

OMEDI HAND SANITIZER- ethyl alcohol gel
Natural Korea 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.

[OMEDI HAND SANITIZER 500 ml : 74646-0500-1



OMEDI HAND SANITIZER				
ethyl alcohol gel				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74646-0500	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	350 mL in 500 mL	
Inactive Ingredients				
	Ingredient Name	Strength		
	ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
	MENTHOL (UNII: L7T10EIP3A)			
	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
	GLYCERIN (UNII: PDC6A3C0OX)			
	DIMETHICONE (UNII: 92RU3N3Y1O)			
	GREEN TEA LEAF (UNII: W2ZU1RY8B0)			
	WATER (UNII: 059QF0K00R)			
	CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)			
	ARGININE (UNII: 94ZLA3W45F)			
	GRAPEFRUIT (UNII: O82C39RR8C)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:74646-0500-1	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/20/2020	
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Marketing Information

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

Labeler - Natural Korea Co., Ltd. (688729438)

Establishment

Name	Address	ID/FEI	Business Operations
Natural Korea Co., Ltd.		688729438	manufacture(74646-0500)

Revised: 4/2020

Natural Korea Co., Ltd.