SUNGSU CLEAN HAND SANITIZER- alcohol gel
SUNGSUBIOTEK 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% v/v

INACTIVE INGREDIENTS

Aloe Extract, Butylene Glycol, CARBOMER, DL-Panthenol, Polyoxyethylene Hydrogenetated Caster Oil, Triethanolamine, Water

PURPOSE

Antiseptic

WARNINGS

For external use only. Flammable. Keep away from heat or flame

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

KEEP OUT OF REACH OF CHILDREN

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

Uses

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

Directions

• Apply to clean, dry hands. Apply sufficient amount to thoroughly wet all surfaces of hands and fingers. Rub onto hands until dry.
• Supervise children in the use of this product.

Other information

• Store between 59-86□ (15-30□)

• Avoid freezing and excessive heat above 104□ (40□)

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

SUNGSU CLEAN HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80454-030
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**
ALOE (UNII: V5VD430YW9)	
Butylene Glycol (UNII: 3XUS85K0RA)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
PANTHENOL (UNII: WV9CM0O67Z)	
TROLAMINE (UNII: 9O3K93S3TK)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80454-030-01	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/01/2020	

Labeler - SUNGSUBIOTEK CO. LTD. (690452683)

Registrant - SUNGSUBIOTEK CO. LTD. (690452683)

Establishment

Name	Address	ID/FEI	Business Operations
SUNGSUBIOTEK CO. LTD.		690452683	manufacture(80454-030)

Revised: 9/2020 SUNGSUBIOTEK CO. LTD.