HAND SANITIZER- ethanol liquid The Hanson Group, 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 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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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right

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, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel















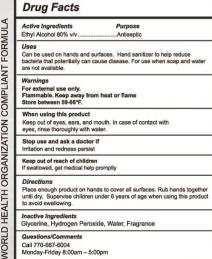


468 mL 75569-100-06



LIQUID FORMULA

2 fl oz (60ml)





75569-100-08





8 fl oz (236ml)

Drug Facts

Ethyl Alcohol 80% v/v.

Purpose Antiseptic

bacteria that potentially can cause disease. For use when soap and water

For external use only. Flammable. Keep away from heat or flam Store between 59-86°F.

When using this product

Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water.

Stop use and ask a doctor if

Keep out of reach of children
If swallowed, get medical help promptly

WORLD HEALTH ORGANIZATION COMPLIANT FORMULA

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.

MANUFACTURED IN USA SUPPORTING AMERICAN WORKERS

Inactive Ingredients

Glycerine, Hydrogen Peroxide, Water, Fragrance

Questions/Comments

Call 770-667-6004 Monday-Friday 8:00am – 5:00pm

The Hanson Group, LLC 3044 Adriatic Court Peachtree Corners, GA 30071

GUARDIANSPORTS.COM







HAND SANITIZER

LIQUID FORMULA

16 F. OZ (468m.)

WORLD HEALTH ORGANIZATION COMPLIANT FORMULA

Drug Facts

Active Ingredients

Purpose

Ethyl Alcohol 80% v/vAntiseptic

Can be used on hands and surfaces. 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

Store between 59-86°F.

When using this product

Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water.

Stop use and ask a doctor if

Irritation and redness persist

Keep out of reach of children

If swallowed, get medical help promptly

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.

Inactive Ingredients

Glycerine, Hydrogen Peroxide, Water, Fragrance

Questions/Comments

Call 770-667-6004

Monday-Friday 8:00am - 5:00pm



MANUFACTURED IN USA SUPPORTING AMERICAN WORKERS

Manufactured By

The Hanson Group, LLC 3044 Adriatic Court Peachtree Corners, GA 30071

GUARDIANSPORTS.COM



HAND SANITIZER

ethanol liquid

Product Information

HUMAN OTC DRUG Item Code (Source) NDC:75569-100 Product Type

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII: 3K9958 V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)	2.5 mL in 100 mL	

WATER (UNII: 059QF0KO0R)	15.95 mL in 100 mL
PEPPERMINT OIL (UNII: AV092KU4JH)	0.05 mL in 100 mL
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	1.5 mL in 100 mL

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75569-100-01	3785 mL in 1 JUG; Type 0: Not a Combination Product	04/17/2020	
2	NDC:75569-100-02	18927 mL in 1 PAIL; Type 0: Not a Combination Product	04/17/2020	
3	NDC:75569-100-03	196841 mL in 1 DRUM; Type 0: Not a Combination Product	04/17/2020	
4	NDC:75569-100-04	10 10 70 0 mL in 1 TANK; Type 0: Not a Combination Product	04/17/2020	
5	NDC:75569-100-05	1893 mL in 1 JUG; Type 0: Not a Combination Product	04/17/2020	
6	NDC:75569-100- 06	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/17/2020	
7	NDC:75569-100- 09	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/17/2020	
8	NDC:75569-100- 08	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/17/2020	
9	NDC:75569-100-10	468 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/17/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/17/2020	

Labeler - The Hanson Group, LLC (021336115)

Registrant - The Hanson Group, LLC (021336115)

Establishment				
Name	Address	ID/FEI	Business Operations	
The Hanson Group, LLC		021336115	manufacture(75569-100)	

Revised: 4/2020 The Hanson Group, LLC