WHO RECOMMENDED HAND RUB- alcohol liquid Duda Energy 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.

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:

- 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

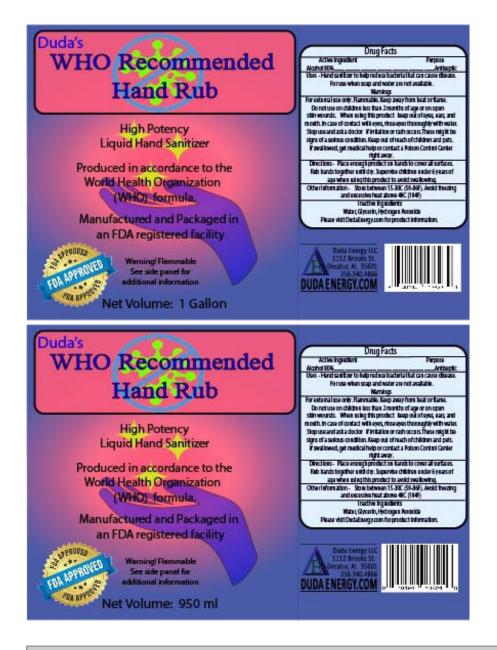
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel





WHO RECOMMENDED HAND RUB alcohol liquid **Product Information Product Type** HUMAN OTC DRUG Item Code (Source) NDC:77209-4934(NDC:65353-4934) **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 HYDROGEN PEROXIDE (UNII: BBX060AN9V) 0.125 mL in 100 mL

1	WATER (UNII: 059QF0KO0R)	
	GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL

34-1 C:77209- 34-2 C:77209-	Package Description 950 mL in 1 BOTTLE; Type 0: Not a Combination Product 3785 mL in 1 JUG; Type 0: Not a Combination Product 18925 mL in 1 PAIL; Type 0: Not a Combination Product	Marketing Start Date 06/10/2020 06/10/2020 06/10/2020	Marketing End Date				
34-1 C:77209- 34-2 C:77209-	Product 3785 mL in 1 JUG; Type 0: Not a Combination Product 18925 mL in 1 PAIL; Type 0: Not a Combination	06/10/2020					
34-2 C:77209-	Product 18925 mL in 1 PAIL; Type 0: Not a Combination						
		06/10/2020					
Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph not part333A		06/10/2020					
M (larketing Category	Application Number or Monograph CitationCategoryCitation	Application Number or Monograph CitationMarketing Start DateDateDate				

Labeler - Duda Energy LLC (023793705)

Registrant - Duda Energy LLC (023793705)

Establishment						
Name	Address	ID/FEI	Business Operations			
Duda Energy LLC		023793705	repack(77209-4934), relabel(77209-4934)			

Revised: 1/2022

Duda Energy LLC