CLEAN AND FRESH F- alcohol gel Korea Life Science 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

ALCOHOL 62.0%

INACTIVE INGREDIENT

Glycerin, Aminomethyl Propanol, Isopropyl Myristate, Water, Carbomer, Tocopheryl Acetate, Propylene Glycol, Fragrance

PURPOSE

SANITIZER

WARNINGS

1.Do not use the product on the following areas:

Around the eyes and ears, in the mouth, large body parts and damaged skin(Irritation may occur)

- 2.If you experience any of the following symptoms, discontinue use of the product immediately and consult a physician or pharmacist.
- 1) Hypersensitivity symptoms, e.g. rash, erythema, itchiness, and edema
- 2)Skin irritation symptoms
- 3. Other precautions
- 1) For external use only (do not swallow).
- 2) Avoid contact with eyes. If contact occurs, wash with clean water and consult a doctor or pharmacist.
- 3)Be careful not to inhale vapors in cases of extended or prolonged use. (Repeating inhaling of large amounts of ethanol vapor may cause irritation of the mucous membranes and headaches).
- (Limited to ethanol-containing products)
- 4) If used repeatedly in the same area, care should be provided as the skin may become rough due to excessive oil removal.
- 5) Do not use sealed bandages, cast bandages, or packs as they may cause irritation.
- 6) Do not use this drug on the anal or vagina areas, or with hot packs, as it may cause irritation or chemical burns.
- 7) Use only for the intended purposes.
- 4. Precautions for storage
- 1) Keep away from direct sunlight and do not expose the product to heating devices or flame.
- 2) Keep out of reach of children and go to the hospital immediately if swallowed.
- 3) After use, close the lid completely to prevent the product from drying or foreign objects from getting inside the container.
- 4) Storing the product in a different container may cause accidents or deterioration of quality. Therefore, keep the product in its original container.

Dust or foreign substances may get on the product while using it.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children and go to the hospital immediately if swallowed.

Uses

Disinfection of hands and skin

Directions

Take an appropriate amount on your hands and rub thoroughly to dry.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



CLEAN AND FRESH F

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74406-080	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	248 mL in 400 mL	

Inactive Ingredients		
Ingredient Name	Strength	
Glycerin (UNII: PDC6 A3C0 OX)		
AminomethylPropanol (UNII: LU49E6626Q)		
Isopropyl Myristate (UNII: 0 RE8 K4LNJS)		

Water (UNII: 059QF0KO0R)		
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)		
.ALPHATO COPHERO L ACETATE (UNII: 9E8X80D2L0)		
Propylene Glycol (UNII: 6DC9Q167V3)		

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:74406-080- 01	400 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/01/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	05/01/2020		

Labeler - Korea Life Science Co.,ltd (694914835)

Registrant - Korea Life Science Co.,ltd (694914835)

Establishment				
Name	Address	ID/FEI	Business Operations	
Korea Life Science Co.,ltd		694914835	manufacture(74406-080)	

Revised: 5/2020 Korea Life Science Co.,ltd