

CLEAN MACHINE- alcohol liquid
Tom's Town Distilling Co.

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.

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

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

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.

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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

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel



Drug Facts	
Active ingredient(s) Alcohol 80% v/v	Purpose Antiseptic
Use(s) Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
Warnings For external use only. Flammable. Keep away from heat or flame.	
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Tom's Town Distilling Co.
1701 Main St., Kansas City, MO 64108
www.toms-town.com



3785.412 ml label NDC 77227-990-01 (NDC code on back label)

TOM'S TOWN

— DISTILLING CO —

CLEAN MACHINE

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

Drug Facts

Active ingredient[s]

Alcohol 80% v/v.....Antiseptic

Purpose

Antiseptic

Use[s]

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

Warnings

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Inactive ingredients glycerin, hydrogen peroxide, purified water USP

1701 Main St., Kansas City, MO 64108

www.toms-town.com

15,141.648ml NDC 77227-990-02 (NDC and Quantity numbers filled in blank box)

TOM'S TOWN
 = DISTILLING CO =

**CLEAN
 MACHINE**

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

Half Gallon (64oz.)

Drug Facts	
Active ingredient[s] Alcohol 80% v/v	Purpose ...Antiseptic
Use[s] Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
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Tom's Town Distilling Co.
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1892.74 ml label NDC 77227-990-03 (NDC code on back label)

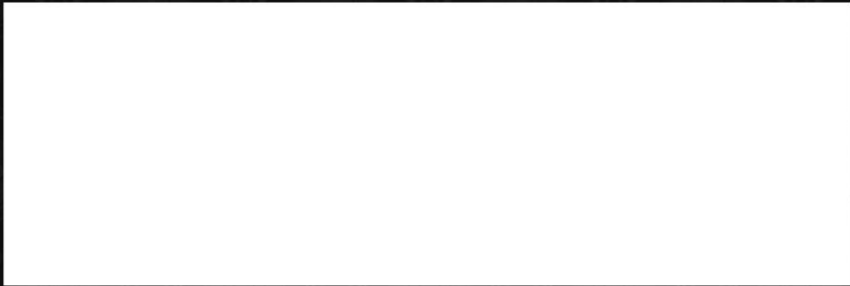
TOM'S TOWN

— DISTILLING CO —

CLEAN MACHINE

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

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1701 Main St., Kansas City, MO 64108

www.toms-town.com

1892.74 ml label 4 pack box NDC 77227-990-04 (NDC and Quantity numbers are filled into blank box)

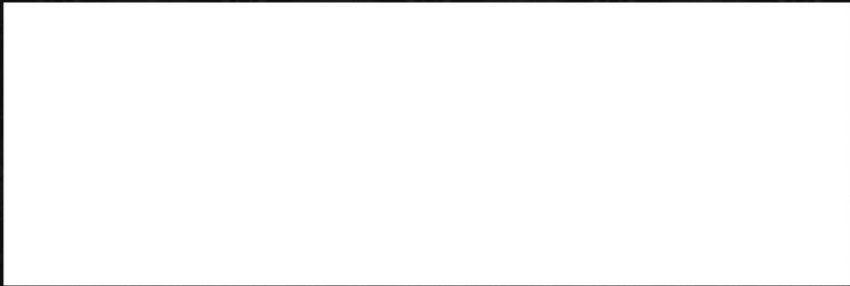
TOM'S TOWN

— DISTILLING CO —

CLEAN MACHINE

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

Drug Facts	
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP	



1701 Main St., Kansas City, MO 64108

www.toms-town.com

1892.74 ml 6 pack box NDC 77227-990-06 (NDC code and quantity filled into blank box)

TOM'S TOWN

— DISTILLING CO —

CLEAN MACHINE

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

Drug Facts

Active ingredient[s]

Alcohol 80% v/v.....Antiseptic

Purpose

Use[s]

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

Warnings

For external use only. Flammable. Keep away from heat or flame

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Other information

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Inactive ingredients glycerin, hydrogen peroxide, purified water USP

1701 Main St., Kansas City, MO 64108

www.toms-town.com

1135623.6 ml (300 gallon tote) NDC 77227-990-05 (NDC code and Quantity filled into blank box.)

CLEAN MACHINE

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77227-990
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77227-990-01	3785.412 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77227-990-04	7570.824 mL in 1 BOX; Type 0: Not a Combination Product	03/30/2020	
3	NDC:77227-990-02	15141.648 mL in 1 BOX; Type 0: Not a Combination Product	03/30/2020	
4	NDC:77227-990-03	1892.706 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
5	NDC:77227-990-05	1135623.54 mL in 1 TANK; Type 0: Not a Combination Product	03/30/2020	
6	NDC:77227-990-06	11356.236 mL in 1 BOX; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Tom's Town Distilling Co. (077716747)**Registrant** - Tom's Town Distilling Co. (077716747)**Establishment**

Name	Address	ID/FEI	Business Operations
Tom's Town Distilling Co.		077716747	manufacture(77227-990)

