BRANTMED HAND SANITIZER 80% ALC. V/V- alcohol liquid BrantMed Inc.

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

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	Inactive ingredients giycerin, hydrogen peroxide, purified water USP	



ALCOHOL ANTISEPTIC 80% Topical Solution

HAND SANITIZER Non-sterile Solution

236 mL

NDC 79362-246-01



LOT

EXP:

BRANTMED INC.
1185 Colborne St E
Brantford ON N3T5M1
info@brantmed.com
www.brantmed.com
Made in Canada

Active ingredient[5] Purposs Alcohol 80% v/v	
	PurposeAntiseptic
USe[s] The profiter to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	ble.
Warnings For external use only. Flammable. Keep away from heat or flame	
Do not use • in children less than 2 months of age	
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Other information • stare between 15-30C (59-86F)	
 Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	



ALCOHOL ANTISEPTIC 80% Topical Solution

HAND SANITIZER Non-sterile Solution

120 mL

NDC 79362-246-02



LOT

EXP.

BRANTMED INC. 1185 Colborne St E Brantford ON N3T5M1 info@brantmed.com www.brantmed.com Made in Canada

Drug Facts
Purpose Active ingredient[s] Purpose Alcohol 80% v/v
Use[s] Hand Sanlister 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
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Other information
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Inactive ingredients giycerin, hydrogen peroxide, purified water USP



ALCOHOL ANTISEPTIC 80% Topical Solution

HAND SANITIZER Non-sterile Solution

500 mL

NDC 79362-246-03



LOT

EXP:

ANTMED INC.

S5 Colborne St E
antford ON N3T5M1
o@brantmed.com
w.brantmed.com

236 mL NDC: 79362-246-01 120 mL NDC: 79362-246-02 500 mL NDC: 79362-246-03

BRANTMED HAND SANITIZER 80% ALC. V/V

alcohol liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79362-246	
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)	1.45 mL in 100 mL			
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL			
WATER (UNII: 059QF0KO0R)				

]	Packaging					
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
:	NDC:79362-246-01	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020			
2	NDC:79362-246-02	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020			
3	NDC:79362-246-03	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020			

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

Labeler - BrantMed Inc. (204984169)

Establishment				
Name	Address	ID/FEI	Business Operations	
BrantMed Inc.		204984169	manufacture(79362-246)	

Revised: 6/2020 BrantMed Inc.