

TOUGH TOWN HAND SANITIZER- alcohol gel
28 MILE DISTILLING 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.

Active Ingredient

Alcohol 80% v/v.

Purpose

Antiseptic

Uses

Hand Sanitizer to help 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.

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 and excessive heat above 40C (104F)

Inactive ingredients

Polyethylene glycol, 1, 2, 3-Propanetriol, 1, 3-Propanediamine, Benzyl benzoate, D-Limonene, .alpha.-Pinene, Hydrogen peroxide, Octanal, 2- (phenylmethylene), Oils (Siberian Fir, Citral, Geraniol Oils, Lemon, Juniper, Ethanone, Oils, Coriander, Sweet Orange, Petitgrain, Citronella, Citronellol, Geranium, Eucalyptus, Mandarin, Lime, Camphor oil, Linalool, Cyclohexanone

For External Use Only Do Not Drink

Package Label - Principal Display Panel

In response to changes in the global environment 28 Mile Distilling Co. has switched our production to respond to public health concerns and the safety of the public.

We are proud to be able to use our expertise and distillery to produce this hand sanitizer.

Stay clean, stay healthy

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

Alcohol Antiseptic 80% Topical Solution
Hand Sanitizer Non-sterile Solution



TOUGH TOWN

HAND SANITIZER

16 fl oz (473 mL) 80% Ethanol

Drug Facts

Active Ingredient Alcohol 80% w/v. **Purpose** Antiseptic

USE[s] Hand sanitizer to reduce bacteria that potentially can cause disease. For use with soap and water and 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 • Rub 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.

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Inactive Ingredients

Polyethylene glycol, 1,2,3-Propanetriol, 1,3-Propanediol, Benzyl benzoate, D-Limonene, alpha-Pinene, Hydrogen peroxide, Octanol, 2-(phenylmethyl)urea, Oils (Santal, Fir, Cedar, Geraniol, Oils, Lemongrass, Juniper, Eucalyptus, Geranium, Sweet Orange, Peppermint, Citronella, Citronella, Geranium, Eucalyptus, Mandarin, Lime, Camphor oil), Linalool, Cyclohexanone

For External Use Only Do Not Drink

TOUGH TOWN HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77340-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
GLYCERIN (UNII: PDC6A3C0OX)	
1,2,3-PROPANETRIOL, 2-(4-AMINO BENZOATE) (UNII: 3S4077U0T0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77340-002-01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/04/2020	
2	NDC:77340-002-02	89 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/04/2020	

3	NDC:77340-002-03	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/04/2020	
4	NDC:77340-002-04	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/04/2020	

Labeler - 28 MILE DISTILLING COMPANY, LLC (107153056)

Establishment

Name	Address	ID/FEI	Business Operations
28 MILE DISTILLING COMPANY, LLC		107153056	manufacture(77340-002)

Revised: 10/2020

28 MILE DISTILLING COMPANY, LLC