80% WITH DENATURANT AND FRAGRANCE- easy ecosave liquid Easy Energy Systems, 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.
- e. Denaturant
- f. Fragrance

Active Ingredient(s)

Ethyl Alcohol 80% v/v

Purpose

Antiseptic

Uses

Hand Sanitizer helps reduce germs on the skin that may cause disease.

Warnings

Flammable. Not for Human Consumption

- External Use Only
- Keep away from heat or flame
- Do not use with children less than 2 months old
- Do not use on open skin wounds

If contact with eyes, rinse thoroughly with clean water.

Stop use if irritation or rash appear.

If swallowed, Call Poison Control Center: 800 - 222 - 1222

Directions

Apply a palmful of the product in cupped hand, covering all surfaces well with product.

Rub hands together for 15 seconds, pay attention between fingers, fingernails and cuticles.

Allow to dry without wiping.

Prevent swallowing.

Supervise children less than 6 years old.

Other information

- Store between 59° F and 86° F
- Avoid freezing and high heat (above 104° F)

Inactive ingredients

bitrex, distilled water, fragrance, glycerin, hydrogen peroxide

Package Label - Principal Display Panel



80% WITH DENATURANT AND FRAGRANCE

easy ecosave liquid

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:81184-005 Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	3028 mL in 3785 mL		

Inactive Ingredients				
Ingredient Name	Strength			
COUMARIN (UNII: A4VZ 22K1WT)	17.94 mL in 3785 mL			
GLYCEROL FORMAL (UNII: 3L7GR2604E)	54.9 mL in 3785 mL			
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	4.73 mL in 3785 mL			
WATER (UNII: 059QF0KO0R)	679 mL in 3785 mL			
DENATONIUM BENZOATE ANHYDROUS (UNII: M5BA6GAF10)	15.1 mg in 3785 mL			

F	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:81184- 005-05	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2021			
2	NDC:81184- 005-03	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2021			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	07/01/2021		

Labeler - Easy Energy Systems, Inc. (789869885)

Registrant - Easy Energy Systems, Inc. (789869885)

Establishment				
Name	Address	ID/FEI	Business Operations	
Easy Energy Systems, Inc.		789869885	manufacture(81184-005)	