

HAND SANITIZER GEL- alcohol gel
Cellicon Lab Inc.

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.

81601-001_HAND SANITIZER GEL

Active ingredient

Ethyl alcohol 70.3% w/w

Purpose

Antimicrobial

Use

- Hand sanitizer to help decrease bacteria on the skin

Warnings

Flammable. Keep away from fire or flame.

For external use only

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts

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

Directions

- Put enough product in your palm to cover hands and rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using the product

Other information

- Store below 110°F (43°C)
- May discolor certain fabrics or surfaces

Inactive ingredients

Water, Glycerin, Carbomer, Polyacrylate Crosspolymer-6, Octyldodeceth-16,

Tromethamine, Ammonium Acryloyldimethyltaurate/VP Copolymer, Butylene Glycol, t-Butyl Alcohol, 1,2-Hexanediol, Portulaca Oleracea Extract

언제 어디서나 내 손 안의 건강습관

HAND SANITIZER GEL

핸드 클린 젤

70

ALCOHOL %

65 ml / 2.19 fl. oz.

Jeu'Demeure

Jeu'Demeure
HAND SANITIZER GEL
쥬디메르 핸드 클린 젤

Drug Facts

Active Ingredients	Purposes
Ethyl alcohol 70.3% w/w	Antimicrobial

Uses ■ Hand sanitizer to help decrease bacteria on the skin

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

Directions
■ Wet hands thoroughly with product and allow to dry without wiping

Other Information
■ store below 110°F (43°C)
■ may discolor certain fabrics or surfaces

Inactive ingredients
Water, Glycerin, Carbomer, Polyacrylate Crosspolymer-6, Octyldodeceth-16, Tromethamine, Ammonium Acryloyldimethyltaurate/VP Copolymer, Butylene Glycol, t-Butyl Alcohol, 1,2-Hexanediol, Portulaca Oleracea Extract

[Manufactured by] Cellicon Lab Inc. 58, Baekseok gongdan 1-ro, Seobuk-gu, Cheonan-si, Chung cheongnam-do, Republic of Korea, 31094
[제조번호 및 사용기한] 별도표기 MADE IN KOREA



HAND SANITIZER GEL

alcohol gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:81601-001

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.703 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C00X)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)	
OCTYLDODECETH-16 (UNII: RJV574G0DE)	
TROLAMINE (UNII: 903K93S3TK)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
PURSLANE (UNII: M6S840WYG5)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81601-001-01	65 mL in 1 TUBE; Type 0: Not a Combination Product	04/02/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/02/2021	

Labeler - Cellicon Lab Inc. (689056488)

Registrant - Cellicon Lab Inc. (689056488)

Establishment

Name	Address	ID/FEI	Business Operations
Cellicon Lab Inc.		695097499	manufacture(81601-001)