

HAND SANITIZER- alcohol liquid

Astera International 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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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

118 ML NDC: 77556-580--04



ALCOHOL ANTISEPTIC

80%

TOPICAL SOLUTION

HAND SANITIZER

Non-sterile Solution

4 FL OZ / (118 ML)



Drug Facts	
Active ingredient[s]	Purpose
Alcohol 80% v/v.....	Antiseptic
Use[s]	
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SONITIZER
ASTERA INTERNATIONAL LLC
TEXAS USA
www.Sonitizer.com





ALCOHOL ANTISEPTIC
80%
TOPICAL SOLUTION

ANTISEPTIC HAND RUB
Non-sterile Solution
4 FL OZ / (118 ML)



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59 ML NDC: 77556-580-02



ALCOHOL ANTISEPTIC
80%
TOPICAL SOLUTION

ANTISEPTIC HAND RUB
Non-sterile Solution
2 FL OZ / (59 ML)



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Drug Facts	
Active ingredient[s]	Purpose
Alcohol 80% v/v.....	Antiseptic
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ALCOHOL ANTISEPTIC
80%
TOPICAL SOLUTION

HAND SANITIZER
Non-sterile Solution
2 FL OZ / (59 ML)



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236 ML NDC: 77556-580-08



ALCOHOL ANTISEPTIC
80%
TOPICAL SOLUTION

ANTISEPTIC HAND RUB
Non-sterile Solution
8 FL OZ / (236 ML)



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Drug Facts	
Active ingredient[s]	Purpose
Alcohol 80% v/v.....	Antiseptic
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ALCOHOL ANTISEPTIC
80%
TOPICAL SOLUTION

HAND SANITIZER
Non-sterile Solution
8 FL OZ / (236 ML)



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354 ML NDC: 77556-580-12



ALCOHOL ANTISEPTIC
80%
TOPICAL SOLUTION

ANTISEPTIC HAND RUB
Non-sterile Solution
12 FL OZ / (354 ML)



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Drug Facts	
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ALCOHOL ANTISEPTIC
80%
TOPICAL SOLUTION

HAND SANITIZER
Non-sterile Solution
12 FL OZ / (354ML)



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400 ML NDC: 77556-580-13



ALCOHOL ANTISEPTIC
80%
TOPICAL SOLUTION

ANTISEPTIC HAND RUB
Non-sterile Solution
13.5 FL OZ / (400 ML)



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Drug Facts	
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ALCOHOL ANTISEPTIC
80%
TOPICAL SOLUTION

HAND SANITIZER
Non-sterile Solution
13.5 FL OZ / (400 ML)



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473 ML NDC: 77556-580-16



ALCOHOL ANTISEPTIC
80%
TOPICAL SOLUTION

ANTISEPTIC HAND RUB
Non-sterile Solution
16 FL OZ / (473 ML)



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TEXAS USA
www.Sonitizer.com



Drug Facts	
Active ingredient[s]	Purpose
Alcohol 80% v/v.....	Antiseptic
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ALCOHOL ANTISEPTIC
80%
TOPICAL SOLUTION

HAND SANITIZER
Non-sterile Solution
16 FL OZ / (473 ML)



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946 ML NDC: 77556-580-32



ALCOHOL ANTISEPTIC
80%
TOPICAL SOLUTION

ANTISEPTIC HAND RUB
Non-sterile Solution
32 FL OZ / (946 ML)



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Drug Facts	
Active ingredient[s]	Purpose
Alcohol 80% v/v.....	Antiseptic
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ALCOHOL ANTISEPTIC
80%
TOPICAL SOLUTION

HAND SANITIZER
Non-sterile Solution
32 FL OZ / (946ML)



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1000 ML NDC: 77556-580-33



ALCOHOL ANTISEPTIC
80%
TOPICAL SOLUTION

HAND SANITIZER
Non-sterile Solution
33.8 FL OZ / (1 L)



SONITIZER
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Drug Facts	
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ALCOHOL ANTISEPTIC
80%
TOPICAL SOLUTION

ANTISEPTIC HAND RUB
Non-sterile Solution
33.8 FL OZ / (1 L)



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2000 ML NDC: 77556-580-67



ALCOHOL ANTISEPTIC
80%
TOPICAL SOLUTION

HAND SANITIZER
Non-sterile Solution
67.6 FL OZ / (2L)



SONITIZER
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Drug Facts	
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Alcohol 80% v/v.....	Antiseptic
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ALCOHOL ANTISEPTIC
80%
TOPICAL SOLUTION

ANTISEPTIC HAND RUB
Non-sterile Solution
67.6 FL OZ / (2 L)



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Drug Facts	
Active ingredient[s] Alcohol 80% v/v.....	Purpose Antiseptic
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HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77556-580
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
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

		Marketing Status	
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77556-580-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	
2	NDC:77556-580-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	
3	NDC:77556-580-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	
4	NDC:77556-580-12	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	
5	NDC:77556-580-13	400 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	
6	NDC:77556-580-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	
7	NDC:77556-580-32	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	
8	NDC:77556-580-33	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	
9	NDC:77556-580-67	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	
10	NDC:77556-580-93	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	



ALCOHOL ANTISEPTIC
80%
TOPICAL SOLUTION

HAND SANITIZER
Non-sterile Solution
4 FL OZ / (118 ML)



Drug Facts	
Active ingredient[s]	Purpose
Alcohol 80% v/v.....	Antiseptic
Use[s]	
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Warnings	
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<ul style="list-style-type: none"> 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.	
Directions	
<ul style="list-style-type: none"> 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	
<ul style="list-style-type: none"> Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

SONITIZER
ASTERA INTERNATIONAL LLC
TEXAS USA
www.Sonitizer.com



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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Labeler - Astera International LLC (117509123)

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Astera International LLC