READY4LIFE HAND SANITIZER GEL SUMMERTIME- 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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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: 78794-124-01



Alcohol Antiseptic 70% Topical Solution

SUMMERTIME

HAND SANITIZER

SAFE & EFFECTIVE FOR LIFE ON THE GO

(when used as directed)

HELPS KILL GERMS
PARABEN FREE
SMOOTHING MOISTURIZER
www.ready4life.com



2 FL OZ (59 ML)

Drug Facts

Active ingredient

Purpose

Ethyl Alcohol 70% v/v..... Antimicrobial

Use

■ hand sanitizer to help reduce bacteria on the skin

Warnings

Flammable. Keep away from fire or flame.

For external use only

When using this product do not use in or near the eyes, ears or mouth. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions ■ put enough product in your palm to cover all surfaces of both hands and rub hands together briskly until dry ■ children under 6 years of age should be supervised when using this product

Other information ■ store below 110°F

Inactive ingredients

Water, Carbomer, Glycerin, Dimethicone, Triethylamine, Fragrance



DISTRIBUTED BY Hand 2 Hand Industries, LLC 1901 N Clarkwood Road Corpus Christi, TX 78409



237 mL NDC: 78794-124-02

CITRUS SCENT SMOOTHING MOISTURIZER

HELPS KILL GERMS PARABEN FREE

www.ready4life.com



Alcohol Antiseptic 70% Topical Solution

SUMMERTIME

SAFE & EFFECTIVE FOR LIFE ON THE GO



13 FL OZ (384ML)

Drug Facts Active ingredient Ethyl Alcohol 70% v/v.

Purpose

■ hand sanitizer to help reduce bacteria on the skin

Warnings Flammable. Keep away from fire or flame.

For external use only

When using this product do not use in or near the eyes, ears or mouth. In case of contact, rinse eyes thoroughly with water

Stop use and ask a doctor if irritation or rash appears

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions ■ put enough product in your palm to cover all surfaces of both hands and rub hands together briskly until dry ■ children under 6 years of age should be supervised when using this product

Other information ■ store below 110°F

Inactive ingredients Water, Carbomer, Glycerin, Dimethicone, Triethylamine, Fragrance



Hand 2 Hand Industries, LLC 1901 N Clarkwood Road Corpus Christi, TX 78409



384 mL NDC: 78794-124-03

CITRUS SCENT SMOOTHING MOISTURIZER

HELPS KILL GERMS PARABEN FREE



www.ready4life.com



Alcohol Antiseptic 70% Topical Solution

SAFE & EFFECTIVE FOR LIFE ON THE GO



13 FL 0Z (384ML)

Drug Facts

Active ingredient Ethyl Alcohol 70% v/v...

Purpose Antimicrobial

Use■ hand sanitizer to help reduce bacteria on the skin

Warnings Flammable. Keep away from fire or flame.

For external use only

When using this product do not use in or near the eyes, ears or mouth. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions ■ put enough product in your palm to cover all surfaces of both hands and rub hands together briskly until dry ■ children under 6 years of age should be supervised when using this product

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READY4LIFE HAND SANITIZER GEL SUMMERTIME

alcohol liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:78794-124

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL 73.0166 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
.ALPHATERPINEO L (UNII: 21334LVV8W)	0.01734 mL in 100 mL
LIMO NENE, (+)- (UNII: GFD7C86Q1W)	0.01734 mL in 100 mL
PEG-10 DIMETHICO NE (600 CST) (UNII: 8 PR7V1SVM0)	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)	
DIHYDROMYRCENOL (UNII: 46L1B02ND9)	0.01734 mL in 100 mL
LEVOMENTHOL (UNII: BZ1R15MTK7)	0.01734 mL in 100 mL
CITRAL (UNII: T7EU0O9VPP)	0.01734 mL in 100 mL

F	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:78794-124- 01	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/09/2020			
2	NDC:78794-124- 02	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/09/2020			
3	NDC:78794-124- 03	384 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/09/2020			

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC 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(78794-124)			

Revised: 10/2020 Hand 2 Hand Industries, LLC