COTTONWOOD SANITIZER GEL - alcohol gel Alpine Distilling

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.

Drug Facts

Active Ingredient(s):

Ethyl Alcohol 65% v/v

Purpose:

Antibacterial

Use(s):

For rinse free hand cleaning when soap and water are not available.

Warning:

For external use only. Flammable. Keep away from heat or flame.

When using this product: Avoid contact with eyes, ears and mouth. In case of eye contact, rinse with water. Stop use and ask a doctor if irritation or rash occurs, these may be signs of a serious condition.

Keep out of reach of children & pets. If swallowed, get medical help or contact a Poison Control Center Right away.

Directions:

Apply to dry hands, rub into skin, no rinsing required.

Other Information:

Store between 15-30C (59-86F)

Inactive Ingredients:

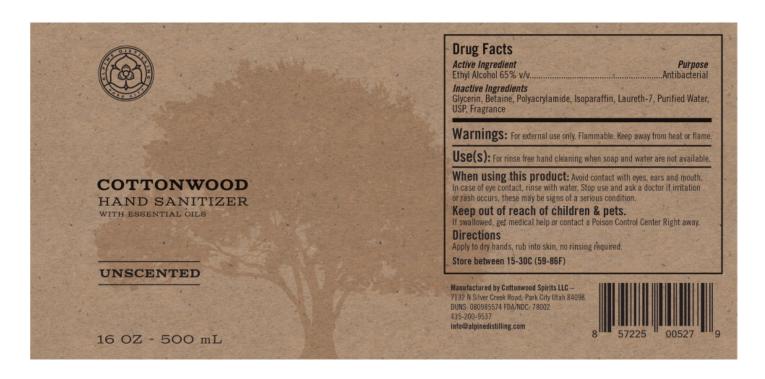
Glycerin, Betaine, Polyacrylamide, Isoparaffin, Laureth-7, Purified Water USP, Fragrance Manufactured by Cottonwood Spirits LLC – 7132 N Silver Creek Road, Park City Utah 84098 DUNS: 080985574 FDA/NDC: 78002

435-200-9537 info@alpinedistilling.com

Principal Display Panel – 500 mL Bottle Label

COTTONWOORD
HAND SANITIZER
WITH ESSENTIAL OILS

UNSCENTED



COTTONWOOD SANITIZER GEL

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG Item Code (Source)		NDC:78002-101	
Route of Administration TOPICAL				

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65 mL in 100 mL	

Inactive Ingredients				
Ingredient Name	Strength			
Glycerin (UNII: PDC6A3C0OX)				
Betaine (UNII: 3SCV180C9W)				
Polyacrylamide (Crosslinked; 0.01-0.2 Mole Percent Bisacrylamide) (UNII: RHA9LWJ494)				
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)				
Laureth-7 (UNII: Z95S6G8201)				
Water (UNII: 059QF0KO0R)				

Packaging					
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1	NDC:78002-101-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/06/2020	

2 NDC:78002-101-02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/06/2020			
3 NDC:78002-101-03	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/06/2020			
4 NDC:78002-101-04	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/06/2020			
Marketing Information					
9					
Marketing Categor	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
	V 11	Marketing Start Date 07/06/2020	Marketing End Date		

Labeler - Alpine Distilling (080985574)

Establishment					
Name	Address	ID/FEI	Business Operations		
Alpine Distilling		080985574	MANUFACTURE(78002-101)		

Revised: 7/2020 Alpine Distilling