Oil, Panthenol, Saccharide Isomerate, Sodium Citrate, Sodium Hyaluronate, Styrene/Acrylates Copolymer, Tocopheryl Acetate, Water

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



MEDIFENSE CLEAN HAND SERUM TROPICAL FRUIT

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74005-070
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	31 mL in 50 mL

Inactive Ingredients

Ingredient Name	Strength
1,2-Hexanediol (UNII: TR046Y3K1G)	
3-O-Ethyl Ascorbic Acid (UNII: 6MW60CB71P)	
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E)	
AminomethylPropanol (UNII: LU49E6626Q)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
Cetyl Alcohol (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
Lemon (UNII: 24RS0A988O)	
Grapefruit (UNII: O82C39RR8C)	
Glycerin (UNII: PDC6A3C0OX)	

OLIVE OIL (UNII: 6UYK2W1W1E)	
Panthenol (UNII: WV9CM0O67Z)	
ROSEMARY (UNII: IJ67X351P9)	
Saccharide Isomerate (UNII: W8K377W98I)	
Sage (UNII: 065C5D077J)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
Water (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74005-070-01	50 mL in 1 CONTAINER; Type 0: Not a Combination Product	11/01/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/01/2020	

Labeler - L&P Cosmetic Co., Ltd. (557821713)

Registrant - L&P Cosmetic Co., Ltd. (557821713)

Establishment			
Name	Address	ID/FEI	Business Operations
E.CIS COSMETIC.,Co.Ltd		689846270	manufacture(74005-070)

Revised: 11/2020

L&P Cosmetic Co., Ltd.