# 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.

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#### **Active Ingredient**

Alcohol 70% 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.

**IKeep 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**

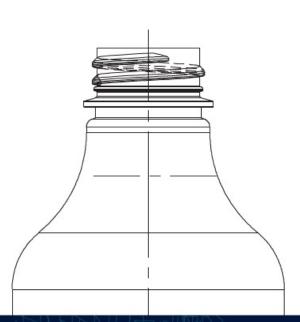
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

#### For external use only, do not drink.

## **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

#### 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 gin scented hand sanitizer.

Stay clean, stay healthy

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

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





DISTILLING CO. HAND SANITIZER

16 fl oz (473 mL) 70% Ethanol

**Drug Facts** 

Active ingredient

Purpose

Alcohol 70% v/v.\_\_\_\_Antiseptic USE[s] Hand sanifizer 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 fla

**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.

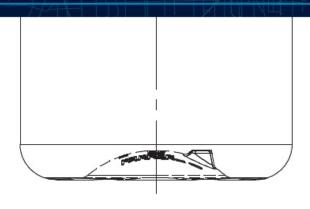
**Directions** • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 6 years of age when using this product to avoid swallowing.

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

Inactive Ingredients Polyethylene glycol

1.2.3-Propanetrid 1.3-Propanetismine, Besoyl berzoete,
D-Immente, alpina-Pinene, Hydrogen persoide, Octard.
2- (phenylmethylene), Olis (Sherian Hr, Citral, Gerandor),
D-Immente, Besoyl Carlotte, Carlotte, Carlotte,
D-Immente, Besoyl Carlotte,
D-Immente, Charlotte, Charlotte, Seerel Orange,
Petityrain, Chronella, Chronella, Geranium, Eucalybus,
Managieni, Line, Caraboto, ali Linead Mutchariane 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:77340-003	
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)				
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)				
GLYCERIN (UNII: PDC6A3C0OX)				
1,2,3-PROPANETRIOL, 2-(4-AMINOBENZOATE) (UNII: 3S4077U0T0)				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:77340-003- 01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/04/2020	

2	NDC:77340-003- 02	89 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/04/2020	
3	NDC:77340-003- 03	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/04/2020	
4	NDC:77340-003- 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(77340-003)	

Revised: 10/2020 28 MILE DISTILLING COMPANY, LLC