28 MILE TOUGH TOWN HAND SANITIZER- ethyl alcohol gel 28 Mile Vodka Company LLC

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

Ethyl Alcohol 70%

Purpose

Hand and Skin Antiseptic

Uses

Hand & Skin Antiseptic to help decrease pathogens (germs) on the skin

Warning

For extgernal use only

Flammable

Keep away from heat or flame

Do not use

- * In Children less than 2 months of age
- * On open skin wounds

Ask a doctor before use if you have

* Irritation or rash occurs

Stop use and ask docotr if

* redness or skin irritation develop after use.

Keep out of reach of children

Supervise children under 6 years of age when using this product to avoid swallowing

Directions

- * Place enough product on hands to cover all surfaces
- * Rub Hands together until dry

Inactive ingredients

Water, Glycerine, PEG-6, Acrylates/Vinyl Cross polymer, Polyethylene Glycol, 1,2,3 - Propanetriol, 1,3-Propanediamine, Gycerol, Xanthan Gum, Maltodextrin, Fragrance

Principal Display Panel

28 Mile Tough Town Hand sanitizer

Tough Town Hand Sanitizer

Cumuber Mint Scented

Lavebder Rose Scented

Unscented

For external use only,

Do not Drink

28 Mile Distilling Company and Tough Town Hand Sanitizer are aptly named after Highwood, IL, the place we call home. Situated just 28 miles north of Chicago, Highwood had a reputation that once led President Theodore Roosevelt to call it "the toughest town in America". Out toughness and resiliency still holds true today as is reflected in the products we produce. Stay safe, stay clean, stay tough.

Produce by:

28 Mile Distilling Co.

454 Sheridon Road, Highwood

IL 60040

Alcohol Antiseptic 70% Topical Solution

Hand Sanitizer Non-sterile solution

NDC: 77340-004-xx; 77340-005-xx; 77340-006-xx; 77340-007-xx; 77340-008-xx; 77340-009-xx



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28MLE

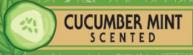
Produced by: 28 Mile Distilling Co. 454 Sheridan Road, Highwood, IL 60040

Alcohol Antiseptic 70% Topical Solution Hand Sanitizer Non-sterile Solution





HAND SANTIZER



16 fl oz (473 mL) 70% Ethanol

Drug Facts

Active ingredient Alcohol 70% v/v......

...Antiseptic

USE[s] Hand sanitizer to reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings
For external use only, Hammable, Keep away from heat or flar

Do not use
• In children less than 2 months of age, • On open skin wounds.
When using this product keep out of eyes, ears, and mouth, in case of contact with eyes, rises yes throughly with water,
Stop use and ask a doctor if initiation or rash occurs.
These may be signs of a serious condition.

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

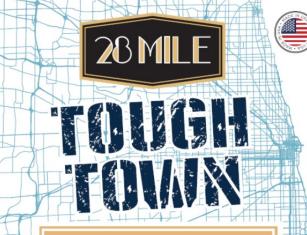
Directions • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 6 years of age when using this product to avoid swallowing.

Other information • Store between 15-30C (59-86F)
• Avoid freezing & excessive heat above 40C (104F)

Inactive Ingredients Sterile Water, Glycerol, Xanthan Gum, Maltodextrin, Fragrance.

For External Use Only Do Not Drink

MADE IN THE USA



UNSCENTED

HAND SANITIZER

1 Gallon (128 fl oz, 3.78 L)

68% Ethanol

Drug Facts

Active ingredient

Alcohol 68% v/v.....

Purpose ...Antiseptic

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For External Use Only • Do Not Drink MADE IN USA

Produced By: 28 Mile Distilling Co. 454 Sheridan Road, Highwood, IL 60040

Alcohol Antiseptic 68% Topical Solution Hand Sanitizer Non-sterile Solution



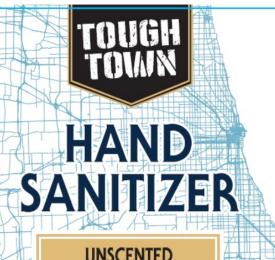
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28 MILE

Produced by: 28 Mile Distilling Co. 454 Sheridan Road, Highwood, IL 60040

Alcohol Antiseptic 70% Topical Solution Hand Sanitizer Non-sterile Solution





UNSCENTED

70% Ethanol 16 fl oz (473 mL)

Drug Facts

Active ingredient Alcohol 70% v/v.....

Purpose ...Antiseptic

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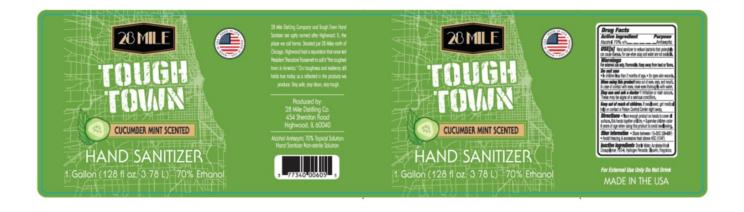
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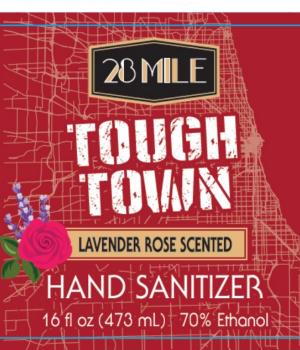


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Drug Facts

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Purpose ._Antiseptic

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Inactive Ingredients Sterile Water, Acrylates/Vinyl Crosspolymer, PEG-6, Hydrogen Peroxide, Glycerin, Fragrance.

For External Use Only Do Not Drink

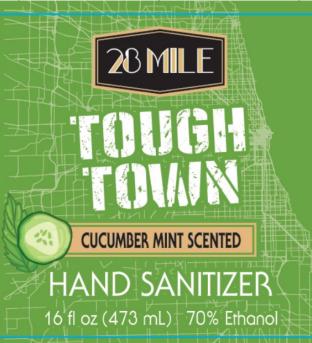
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Drug Facts

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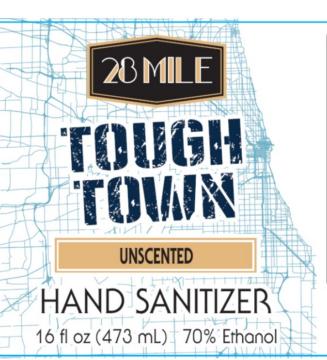
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Drug Facts Active ingredient

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Inactive Ingredients Sterile Water, Acrylates/Vinyl Crosspolymer, PEG-6, Hydrogen Peroxide, Glycerin.

For External Use Only Do Not Drink MADE IN THE USA

28 MILE TOUGH TOWN HAND SANITIZER

ethyl alcohol gel

Product Information

HUMAN OTC DRUG NDC:77340-004 Product Type Item Code (Source)

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL 70 mL in 100 mL

Inactive Ingredients

Ingredient Name Strength RAPIDGEL EZ1 (UNII: 33JH4A7R2K) HYDROGEN PEROXIDE (UNII: BBX060AN9V) GLYCERIN (UNII: PDC6A3C0OX) WATER (UNII: 059QF0KO0R)

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:77340-004- 04	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/07/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	09/07/2020		

28 MILE TOUGH TOWN HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77340-006
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Route of Administration	TOPICAL
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ı	0	3			
		Ingredient Name	Basis of Strength	Strength	
	ALCOHOL (UNII: 3K9958V9	0M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL	

Inactive Ingredients

mactive ingredients		
Ingredient Name	Strength	
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)		
GLYCERIN (UNII: PDC6 A3C0 OX)		
RAPIDGEL EZ1 (UNII: 33JH4A7R2K)		
WATER (UNII: 059QF0KO0R)		

Packaging

п		0 0			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:77340-006- 05	3785.41 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/07/2020	
		NDC:77340-006- 04	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/07/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/07/2020	

TOUGH TOWN HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77340-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
MALTO DEXTRIN (UNII: 7CVR7L4A2D)		
GLYCERIN (UNII: PDC6A3C0OX)		
XANTHAN GUM (UNII: TTV12P4NEE)		

Ш	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:77340-007- 04	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/07/2020		
	NDC:77340-007- 05	3785 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/30/2020		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/07/2020	

TOUGH TOWN HAND SANITIZER

ethyl alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77340-008	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
XANTHAN GUM (UNII: TTV12P4NEE)	

WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:77340-008- 04	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/07/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/07/2020	

TOUGH TOWN HAND SANITIZER

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77340-009
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
XANTHAN GUM (UNII: TTV12P4NEE)		
MALTO DEXTRIN (UNII: 7CVR7L4A2D)		
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		

l	Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
		NDC:77340-009- 04	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/07/2020		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/07/2020	

28 MILE TOUGH TOWN HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:77340-005

Route of Administration TOPICAL

Active Ingredient/Active Moiety

ı	0	9			
		Ingredient Name	Basis of Strength	Strength	
	ALCOHOL (UNII: 3K9958V	90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL	

Inactive Ingredients

Ingredient Name	Strength			
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
HYDRO GEN PERO XIDE (UNII: BBX060 AN9 V)				
RAPIDGEL EZ1 (UNII: 33JH4A7R2K)				

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:77340-005- 04	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/07/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/07/2020	

Labeler - 28 Mile Vodka Company LLC (107153056)

Registrant - 28 Mile Vodka Company LLC (107153056)

Establishment

Listabilistinicit			
Name	Address	ID/FEI	Business Operations
28 Mile Vodka Company LLC		107153056	manufacture(77340-004, 77340-005, 77340-006, 77340-007, 77340-008, 77340-009), label(77340-004, 77340-005, 77340-006, 77340-007, 77340-008, 77340-009)

Revised: 10/2020