HAPPY FARM HAND SANITIZER- hand sanitizer liquid AETHERA HAND SANITIZER- hand sanitizer liquid Happy Farm Botanicals 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.

Hand Sanitizer Product Listing

Active Ingredient Section

Active Ingredients: Purpose

Ethyl Alcohol 80% v/vAntiseptic

Purpose

Antiseptic

Use[s]

Use[s]

Healthcare Personnel hand rub to help reduce bacteria that potentially can cause disease.

Warnings

Warnings

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

Do not use

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop Use and ask a doctor

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

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

Directions

Directions

- Place enought product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing

Other Information

Ohter Information

- Store between 15-30C (59-86F)
- Avoid Freezing and excessive heat above 40C (104F)

Inactive Ingredients

Inactive Ingredients glycerin, hydrogen peroxide, purified water USP

Principal Display Panel Front of Package



Aethera 80% - Hand Cleanser

Dark Gray

PMS 447 C (50% Opacity) C50,M30,Y40,K90 R55,G58,B54 #373a36





hand sanitizer liquid

Product Information

Product Type HUMAN OTC DRUG NDC:73964-018 Item Code (Source)

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)	18.3 mL in 100 mL			
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL			
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.25 mL in 100 mL			

Ш	- ucing mg					
# Item Code Package Description		Marketing Start Date	Marketing End Date			
		NDC:73964-018- 08	236.588 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2020		

	NDC:/3964-018- 08	Product Product POMP; Type 0: Not a Combination	04/01/2020	
2	NDC:73964-018- 12	354.882 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2020	
3	NDC:73964-018- 16	473.176 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2020	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	04/01/2020			

AETHERA HAND SANITIZER

hand sanitizer liquid

Packaging

Prod	luct	Info	rma	tion
Prou	luct	$\mathbf{H}\mathbf{H}\mathbf{U}$	10116	HOH

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73964-019

TOPICAL **Route of Administration**

	Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength		
ı	ALCOHOL (UNIL DIZOCEOXIONA (ALCOHOL UNILDIZOCEOXIONA	AT COHOL	0.0 I : 10.0 I		

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL 80 mL in 100 mL

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)	18.3 mL in 100 mL			
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL			
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.25 mL in 100 mL			

F	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:73964-019- 02	60 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2020				
2	NDC:73964-019- 12	354.882 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2020				
3	NDC:73964-019- 16	473.176 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2020				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	04/01/2020			

Labeler - Happy Farm Botanicals Inc. (022653140)

Establishment					
Name	Address	ID/FEI	Business Operations		
Happy Farm Botanicals Inc.		022653140	manufacture(73964-018, 73964-019), pack(73964-018, 73964-019), label(73964-018, 73964-019)		

Revised: 4/2020 Happy Farm Botanicals Inc.