PURUS HAND SANITIZER GEL- alcohol gel
The fab Korea 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.

The fab Korea Co., Ltd. - Purus hand sanitizer gel 500ml

Alcohol

water, glycerin, dipropylene glycol, carbomer, isopropyl myristate, triethanolamine, sodium hyaluronate, camellia sinensis leaf extract

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

keep out of reach of the children

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.

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 thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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

for external use only

Drug Facts

Active Ingredient — Purpose

Alcohol 70 % ---------- Antiseptic

Uses

■ Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

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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 15-30C (59-86F)

■ Avoid freezing and excessive heat above 40C (104F)

Inactive Ingredients

Water, glycerin, dipropylene glycol, carbomer, isopropyl myristate, triethanolamine, sodium hyaluronate, camellia sinensis leaf extract

PURUS HAND SANITIZER GEL

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77504-0001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	350 mL in 500 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
TROLAMINE (UNII: 9O3K93S3TK)	

HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77504-0001-1	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/04/2020	

Labeler - The fab Korea Co., Ltd. (694885775)

Registrant - The fab Korea Co., Ltd. (694885775)

Establishment

Name	Address	ID/FEI	Business Operations
Pf Nature		694526459	manufacture(77504-0001)

Establishment

Name	Address	ID/FEI	Business Operations
The fab Korea Co., Ltd.		694885775	label(77504-0001)

Revised: 5/2020 The fab Korea Co., Ltd.