POPPY AND IVY HAND SANITIZER- 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, Glycerin, Carbomer, Tetrahydroxypropyl Ethylenediamine, Fragrance, Sodium Hyaluronate, 1,2-Hexanediol, Aloe Arborescens Leaf Extract, Butylene Glycol, Camellia Sinensis Leaf Extract

PURPOSE

Purpose: ANTISEPTIC

WARNINGS

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 eyes thoroughly with water.

Stop use and consult a doctor if irritation and redness develop and persist for more than 72 hours.

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

Uses

Uses:

For handwashing to decrease bacteria on the skin

Recommended for repeated use

Directions

Directions:

Wet hands thoroughly with product

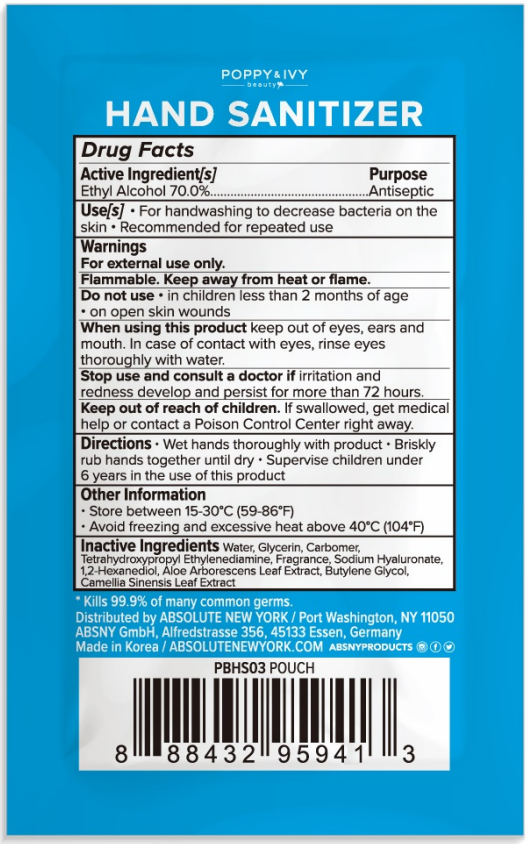
Briskly rub hands together until dry

Supervise children under 6 years in the use of this product

Other Information

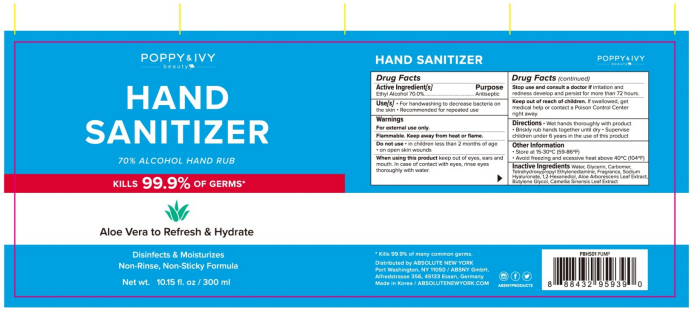
Other Information:
Store at 15-30 °C (59-86 °F)
Avoid freezing and excessive heat above 40 °C (104 °F)

PACKAGE LABEL - POPPY & IVY HAND SANITIZER 2 mL Pouch



PACKAGE LABEL - POPPY & IVY HAND SANITIZER 60mL Tube

PACKAGE LABEL - POPPY & IVY HAND SANITIZER 300mL Bottle



POPPY AND IVY HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:74004-020
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)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
EDETOL (UNII: Q4R969U9FR)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
ALOE ARBORESCENS LEAF (UNII: 09TD8L5SQV)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:74004-020			

1	NDC:74004-020-01	2 mL in 1 POUCH; Type 0: Not a Combination Product	03/01/2020	
2	NDC:74004-020-02	60 mL in 1 TUBE; Type 0: Not a Combination Product	03/01/2020	
3	NDC:74004-020-03	300 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(74004-020)

Revised: 11/2020 Ester Co., Ltd.