

HAND SANITIZER- 80% alcohol liquid
Brand Innovate Ltd

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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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

3.78 L NDC: 77214-001-05

Drug Facts	
Active ingredient(s) Alcohol 80% w/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 • in open skin wounds
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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.	Inactive ingredients • glycerin, hydrogen peroxide, purified water USP
Other information * Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)	 6 70534 66723 2
Distributed by: PRODUCT SUPPLY LAB, LLC Boulder, CO, 833-738-7875	

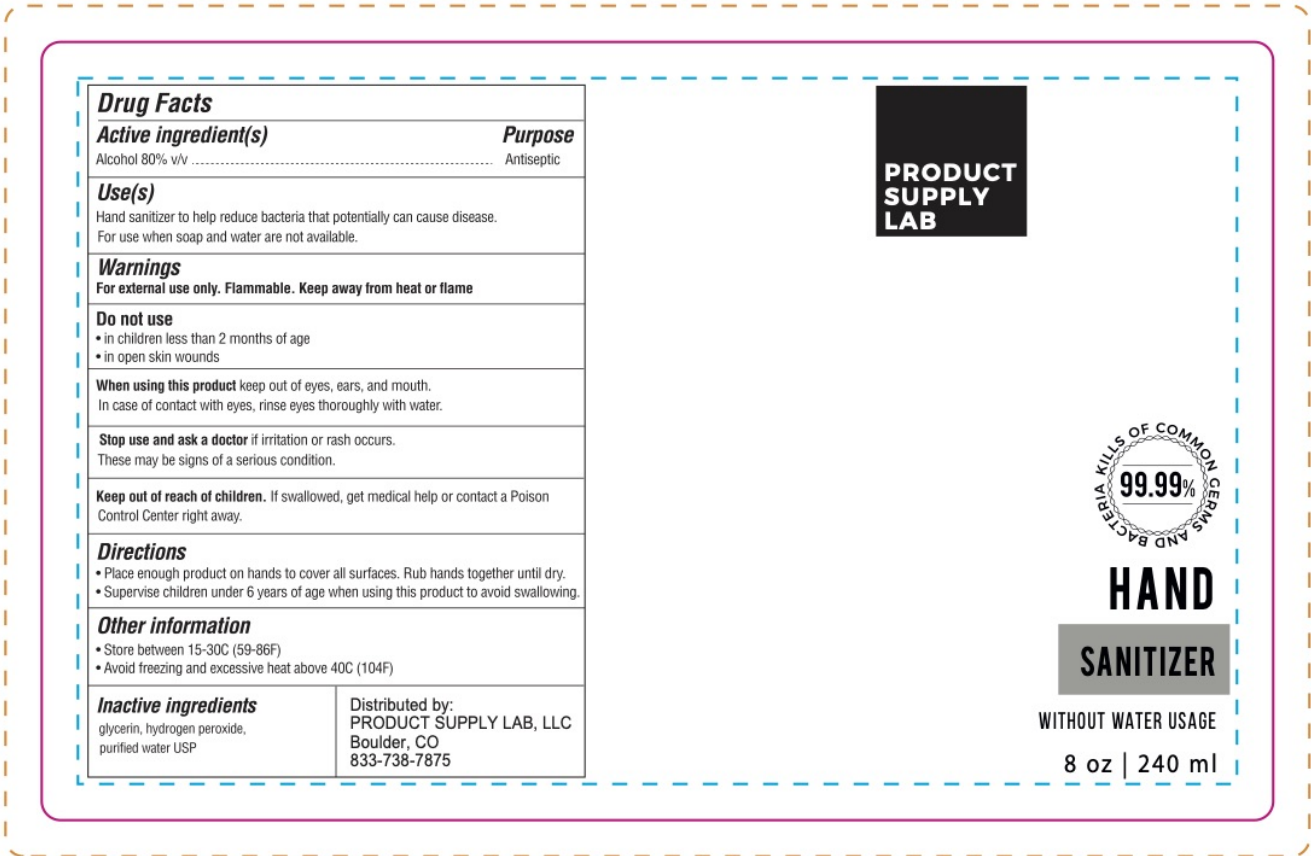
PRODUCT SUPPLY LAB

99.99%
BACTERIA KILLS OF COMMON GERMS AND
**HAND
SANITIZER**

WITHOUT WATER USAGE
1 gallon | 3.78 L

Label size: 18.1875" x 6.457"

- - - - - Safety Line (no text or important images should go outside of this line)
- Cut Line (where the label will be cut to finished size)
- - - - - Bleed Line (any background imagery that is supposed to go to the edge of the label should extend to this line)



Drug Facts

Active ingredient(s)	Purpose
Alcohol 80% v/v	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
- in open skin wounds

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Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
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Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients glycerin, hydrogen peroxide, purified water USP	Distributed by: PRODUCT SUPPLY LAB, LLC Boulder, CO 833-738-7875
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**HAND
 SANITIZER**

WITHOUT WATER USAGE
 8 oz | 240 ml

Label size: 6.8 x 4.3 inches

- - - - - = Safety Line (no text or important images should go outside of this line)
- = Cut Line (where the label will be cut to finished size)
- - - - - = Bleed Line (any background imagery that is supposed to go to the edge of the label should extend to this line)

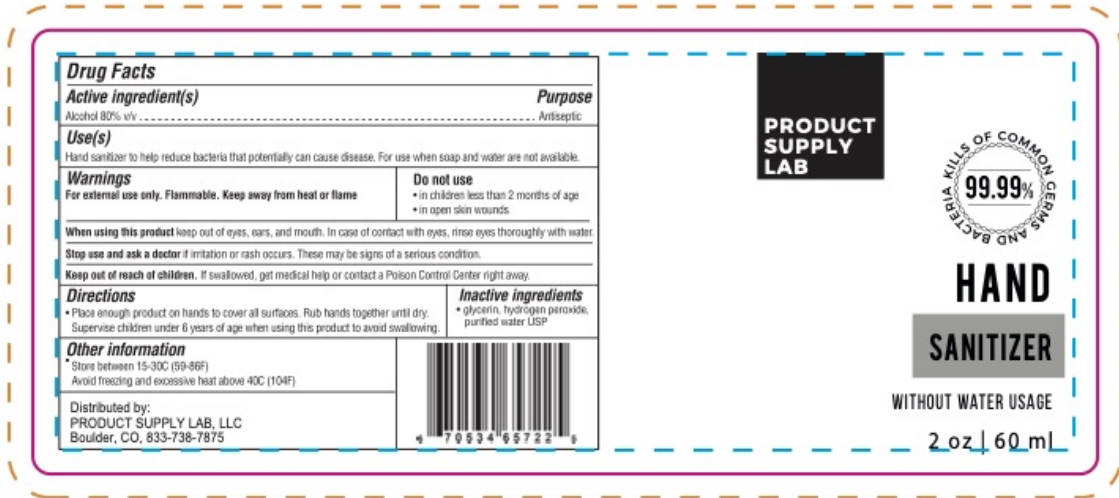
240 mL NDC: 77214-001-04

Drug Facts		PRODUCT SUPPLY LAB
Active ingredient(s) Alcohol 80% w/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.		 HAND SANITIZER WITHOUT WATER USAGE 4 oz 120 ml
Warnings For external use only. Flammable. Keep away from heat or flame		
Do not use • in children less than 2 months of age • in 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	
Distributed by: PRODUCT SUPPLY LAB, LLC Boulder, CO, 833-738-7875		

Label size: 5 x 3.25 inches

- - - - - = Safety Line (no text or important images should go outside of this line)
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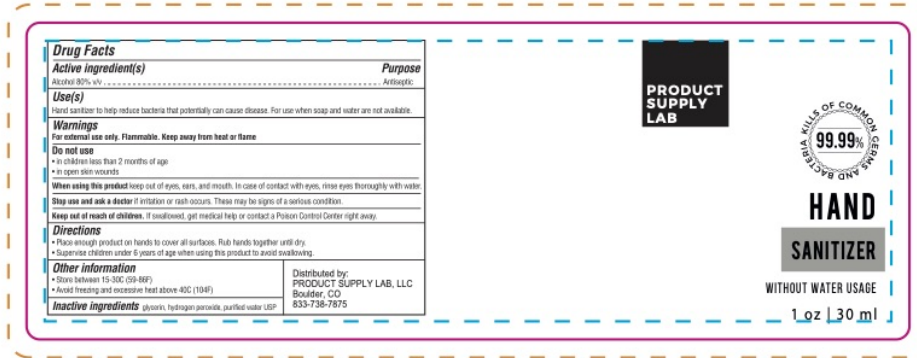
120 mL NDC: 77214-001-03



Label size: 4.5 x 1.875 inches

- - - - - = Safety Line (no text or important images should go outside of this line)
- = Cut Line (where the label will be cut to finished size)
- - - - - = Bleed Line (any background imagery that is supposed to go to the edge of the label should extend to this line)

60 mL NDC: 77214-001-02



Label size: 4 7/8" x 1 3/4" (4.8750 x 1.7500 inches)

- - - - - = Safety Line (no text or important images should go outside of this line)
- - - - - = Cut Line (where the label will be cut to finished size)
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30 mL NDC: 77214-001-01

HAND SANITIZER

80% alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77214-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 80 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	

GLYCERIN (UNII: PDC6A3C0OX)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77214-001-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
2	NDC:77214-001-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
3	NDC:77214-001-03	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
4	NDC:77214-001-04	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
5	NDC:77214-001-05	3780 mL in 1 JUG; Type 0: Not a Combination Product	04/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/01/2020	

Labeler - Brand Innovate Ltd (128887065)

Establishment

Name	Address	ID/FEI	Business Operations
Brand Innovate Ltd		128887065	manufacture(77214-001)

Revised: 4/2020

Brand Innovate Ltd