BTS-72- alcohol liquid
Didion Ethanol, 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.

Alcohol for Hand Sanitizer

This is a denatured ethanol manufactured for a hand sanitizer 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 denatured ethanol 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) (95%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.

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 95% v/v. Purpose: Antiseptic

Purpose

For use in production of Antiseptic, Hand Sanitizer

Use

Denatured Ethanol for use in production of 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

- For use in production of Hand Sanitizer that meets the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

Other information

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

Inactive ingredients

Denatonium Benzoate

Package Label - Principal Display Panel

DENATURED Alcohol [Denatonium Benzoate (Bitrex anhydrous)]

Ethanol (ethyl alcohol) 95%, as determined by a gravity density meter

[Insert Volume of Product in Liters]

For use in production of hand sanitizers (antiseptic hand rubs) only.

Non-potable.

Manufactured by: Didion Ethanol, LLC, N7088 South Hwy 146, Cambria, WI 53923

Point of Contact: Garret Beckett @ 920-348-6860

gbeckett@didionmilling.com

Manufacturer FDA registration number (DUNS): 804407612

Manufactured on: <Insert Date>

Released on: <Insert Date>

Batch Number:

alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:74519-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	95 L in 100 L

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
DENATONIUM BENZOATE ANHYDROUS (UNII: M5BA6GAF1O)	0.000488336 L in 100 L

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:74519-000-00	30280 L in 1 TANK; Type 0: Not a Combination Product	04/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/01/2020	

Labeler - Didion Ethanol, LLC (804407612)

Revised: 4/2020 Didion Ethanol, LLC