

CLASSY 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.-Classy Hand Sanitizer Gel] 1 Gallon : 74004-128-01



CLASSY HAND SANITIZER GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74004-128
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	2649.5 mL in 3785 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:74004-128-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/05/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/05/2020	

Labeler - Ester Co., Ltd. (688425766)

Establishment

Name	Address	ID/FEI	Business Operations
Ester Co., Ltd.		688425766	manufacture(74004-128)

Revised: 6/2020

Ester Co., Ltd.