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

16 OZ – 500 mL

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				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
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

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/06/2020	

Labeler - Alpine Distilling (080985574)

Establishment

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

Revised: 7/2020 Alpine Distilling