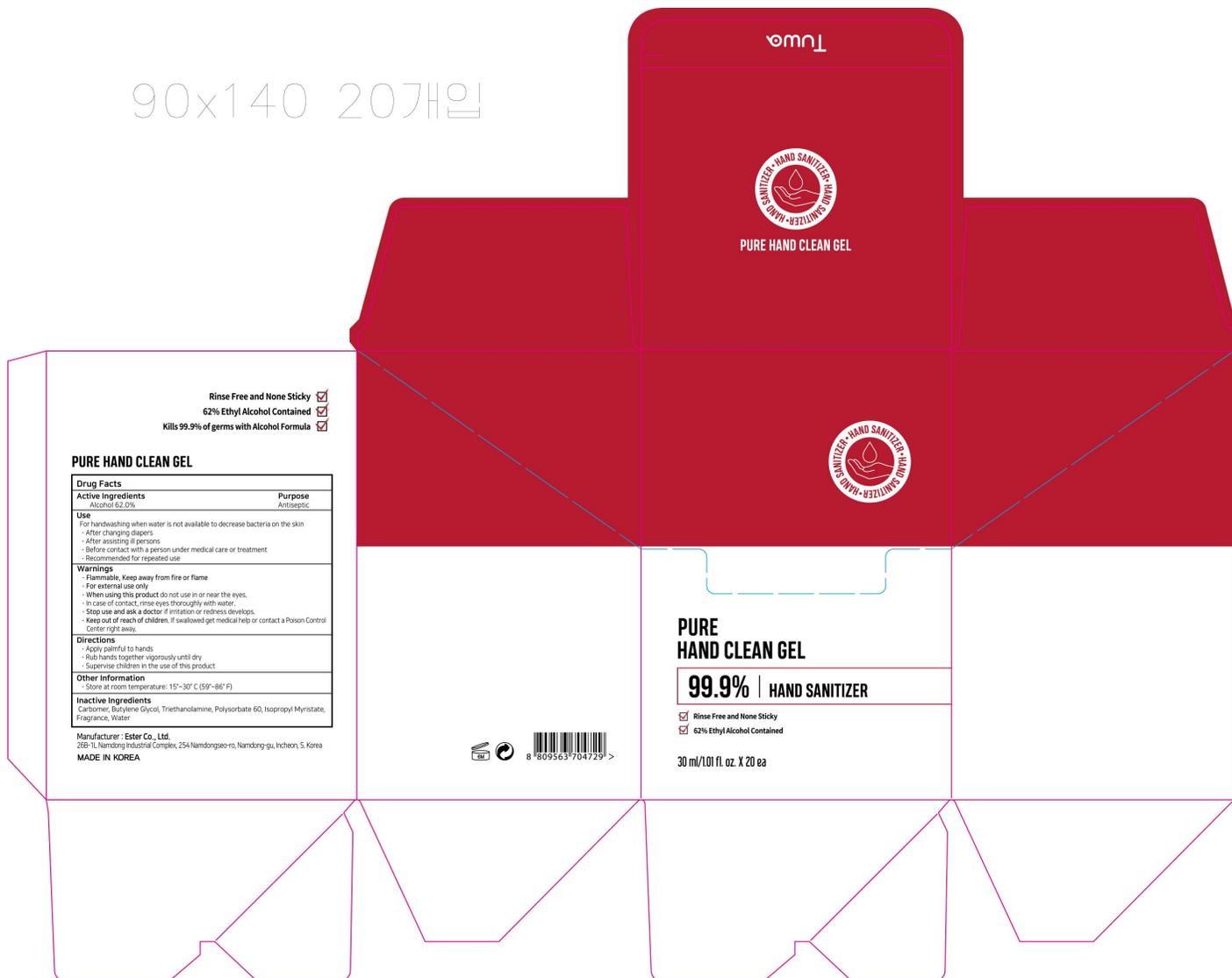


PURE HAND CLEAN GEL- alcohol gel
Ester Co., Ltd.

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.-PURE HAND CLEAN Gel] 30 ml X 20 : 74004-132-20

90x140 20개입



퓨어 핸드 크린 젤 인세사양 : 인세2도(별색1도+흑색) 사이즈 : 118*107*171 재질 : 로말아이보리400 후가공 : 무광라미	인쇄칼라  흑색 PENTONE 200 무광
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PURE HAND CLEAN GEL
 alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74004-132
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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:74004-132-20	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(74004-132)

Revised: 4/2020

Ester Co., Ltd.