

**HAUTIAN PURE HAND CLEAN 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.-HAUTIAN PURE HAND CLEAN Gel] 30 ml X 20 : 74004-136-20**



<b>HAUTIAN PURE HAND CLEAN GEL</b>			
alcohol gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74004-136
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	18.6 mL in 30 mL

## Inactive Ingredients

Ingredient Name	Strength
POLYSORBATE 60 (UNII: CAL22UVI4M)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
WATER (UNII: 059QF0K00R)	
TROLAMINE (UNII: 9O3K93S3TK)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74004-136-20	20 in 1 BOX	04/16/2020	
1		30 mL in 1 POUCH; Type 0: Not a Combination Product		

## 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(74004-136)

Revised: 4/2020

Ester Co., Ltd.