HANDS SANITIZING- alcohol gel
Egtech 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

Active ingredients: ALCOHOL 62.0%

INACTIVE INGREDIENT

Inactive ingredients:

Water, Carbomer, Triethanolamine, Glycerin, Propylene Glycol, Green Tea Extract, Aloe Vera Gel, Fragrance, Sodium Hyaluronate

PURPOSE

Purpose: SANITIZER

WARNINGS

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

Uses:

Disinfection of hands and skin

Directions

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

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

HANDS SANITIZING

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76767-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	310 mL in 500 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
Glycerin (UNII: PDC6A3C0OX)	
Propylene Glycol (UNII: 6DC9Q167V3)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76767-010-01	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/01/2020	

Labeler - Egtech co., Ltd. (690074770)

Registrant - Egtech co., Ltd. (690074770)

Establishment

Name	Address	ID/FEI	Business Operations
Korea Life Science Co.,ltd		694914835	manufacture(76767-010)

Revised: 4/2020 Egtech co., Ltd.