

BIOMEDIK PREMIUM HAND SANITIZER GEL- alcohol gel SISKINKOREA 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.

BIOMEDIK Premium Hand Sanitizer Gel [74514-7250-1] 250 mL, Bottle+Pump



BIOMEDIK PREMIUM HAND SANITIZER GEL

ANTHROPIC

70% Alcohol with panthenol and hyaluronic acid to keep your hands fresh and clean.

Drug Facts

Active ingredient Purpose
Alcohol 70% Antiseptic

Uses
To help reduce bacteria that potentially can cause disease.
For use when soap and water are not available.

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 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 if swallowed, get medical help or contact a Poison Control Center right away.

Directions
• Place enough product on hands to cover all surfaces. Rub hands together until dry.

• Supervise children under 6 years of age when using this product to avoid swallowing.

• Avoid direct inhalation of vapors during application. (Irritation and inhibition to mucous membranes may occur when directly inhaled.)

• This product is intended only for hand sanitizing.

• To prevent contents from drying out and contaminants from entering, close lid completely after use.

• Keep product in its original container as storing the product in anything other than the original container may result in accidents or cause the integrity of the product to diminish.

• Do not use over nicks, cuts, grazes, etc. as irritation may occur.

Other information
• Store between 15-30 °C (59-86 °F)

• Avoid freezing and excessive heat above 40 °C (104 °F)

Inactive ingredients Water, Carbomer, Glycerin, Aminomethyl Propanol, Sodium Hydroxide, Panthenol

MANUFACTURED BY SISKINKOREA CO.,LTD.
50, Dae-ro 20(Seon)-gil, Busan-se, Gyeongsang-do, 46557 KOREA

[LOT/EXP. DATE] MARKED SEPARATELY
[BEST BEFORE] 36 MONTHS FROM THE DATE OF MANUFACTURE.

MADE IN KOREA

Under California's Safe Drinking Water and Toxic Enforcement Act, better known as Proposition 65, we are required to advise you if this product contains chemicals known to the State of California to cause cancer or reproductive toxicity. This product does not contain any of these chemicals. For more information, go to www.P65Warnings.ca.gov

BIOMEDIK PREMIUM HAND SANITIZER GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74514-7250
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	175 mL in 250 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
PANTHENOL (UNII: WV9CM0O67Z)	
WATER (UNII: 059QF0K00R)	

HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74514-7250-1	250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/15/2020	

Labeler - SISKINKOREA CO.,LTD. (695625974)

Establishment

Name	Address	ID/FEI	Business Operations
SISKINKOREA CO.,LTD.		695625974	manufacture(74514-7250)

Revised: 6/2020

SISKINKOREA CO.,LTD.