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



expertise and distillery to produce this hand sanitizer.

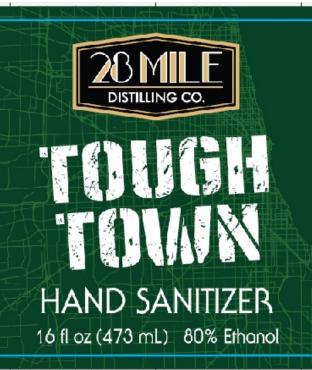
Stay dean, stay healthy

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

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







Drug Facts

Active ingredient Alcohol 80% v/v.... Purpose ...Antiseptic

USE[5] Hand sanitizer to reduce bacteria that potentially can cause disease. For use when some and water are not available

WarmingsFor external use only, Hammable, Keep away from heat or fluor

Do mod use• In children less than 2 months of age. • On open skir wound When using this product keep our of eyes, cass and mouth. In case of contact with eyes, rinse eyes thoroughly with water, Stop use and ask a doctor it initation or rash occurs These may be signs of a serious condition.

Reep out of reach of children. If swallowed, not medica held or contact a Poison Control Center right away.

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

Other Information • Store between 15-300 [59-86] Avoid freezing & excessive heat above 400 (104F)

Inscrine Ingredients - Folyethylene glytol, 1,23-hopparetiol, 1,3-frogenoderine Betzyl benatete, C-Limonere, alpha-Phene, hydrogen percode, Octand, 2- (benylmethylene, Clas (Shehia Fr, Chra), Geranid Ols, Lemon, Junger, Elbirone Ollo, Corrante, Saer Dange, Feltigrain, Ottonella, Chonella, Geranium, Eucalyptus, Mandarin, Line, Camphor oll), Linalcol, Cyddhexanche

For External Use Only Do Not Drink

TOUGH TOWN HAND SANITIZER

alcohol gel

Product Information

HUMAN OTC DRUG Product Type NDC:77340-002 Item Code (Source)

TOPICAL. Route of Administration

Active Ingredient/Active Moiety

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

Inactive Ingredients Ingredient Name Strength WATER (UNII: 059QF0KO0R) HYDROGEN PEROXIDE (UNII: BBX060AN9V) GLYCERIN (UNII: PDC6A3C0OX) **1,2,3-PROPANETRIOL, 2-(4-AMINOBENZOATE)** (UNII: 3S4077U0T0)

F	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 Categ	ory Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
О	TC monograph not	final part333A 0	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