

BIO HAND SANITIZER GE L- ethanol spray
Seoul Food Research & Development 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

Ethanol 75 % v/v

INACTIVE INGREDIENTS

Glycerin, Hydroxy Propyl Methyl Cellulose, Water

PURPOSE

Antimicrobial

WARNINGS

For external use only

Flammable. Keep away from heat and flame.

When using this product ■ Keep out of eyes. In case of contact with eyes, flush thoroughly with water.

■ Avoid contact with broken skin. ■ Do not inhale or ingest.

Stop use and ask a doctor if skin irritation or rash develops.

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

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 on the skin that could cause disease

■ Recommended for repeated use

Directions

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

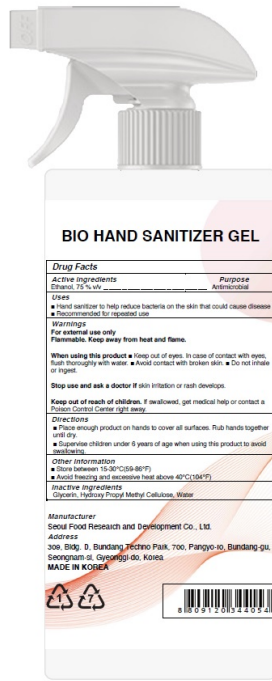
■ Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

■ Store between 15-30°(59-86°)

■ Avoid freezing and excessive heat above 40°(104°)

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



BIO HAND SANITIZER GEL

ethanol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80642-020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	375 mL in 500 mL

Inactive Ingredients

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
Water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80642-020-01	500 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/01/2020	

Labeler - Seoul Food Research & Development Co., Ltd. (688787758)

Registrant - Seoul Food Research & Development Co., Ltd. (688787758)

Establishment

Name	Address	ID/FEI	Business Operations
Seoul Food Research & Development Co., Ltd.		688787758	manufacture(80642-020)

Revised: 10/2020

Seoul Food Research & Development Co., Ltd.