

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 external 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 doctor 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, Glycerol, 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 Sheridan 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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28 MILE

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454 Sheridan Road,
Highwood, IL 60040

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

TOUGH TOWN

HAND SANITIZER

LAVENDER ROSE SCENTED

16 fl oz (473 mL) 70% Ethanol

Drug Facts

Active Ingredient	Purpose
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, Flammable. Keep away from heat or flame.

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, rinse eyes thoroughly 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. If swallowed, get medical 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, Methylparaben, Fragrance.

For External Use Only Do Not Drink
MADE IN THE USA

3 77340 00904 9

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Hand Sanitizer Non-sterile Solution



HAND SANITIZER



CUCUMBER MINT
SCENTED

16 fl oz (473 mL) 70% Ethanol

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MADE IN THE USA

28 MILE

TOUGH TOWN

UNSCENTED

HAND SANITIZER

1 Gallon (128 fl oz, 3.78 L)

68% Ethanol



Drug Facts

Active ingredient	Purpose
Alcohol 68% v/v	Antiseptic

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Ingredients • Sterile Water, Glycerol, Xanthan Gum, Maltodextrin

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MADE IN USA

Produced By: 28 Mile Distilling Co.
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Alcohol Antiseptic 68% Topical Solution
Hand Sanitizer Non-sterile Solution



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HAND SANITIZER

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Inactive ingredients Sterile Water, Androsylol, Glycerol, PEG-4, Hydroxybenzyl, Methyl, Propylol.

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TOUGH TOWN



LAVENDER ROSE SCENTED

HAND SANITIZER

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Drug Facts

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Alcohol 70% v/v	Antiseptic

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

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TOUGH TOWN

UNSCENTED

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

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28 MILE TOUGH TOWN HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77340-004
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: 059QF0K00R)	

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77340-006-05	3785.41 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/07/2020	
2	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)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
GLYCERIN (UNII: PDC6A3C0OX)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77340-007-04	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/07/2020	
2	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)	
MALTODEXTRIN (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: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
XANTHAN GUM (UNII: TTV12P4NEE)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	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

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

Inactive Ingredients

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

Packaging

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

Marketing Information

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OTC monograph not final	part333A	09/07/2020	

Labeler - 28 Mile Vodka Company LLC (107153056)

Registrant - 28 Mile Vodka Company LLC (107153056)

Establishment

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)

