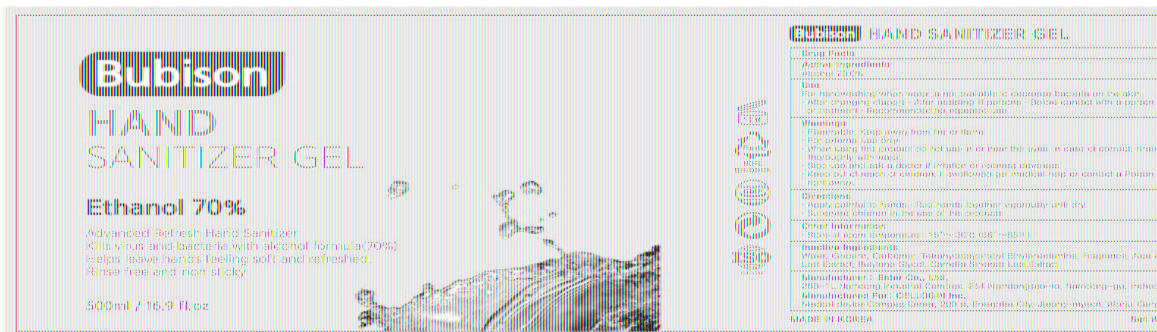


BUBISON HAND SANITIZER GEL- alcohol gel
Ester Co., Ltd.

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.

[Ester Co., Ltd.-BUBISON HAND SANITIZER Gel] 500 ml : 74004-570-01



BUBISON HAND SANITIZER GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74004-570
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	350 g in 500 mL

Inactive Ingredients

Ingredient Name	Strength
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
EDETOL (UNII: Q4R969U9FR)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
WATER (UNII: 059QF0K00R)	
ALOE ARBORESCENS LEAF (UNII: 09TD8L5SQV)	

GLYCERIN (UNII: PDC6A3C0OX)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74004-570-01	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/17/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/16/2020	

Labeler - Ester Co., Ltd. (688425766)

Establishment

Name	Address	ID/FEI	Business Operations
Ester Co., Ltd.		688425766	manufacture(74004-570)

Revised: 4/2020

Ester Co., Ltd.