

**77 DISINFECTION ETHANOL LIQUID- alcohol spray  
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.*

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**ACTIVE INGREDIENT**

Alcohol 83% v/v

**INACTIVE INGREDIENT**

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

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**When using this product** keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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**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**

- disinfection of hard object surfaces

**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



## 77 DISINFECTION ETHANOL LIQUID

alcohol spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80454-010
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Alcohol (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	Alcohol	415 mL in 500 mL

### Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80454-010-01	500 mL in 1 BOTTLE, SPRAY; 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(80454-010)

Revised: 9/2020

SUNGSUBIOTEK CO. LTD.