READY4LIFE HAND SANITIZER GEL WILDWOODS- alcohol liquid Hand 2 Hand Industries, 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:

- 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 70% 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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away.

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, water USP, carbomer, dimethicone, triethlyamine, fragrance

Package Label - Principal Display Panel

60 mL NDC: 78794-122-01

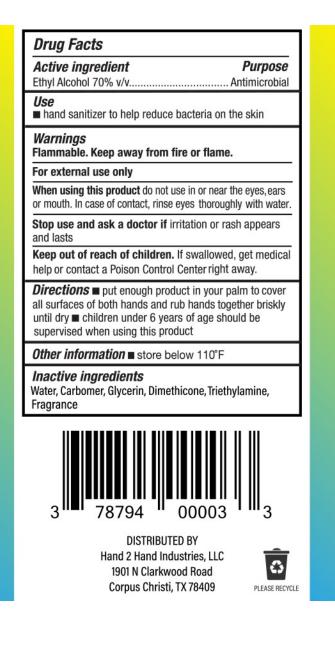


SMOOTHING MOISTURIZER www.ready4life.com



2 FL OZ (59 ML)

237 mL NDC: 78794-122-02





READY4LIFE HAND SANITIZER GEL WILDWOODS

alcohol liquid

Product Information							
Product Type	HUMAN OTC DRUG	Ite m C	ode (Source)	NDC:78794-125			
Route of Administration	TOPICAL						
Active Ingredient/Active M	oiety						
-	oiety dient Name		Basis of Strength	Strength			
Ingre	dient Name		Basis of Strength ALCOHOL	Strength 73.0166 mL in 100 mL			
Active Ingredient/Active M Ingre ALCOHOL (UNII: 3K9958V90M) (4	dient Name						
Ingre	dient Name						

Ingredient Name	Strength
CITRAL (UNII: T7EU0O9VPP)	0.00155 mL in 100 mL
DIHYDRO PENTAMETHYL INDANONE (UNII: BZR4438 MY4)	0.00155 mL in 100 mL
DIHYDROMYRCENOL (UNII: 46L1B02ND9)	0.00155 mL in 100 mL
LAVANDIN OIL (UNII: 9RES347CKG)	0.00155 mL in 100 mL
ROSEMARY OIL (UNII: 8LGU7VM393)	0.00155 mL in 100 mL
2,4-DIMETHYL-3-CYCLOHEXENE CARBOXALDEHYDE (UNII: 452GFV2AFS)	0.00155 mL in 100 mL
BENZYL BENZOATE (UNII: N863NB338G)	0.00155 mL in 100 mL
GERANYL ACETATE (UNII: 3W81YG7P9R)	0.00155 mL in 100 mL
HEXYL ACETATE (UNII: 7U7KU3MWT0)	0.00155 mL in 100 mL
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	0.0666 mL in 100 mL
TRIETHYLAMINE (UNII: VOU72806AY)	0.134 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.25 mL in 100 mL
CARBOMER 980 (UNII: 4Q93RCW27E)	
WATER (UNII: 059QF0KO0R)	
ISOBORNYL ACETATE (UNII: 54T6CCU09Z)	0.00155 mL in 100 mL
HEXAMETHYL INDANO PYRAN (UNII: 14170060AT)	0.00155 mL in 100 mL
GERANIOL (UNII: L837108USY)	0.00155 mL in 100 mL
VANILLIN (UNII: CHI530446X)	0.00155 mL in 100 mL
BENZYL SALICYLATE (UNII: WAO5MNK9TU)	0.00155 mL in 100 mL
LINALOOL, (+/-)- (UNII: D8 1Q Y6 I8 8 E)	0.00155 mL in 100 mL
COUMARIN 521 (UNII: 2773GTW04S)	0.00155 mL in 100 mL
LIMONENE, (+)- (UNII: GFD7C86Q1W)	0.00155 mL in 100 mL
.ALPHADAMASCONE (UNII: UP5JTZ982I)	0.00155 mL in 100 mL
1-(2,3,8,8-TETRAMETHYL-1,2,3,4,5,6,7,8-O CTAHYDRO NAPHTHALEN-2-YL)ETHANO NE (UNII: 1GD70DM28 Y)	0.00155 mL in 100 mL
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	0.00155 mL in 100 mL
BORNEOL, (-)- (UNII: 1Y84986J9Q)	0.00155 mL in 100 mL
ISOAMYL SALICYLATE (UNII: M25E4ZMR0N)	0.00155 mL in 100 mL
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	0.00155 mL in 100 mL
LINALYL ACETATE, (-)- (UNII: J7C5I8LV3G)	0.00155 mL in 100 mL
METHYL BENZODIO XEPINO NE (UNII: 0 NQ 136 C313)	0.00155 mL in 100 mL
EUCALYPTUS OIL (UNII: 2R04ONI662)	0.00155 mL

P	Packaging							
#	Item Code		Package Description	Marketing Start Date	Marketing End Date			
1	NDC:78794-125- 01	60 mI Produ	L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination ct	07/09/2020				
2	NDC:78794-125- 02	237 m Produ	L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination ct	07/09/2020				
3	NDC:78794-125- 03	384 m Produ	L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination ct	07/09/2020				
Marketing Information								
	Marketing Categ	ory	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
0	TC monograph not	final	part333A	07/09/2020				

Labeler - Hand 2 Hand Industries, LLC (117545800)

Establishment

Name	Address	ID/FEI	Business Operations
Hand 2 Hand Industries, LLC		117545800	manufacture(78794-125)

Revised: 10/2020

Hand 2 Hand Industries, LLC