

FRESH PURE HAND- alcohol gel
Ester 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 70%

INACTIVE INGREDIENT

Inactive ingredients:

Water, Butylene Glycol, Carbomer, Triethanolamine, Polysorbate 60, Isopropyl Myristate, Fragrance

PURPOSE

Purpose: ANTISEPTIC

WARNINGS

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 redness 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

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Uses

Uses:

For handwashing when water is not available to decrease bacteria on the skin

- After changing diapers
- After assisting ill persons
- Before contact with a person under medical care or treatment
- Recommended for repeated use

Directions

Directions:

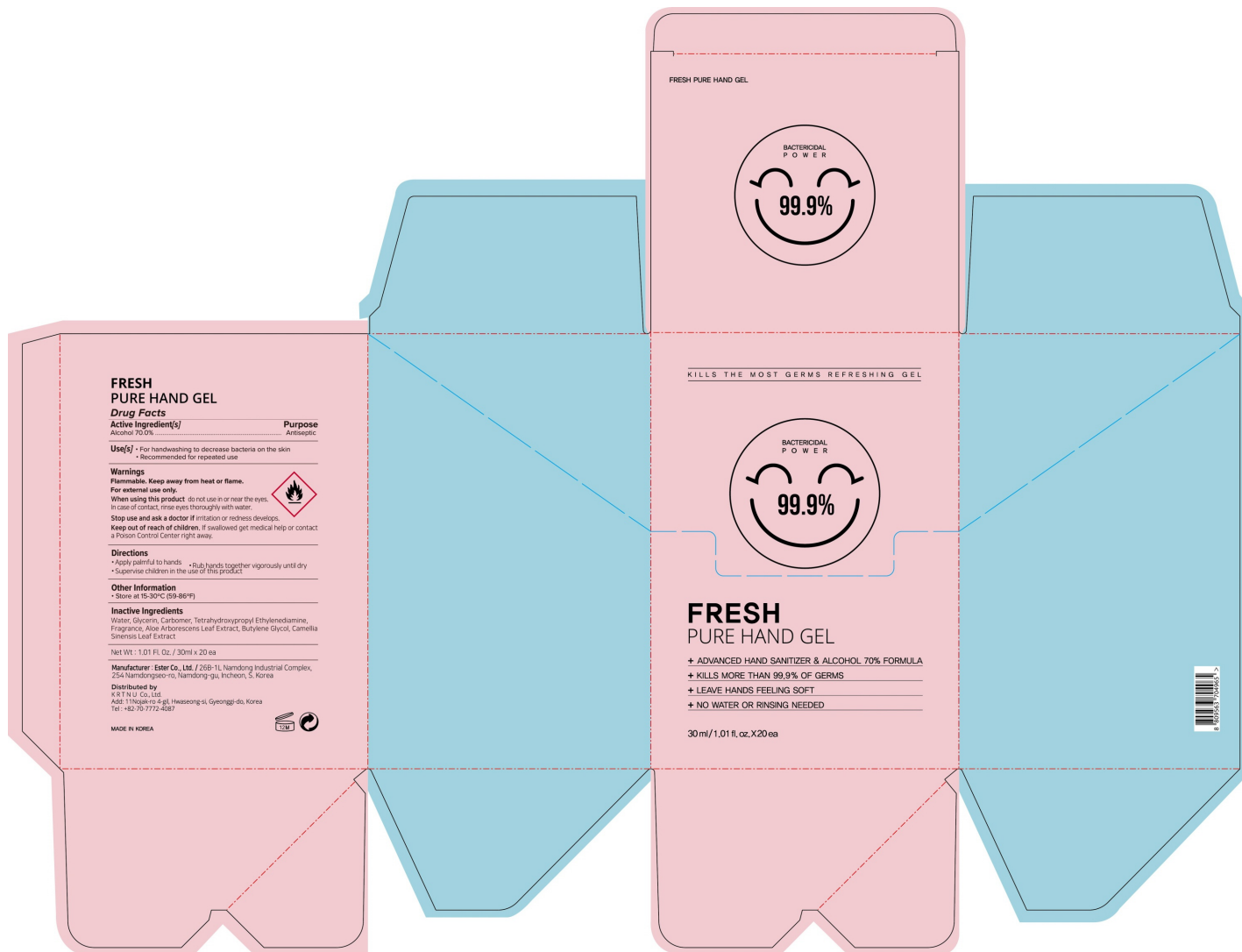
- Apply palmful to hands
- Rub hands together vigorously until dry
- Supervise children in the use of this product

Other Information

Other Information:

Store at room temperature: 15°~30 °C (59°~86 °F)

PACKAGE LABEL - FRESH PURE HAND GEL 30mL * 20ea Carton



PACKAGE LABEL - FRESH PURE HAND GEL 500mL Bottle

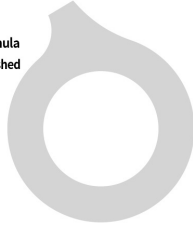
Antimicrobial 99.9%

Fresh Pure Hand Gel

Ethanol 70%

Advanced Refresh HAND SANITIZER
Kills 99.9% of germs with Alcohol Formula
Helps leave hands feeling soft and refreshed
Rinse Free and None Sticky

500ml / 16.9 fl.oz



FRESH PURE HAND GEL

Drug Facts

Active Ingredients	Purpose
Alcohol 70.0%	Antiseptic

Use

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Inactive Ingredients

Water, Aloe Barbadensis Leaf Extract, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine

Manufacturer: Ester Co., Ltd.

268-1L Namdong Industrial Complex, 254 Namdongseo-ro, Namdong-gu, Incheon, S. Korea

MADE IN KOREA

Net Wt: 500mL / 16.91 Fl. Oz.



FRESH PURE HAND

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:740 04-030
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74004-030-02	20 in 1 CARTON	03/01/2020	
1	NDC:74004-030-01	30 mL in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:74004-030-03	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	03/01/2020	

Labeler - Ester Co., Ltd. (688425766)

Registrant - Ester Co., Ltd. (688425766)

Establishment

Name	Address	ID/FEI	Business Operations
Ester Co., Ltd.		688425766	manufacture(74004-030)

Revised: 11/2020

Ester Co., Ltd.