

HAND SANITIZER- isopropyl alcohol liquid

ACS Natural

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. Isopropyl Alcohol (75%, 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)

Isopropyl Alcohol 75% 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

American Cosmetic Supply

KILLS 99.99% OF GERMS

HEALTH CARE RAPID SANITIZER

Antiseptic Hand Rub Topical Solution

Net Weight: 1 Gallon • 128 oz (3.785L)

Manufactured by: ACS NATURAL LLC
10405 Rockley Rd.
Houston, TX 77099

MADE IN USA

Drug Facts

Active Ingredient(s)
Isopropyl alcohol 75% w/v

Use(s)
• Health care personnel hand cause disease.

Warnings
For external use only.

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Stop use and ask a doctor
of a serious condition.

Keep out of reach of child
Poison Control Center right av

Directions:
• Place enough product on h
until dry.
• Supervise children under 6
swallowing.

Other Information:
• Store between 15-30C (59-
• Avoid freezing and excessiv

Inactive Ingredients: ge



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16 oz (473 mL)

D

Active Ingredients
Isopropyl Alcohol

Uses: Health care
reduce bacteria tha

Warnings: For e
Flammable. Keep

- Not for children
- Do not use on o
- Keep out of reac
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Other Informati

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12 oz (355 mL)

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8 oz (236 mL)

D

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6 oz (177 mL)

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4 oz (118 mL)

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2 oz (59 mL)

D:

Active Ingredient
Isopropyl Alcohol

Uses: Health care
reduce bacteria tha

Warnings: For e:
Flammable. Keep

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- Do not use on o
- Keep out of reac
- Stop use and ask

Inactive Ingredi
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946 ml NDC: 79256-001-32



American Cosmetic Supply

KILLS 99.99%
OF GERMS

HEALTH CARE HAND SANITIZER

Antiseptic Hand Rub

Topical Solution

(Net Weight: 32 oz (946 mL))

Manufactured by: ACS NATURAL LLC.
10405 Rockley Rd.
Houston, TX 77099



MADE IN USA

Drug Facts

Active Ingredient(s)
Isopropyl alcohol 75% v/v

Use(s)

• Health care personnel hand cause disease.

Warnings

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Inactive Ingredients: q

HAND SANITIZER

isopropyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79256-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	23.425 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79256-001-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/23/2020	
2	NDC:79256-001-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/23/2020	
3	NDC:79256-001-06	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/23/2020	
4	NDC:79256-001-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/23/2020	
5	NDC:79256-001-12	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/23/2020	
6	NDC:79256-001-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/23/2020	

7	NDC:79256-001-93	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/23/2020	
8	NDC:79256-001-32	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/23/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	06/23/2020	

Labeler - ACS Natural (060780107)

Registrant - ACS Natural (060780107)

Establishment			
Name	Address	ID/FEI	Business Operations
ACS Natural		060780107	manufacture(79256-001)