

OFF HAND HAND SANITIZER- alcohol liquid Encore Industrial Products, 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.

Hand Sanitizer

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:

- 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.
- Glycerol (1.45% v/v).
- Hydrogen peroxide (0.125% v/v).
- 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.

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OFF HAND HAND SANITIZER

ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION

HAND SANITIZER NON-STERILE SOLUTION

Net Contents: 355 mL

Drug Facts	
Active ingredient(s) Alcohol 80% v/v	Purpose Antiseptic
Use[s] 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.	
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	

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic



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World Health Organization (WHO) recommendations: Alcohol (USP Food Chemical Codex (FCC) grade) (80%, volume/volume) in a 70% solution denatured according to Alcohol and Tobacco Tax and Trade Regulations in 27 CFR part 20. Glycerol (1.45% v/v). Hydrogen Peroxide (0.01% v/v). Sterile distilled water or boiled cold water. The firm does not contain any inactive ingredients. Different or additional ingredients may affect the potency of the product.

Drug Facts

Active ingredient[s]
Alcohol 80% v/v.

Use[s]

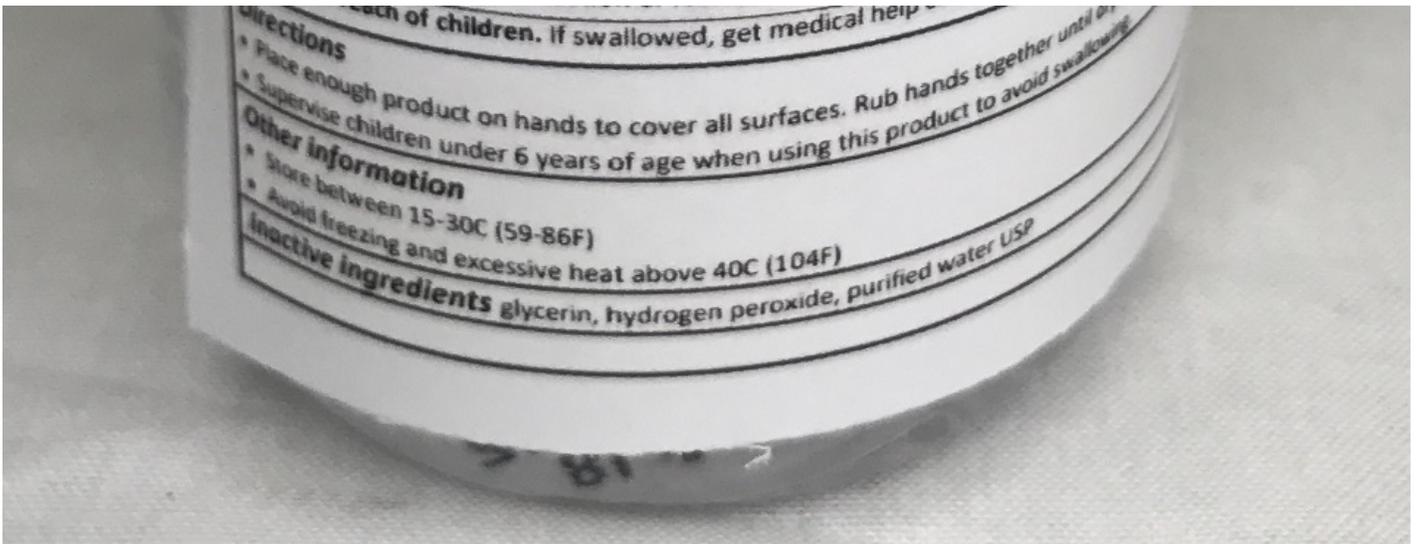
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

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Do not use

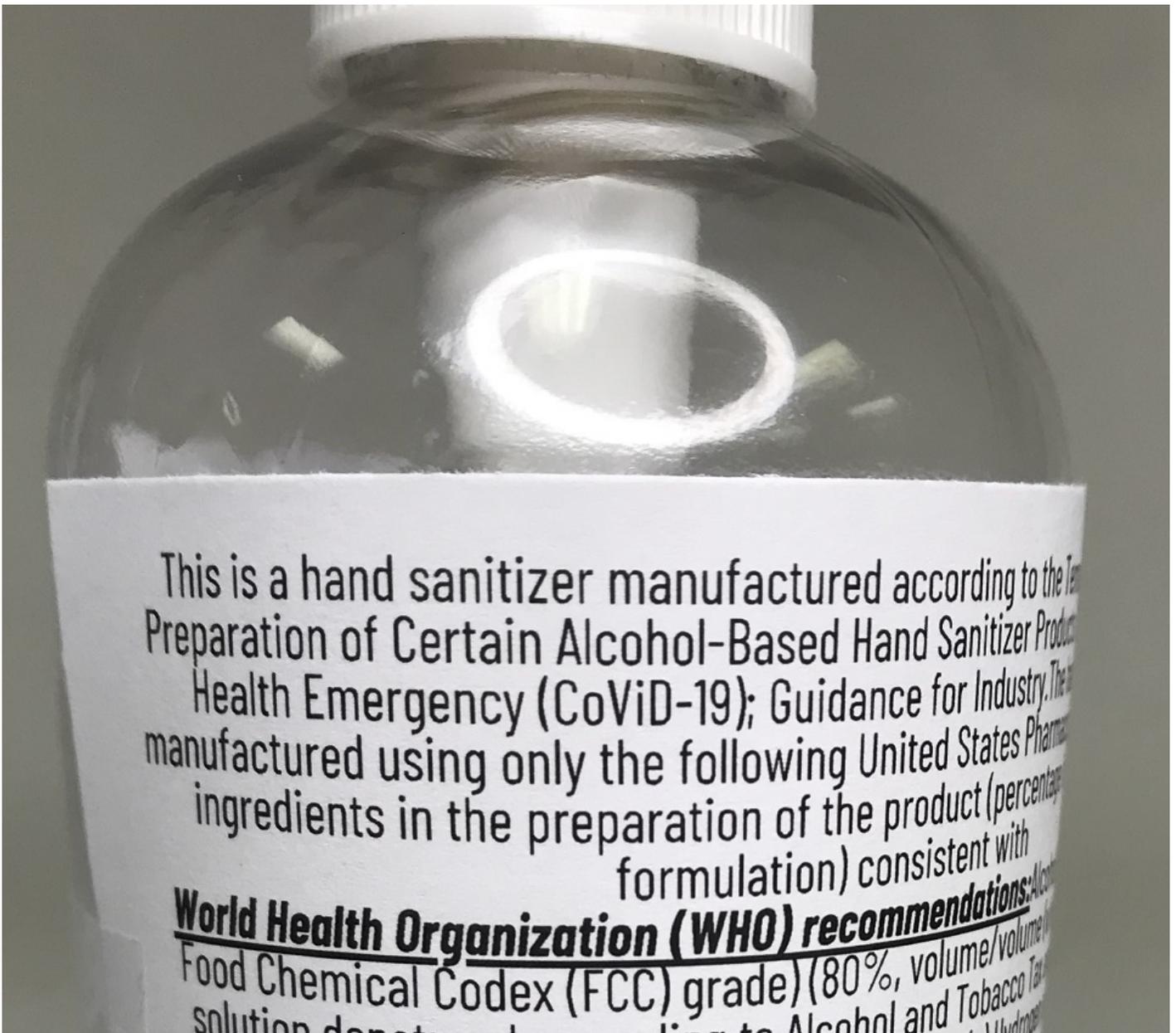
- in children less than 2 months of age
- on open skin wounds

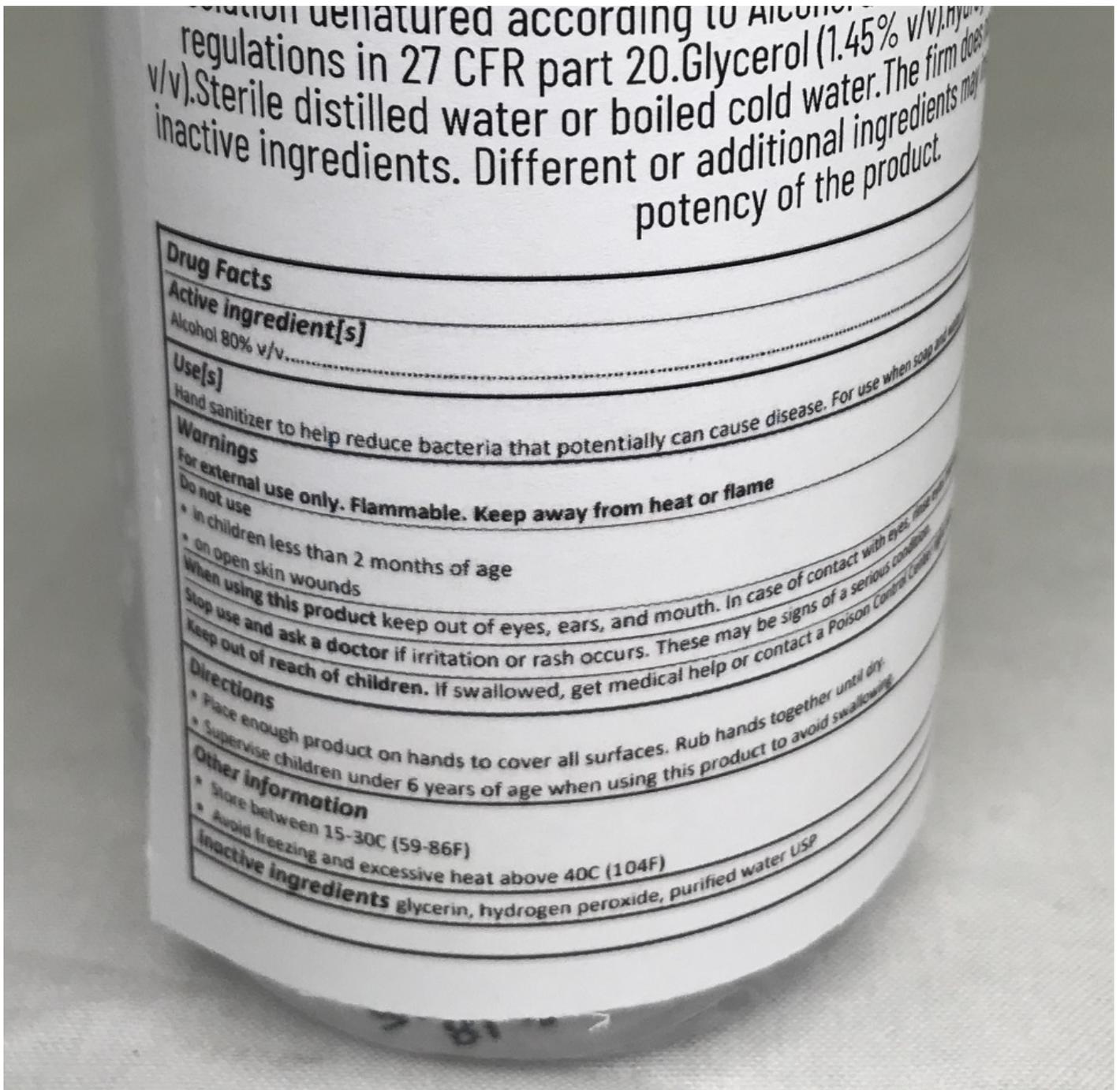
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse with water. Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. For more information or to contact a Poison Control Center, call 1-800-535-5853.



Purpose

Antiseptic, Hand Sanitizer





Use

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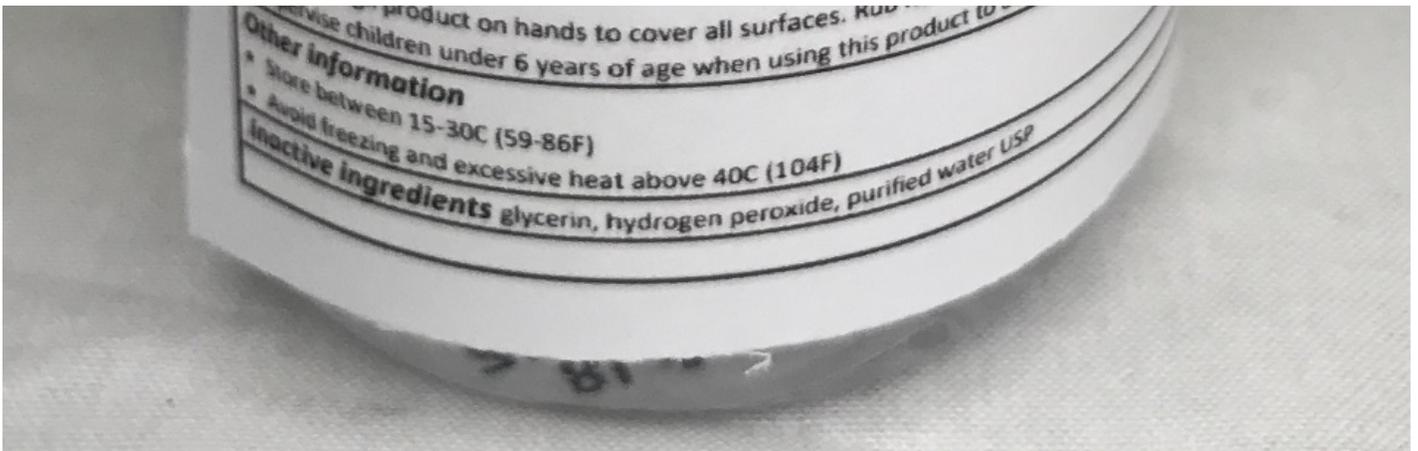
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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center for more information.

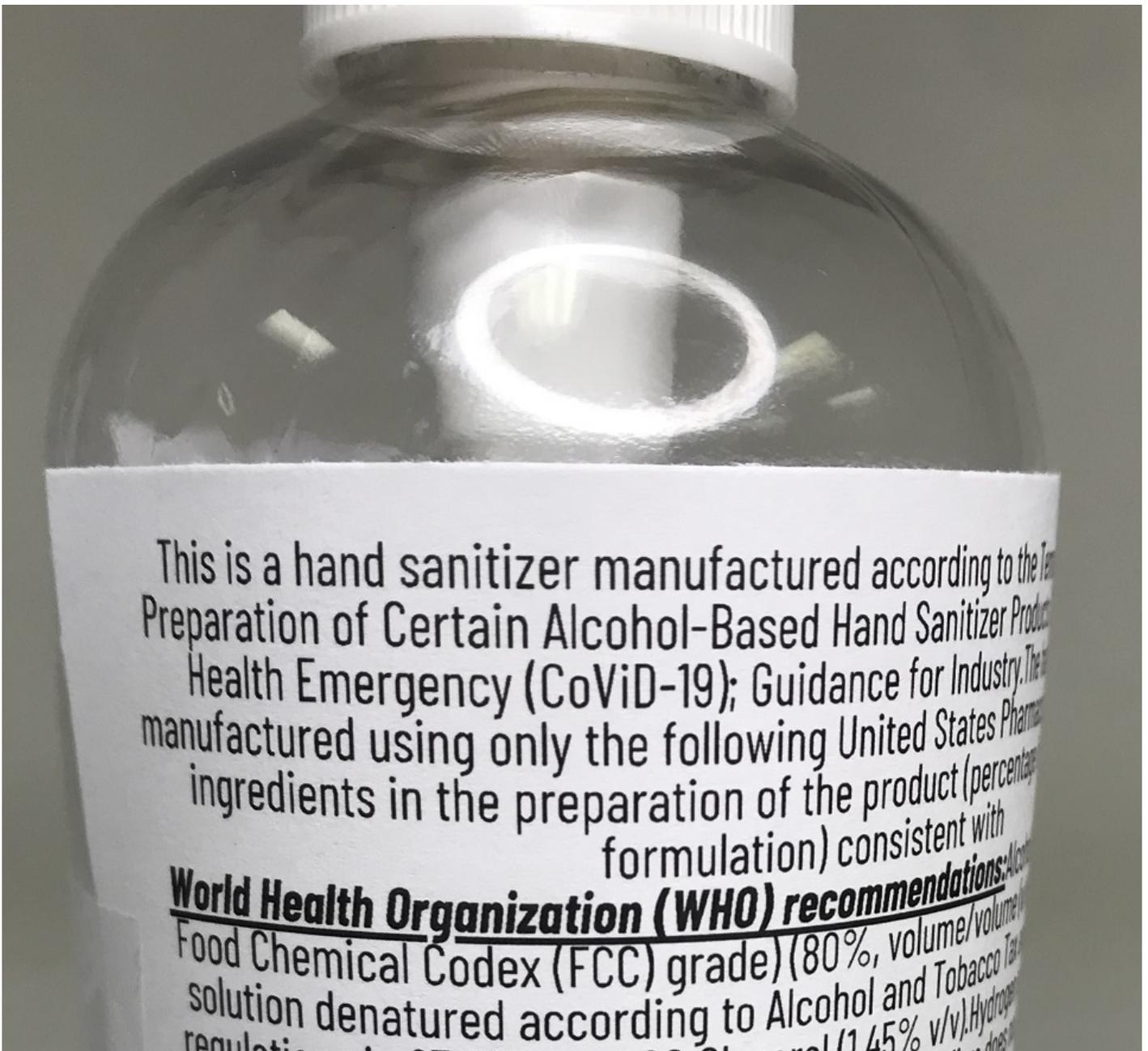
Directions

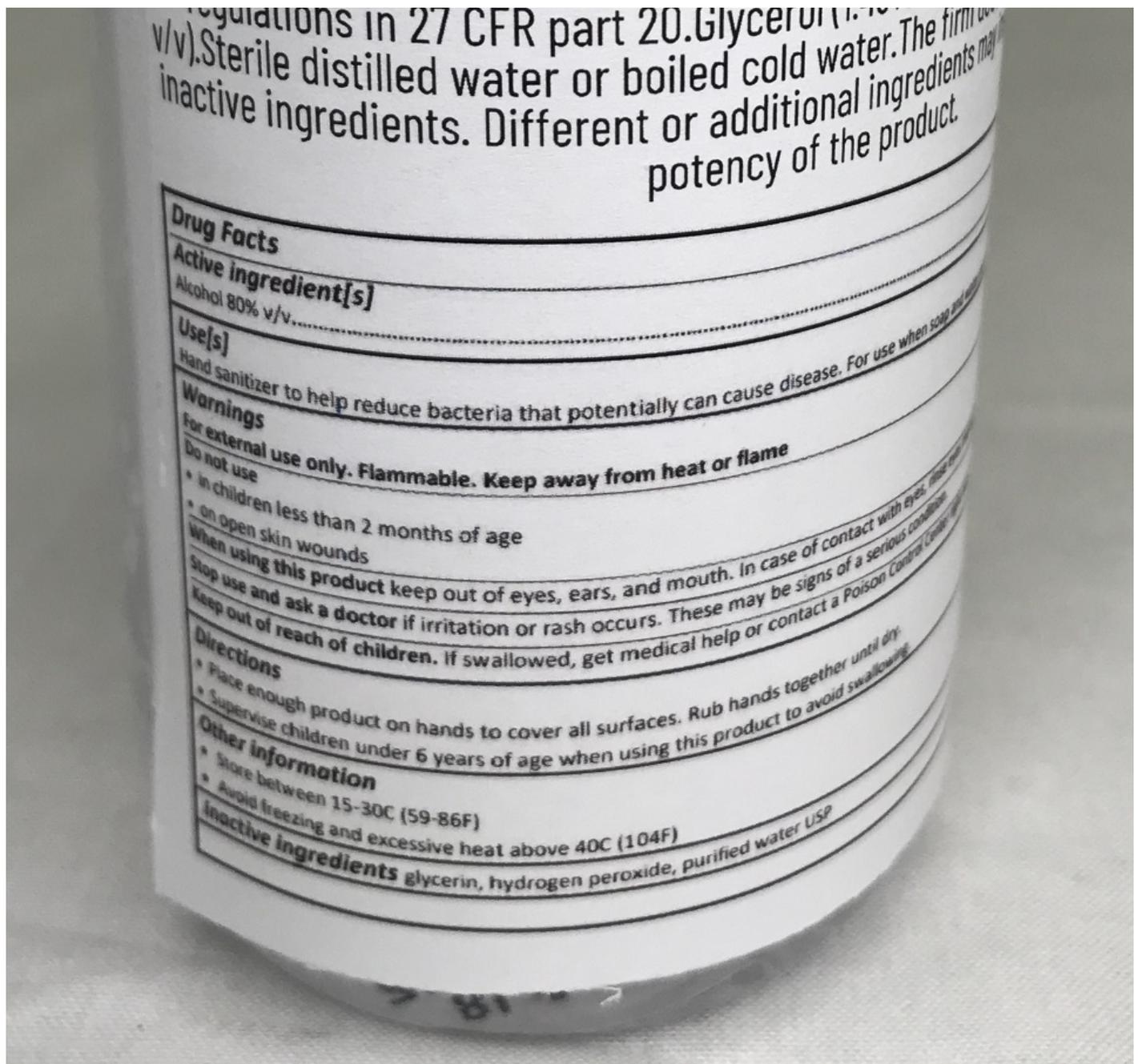
- Place enough product on your hands to cover all surfaces.
- Rub hands together until dry. Do not use a towel to dry your hands. Avoid swallowing.



Do not use

- in children less than 2 months of age
- on open skin wounds

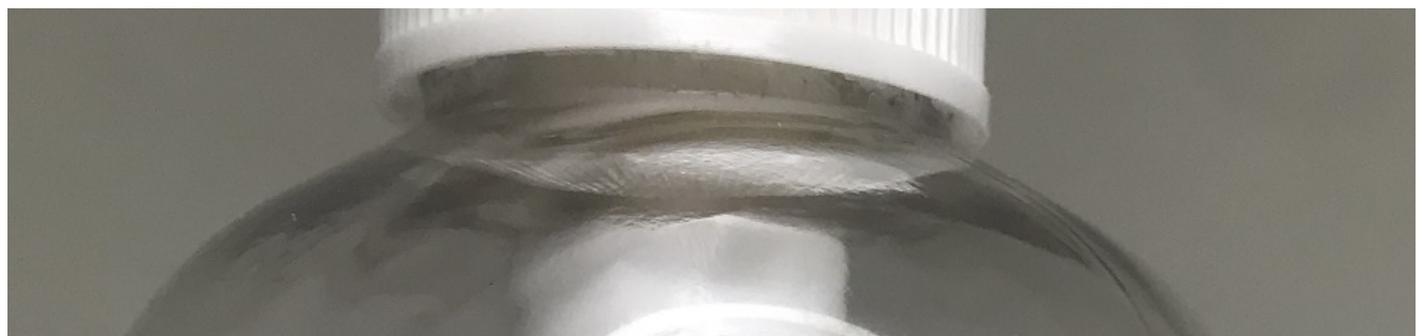




When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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World Health Organization (WHO) recommendations: Alcohol (USP Food Chemical Codex (FCC) grade) (80%, volume/volume)

Hydrogen Peroxide (USP grade) (1.45% v/v). Hydrogen Peroxide solution denatured according to Alcohol and Tobacco Tax and Trade Regulations in 27 CFR part 20. Glycerol (1.45% v/v). Hydrogen Peroxide (3% v/v). Sterile distilled water or boiled cold water. The firm does not contain any inactive ingredients. Different or additional ingredients may affect the potency of the product.

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Alcohol 80% v/v.

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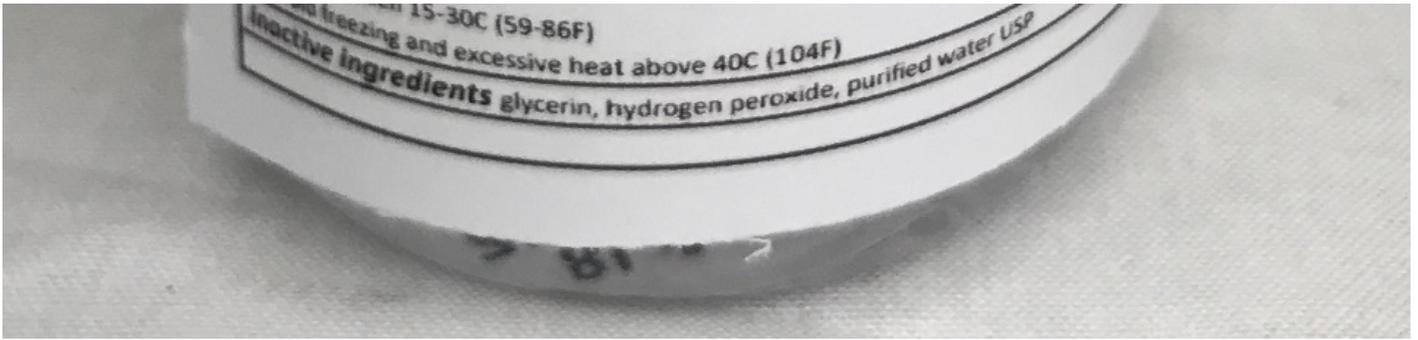
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center for more information.

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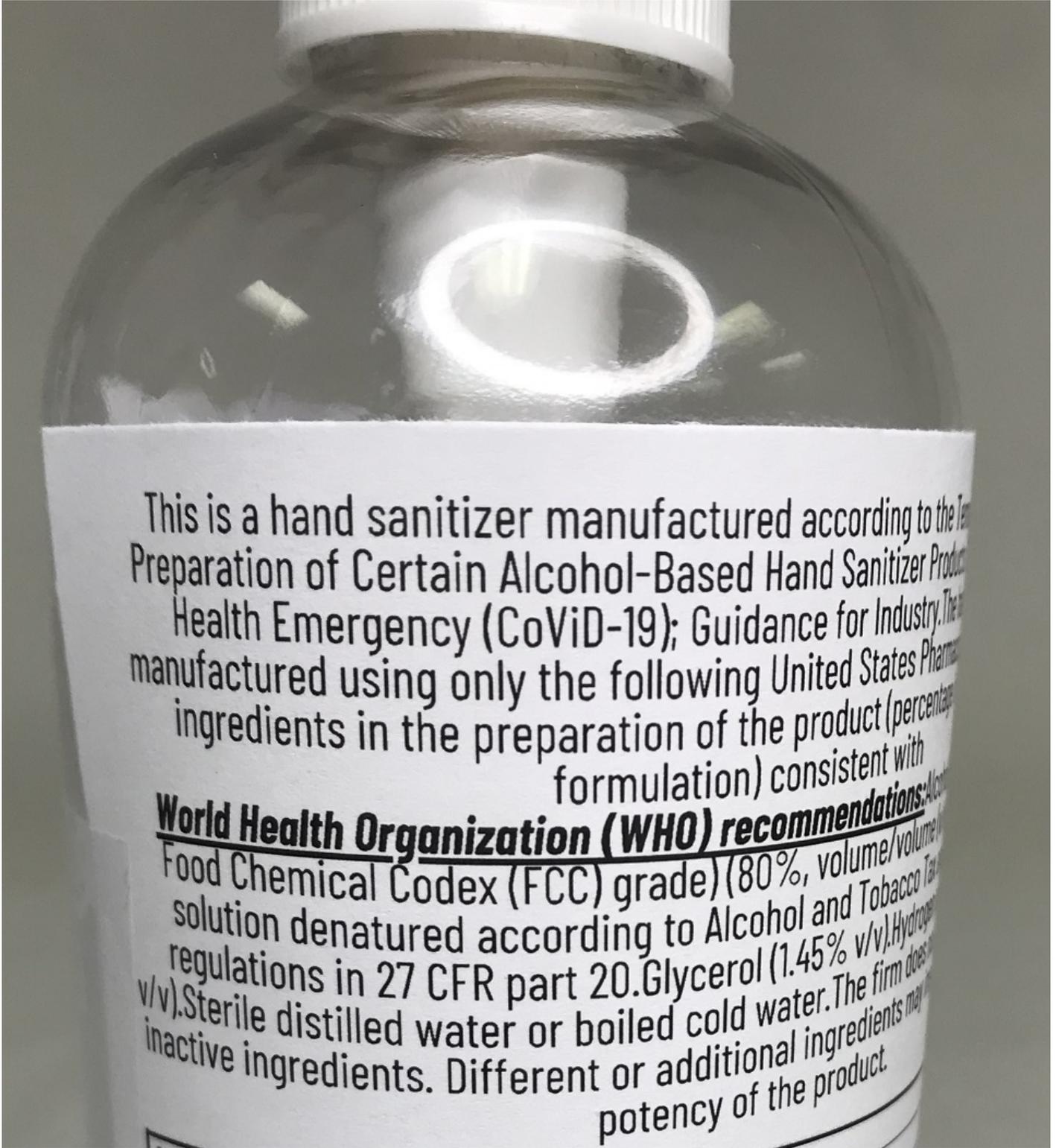
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- Supervise children under 6 years of age when using this product to avoid swallowing.

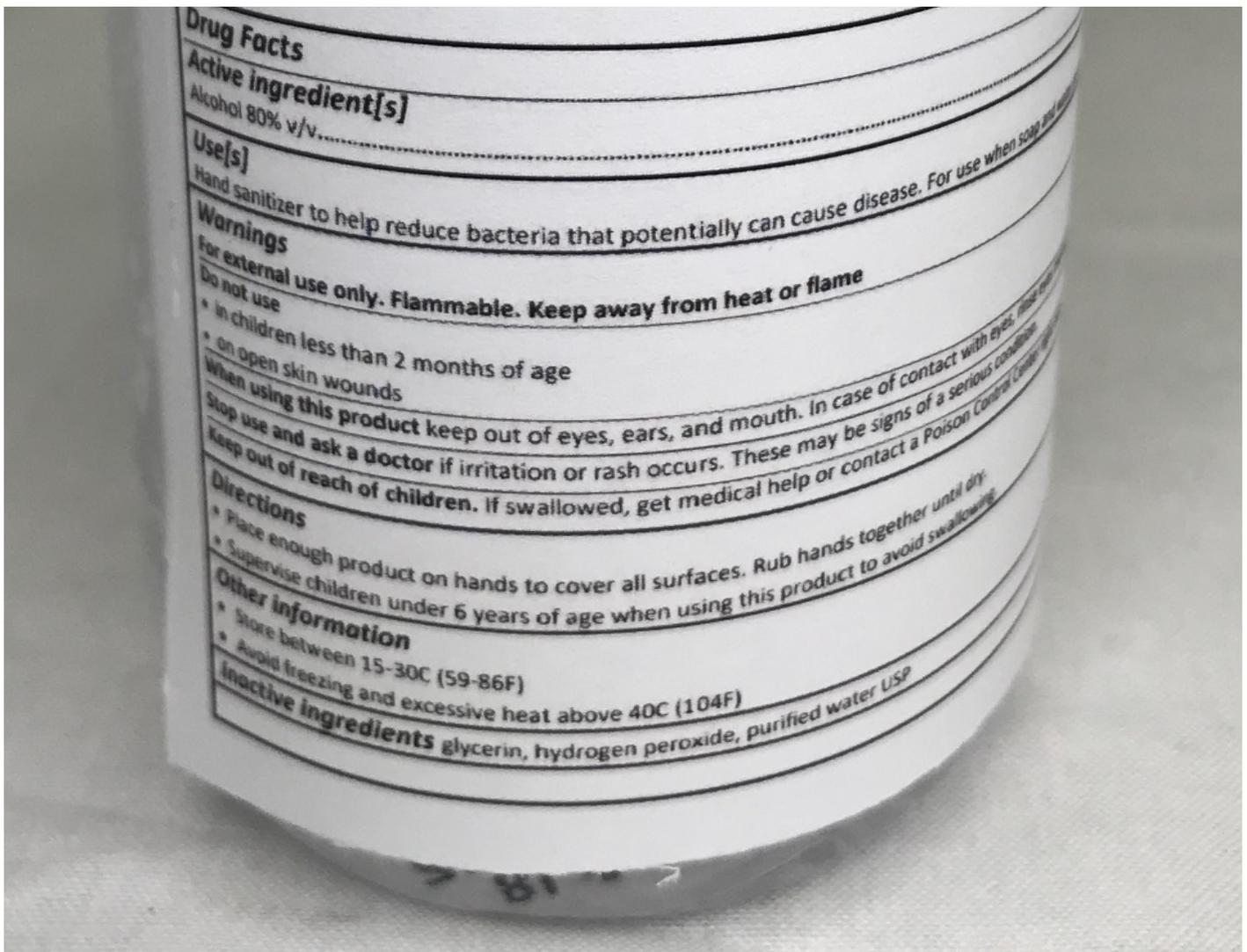
Other information

- Store between 40°F and 75°F.

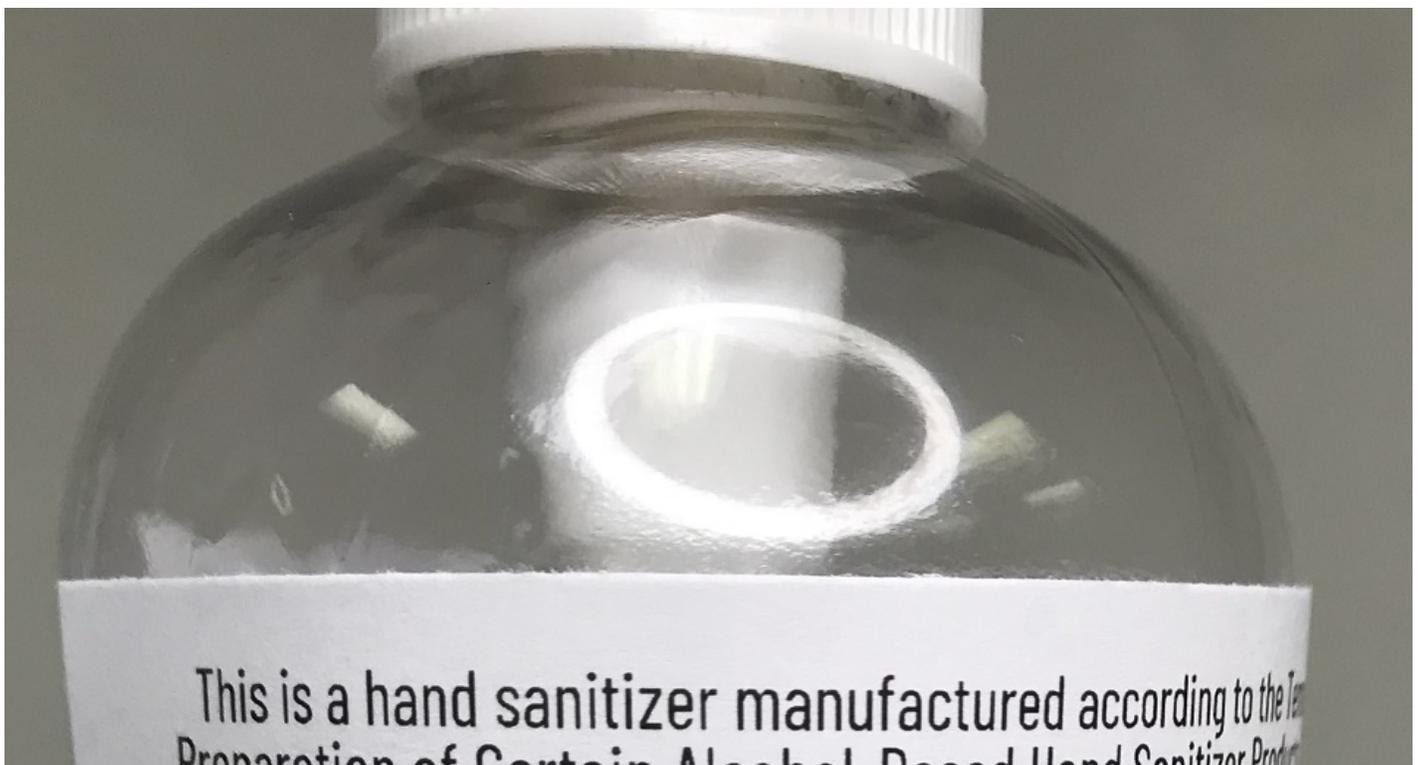


Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.





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



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Directions

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- 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

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TOPICAL SOLUTION**

**HAND SANITIZER
NON-STERILE SOLUTION**

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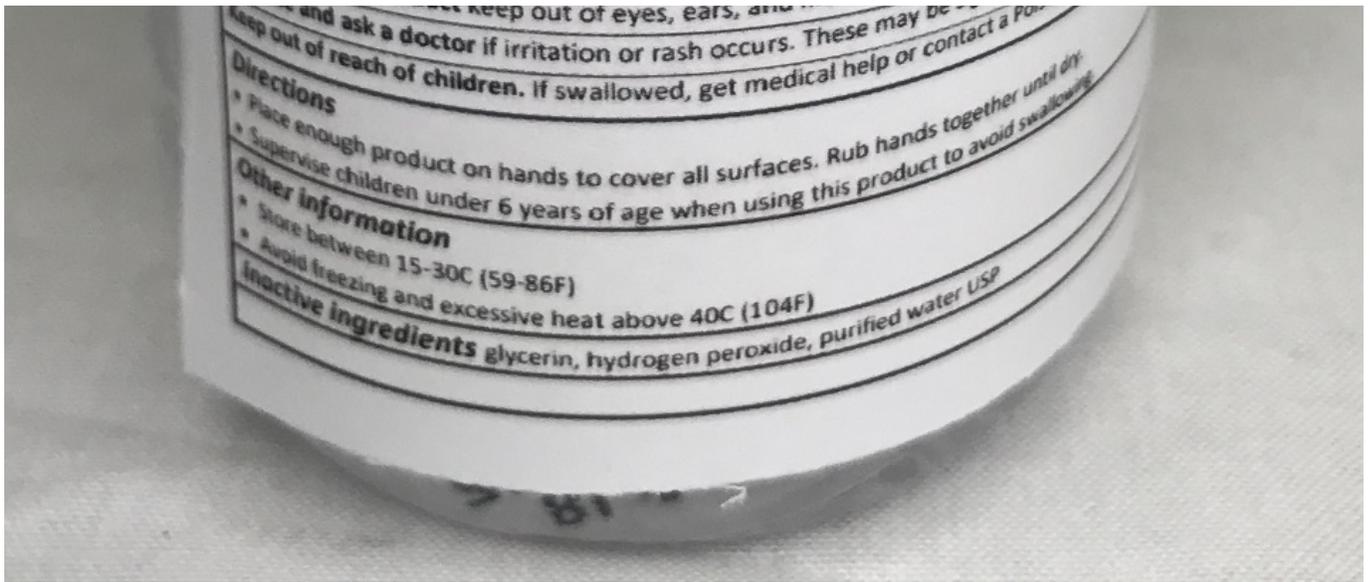
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When using this product keep hands dry.

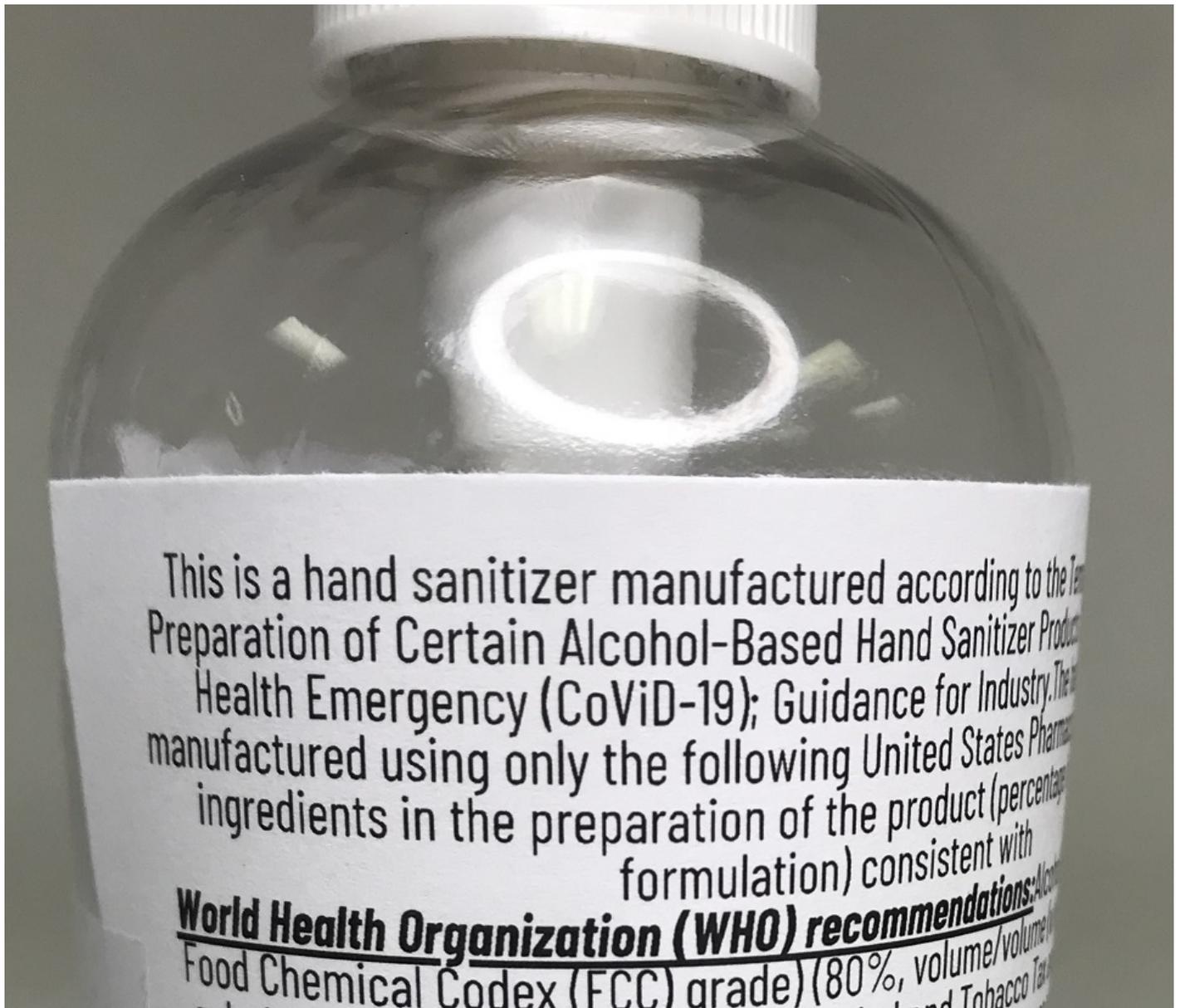
Stop use if:

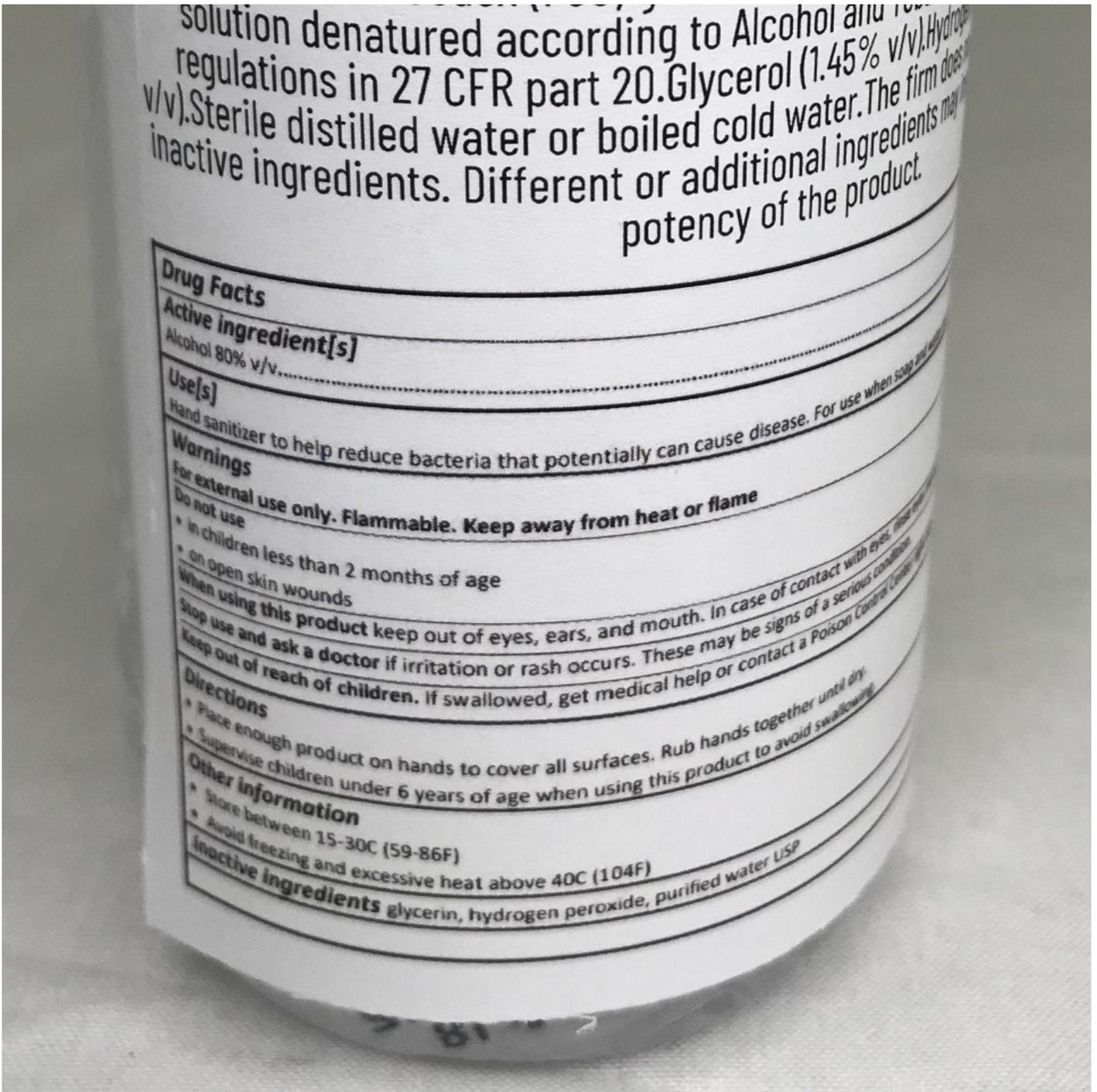
• redness, irritation, or rash develops
• signs of a serious condition develop
• you are pregnant or breastfeeding
• you are using other hand sanitizers



Inactive ingredients

glycerin, hydrogen peroxide, purified water USP





Package Label - Principal Display Panel

355 mL NDC: 74332-000-00





ENCORE™
INDUSTRIAL PRODUCTS

OFF HAND
HAND SANITIZER

ALCOHOL ANTISEPTIC 80%
TOPICAL SOLUTION



OFF HAND HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74332-001
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			

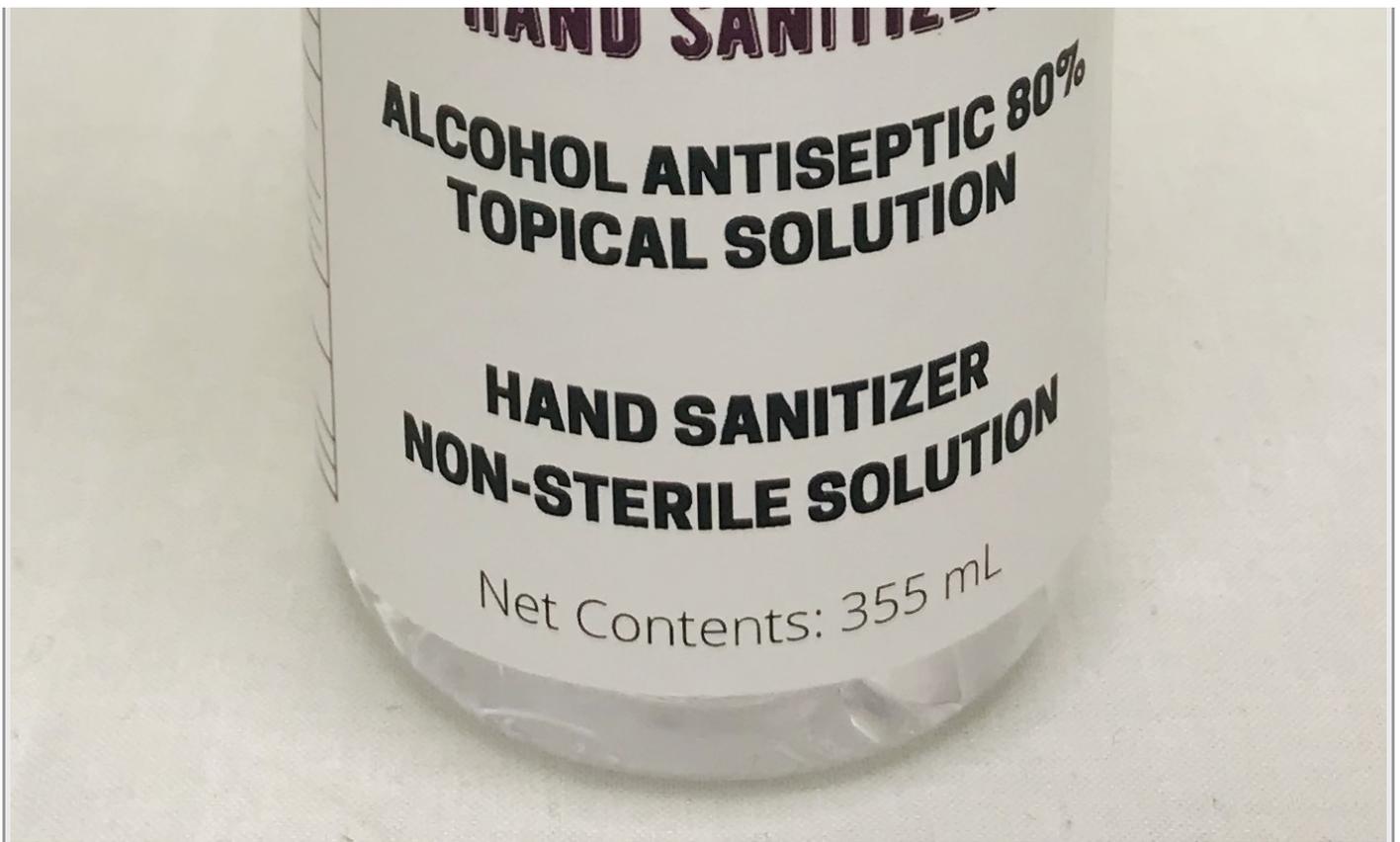
Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74332-001-00	355 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	



ENCORE™
INDUSTRIAL PRODUCTS

OFF HAND
HAND SANITIZER



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Encore Industrial Products, LLC (066166082)

Establishment

Name	Address	ID/FEI	Business Operations
Encore Industrial Products, LLC		066166082	manufacture(74332-001)

Revised: 4/2020

Encore Industrial Products, LLC