EARTH EDITION HAND SANITIZER GEL- ethanol gel Earth Edition Inc.

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.

EARTH EDITION HAND SANITIZER Gel 480 mL 76841-4806-1



EARTH EDITION HAND SANITIZER GEL

ethanol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76841-4806	
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			
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0 FE3FX)				
GLYCERIN (UNII: PDC6A3C0OX)				
ALLANTO IN (UNII: 344S277G0Z)				
ORANGE OIL (UNII: AKN3KSD11B)				
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)				
WATER (UNII: 059QF0KO0R)				
TROLAMINE (UNII: 903K93S3TK)				
PANTHENOL (UNII: WV9CM0O67Z)				

LIMO NENE, (+)- (UNII: GFD7C86Q1W)

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:76841-4806-	480 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/10/2020	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	05/10/2020			

Labeler - Earth Edition Inc. (695625846)

Establishment				
Name	Address	ID/FEI	Business Operations	
Skin n Skin Co., Ltd.		631090037	manufacture(76841-4806)	

Revised: 5/2020 Earth Edition Inc.