ETHYL ALCOHOL- alcohol liquid
DENATURED DT ETHYL ALCOHOL- denatured alcohol liquid
DENATURED D ETHYL ALCOHOL- denatured ethyl alcohol liquid
Bushmill's Ethanol Inc.

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.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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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

UNDENATURED Alcohol

Ethanol (ethyl alcohol) 97%,
as determined by Density Meter

109777L

For use in production of hand sanitizers (antiseptic hand rubs) only. Denaturing required during hand sanitizer production.

Non-potable.

Manufactured by:
Bushmills Ethanol Inc.
17025 HWY 12 NE Atwater, MN 56209
320-337-9048 peter.t@bushmillsethanol.com

Manufacturer FDA registration number (DUNS):
152955394

Manufactured on <Insert Date>

Denatured D Alcohol

Ethanol (ethyl alcohol) 97%,
as determined by Density Meter

1249L

For use in production of hand sanitizers (antiseptic hand rubs) only. Denaturing required during hand sanitizer production.

Non-potable.

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Denatured D Alcohol

Ethanol (ethyl alcohol) 97%,
as determined by Density Meter

30238L

For use in production of hand sanitizers (antiseptic hand rubs) only. Denaturing required during hand sanitizer production.

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Manufactured on <Insert Date>

Denatured D Alcohol

Ethanol (ethyl alcohol) 97%,
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189L

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Manufacturer FDA registration number (DUNS):
152955394

Manufactured on <Insert Date>

ETHYL ALCOHOL

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74630-8303
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
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74630-8303-1	189000 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74630-8303-2	1249000 mL in 1 TANK; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74630-8303-3	30283000 mL in 1 TANK; Type 0: Not a Combination Product	03/30/2020	
4	NDC:74630-8303-4	109777000 mL in 1 TANK; 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	

DENATURED DT ETHYL ALCOHOL

denatured alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74630-0001
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

DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74630-0001-1	189000 mL in 1 DRUM; Type 0: Not a Combination Product	04/07/2020	
2	NDC:74630-0001-2	1249000 mL in 1 TANK; Type 0: Not a Combination Product	04/07/2020	
3	NDC:74630-0001-3	30238000 mL in 1 TANK; Type 0: Not a Combination Product	04/07/2020	
4	NDC:74630-0001-4	109777000 mL in 1 TANK; Type 0: Not a Combination Product	04/07/2020	

Marketing Information

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

DENATURED D ETHYL ALCOHOL

denatured ethyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:74630-0002
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
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74630-0002-1	189000 mL in 1 DRUM; Type 0: Not a Combination Product	04/07/2020	
2	NDC:74630-0002-2	1249000 mL in 1 TANK; Type 0: Not a Combination Product	04/07/2020	
3	NDC:74630-0002-3	30238000 mL in 1 TANK; Type 0: Not a Combination Product	04/07/2020	

4	NDC:74630-0002-4	109777000 mL in 1 TANK; Type 0: Not a Combination Product	04/07/2020	

Marketing Information

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OTC monograph not final	part333A	03/30/2020	

Labeler - Bushmill's Ethanol Inc. (152955394)

Establishment

Name	Address	ID/FEI	Business Operations
Bushmill's Ethanol Inc.		152955394	manufacture(74630-8303, 74630-0001, 74630-0002)

Revised: 4/2020 Bushmill's Ethanol Inc.