

## **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.*

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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**

<b>Drug Facts</b>	<b>Purpose</b>
<b>Active ingredient(s)</b>	Antiseptics
<b>Warnings</b>	
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Directions</b>	
For external use only. Flammable. Keep away from heat or flame.	
• do not use on open skin wounds.	
• do not use on children less than 2 months of age.	
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.	
<b>Other information</b>	
• This product is not intended to cover all surfaces. Rub hands together until dry.	
• Supervise children under 6 years of age when using this product to avoid swallowing.	
<b>Other information</b>	
• Store between 15-30C (59-86F)	
• Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water, USP	

BRANT  
+ MED

ALCOHOL ANTISEPTIC  
80%  
Topical Solution

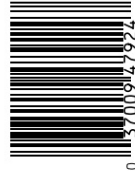
HAND SANITIZER  
Non-sterile Solution

236 mL

NDC 79362-246-01

EXP:

LOT:



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

<b>Drug Facts</b>	<b>Purpose</b>
<b>Active Ingredients</b> Isopropyl Alcohol 70% Aminopic	Antiseptic
<b>Uses</b> Use to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame. Do not use: • on open skin wounds. • 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.	
<b>Directions</b> • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Rub for at least 20 seconds or 15 seconds if using this product to avoid contamination.	
<b>Other Information</b> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive Ingredients</b> glycerin, hydrogen peroxide, purified water USP	



**ALCOHOL ANTISEPTIC  
80%  
Topical Solution**

**HAND SANITIZER  
Non-sterile Solution**

120 mL

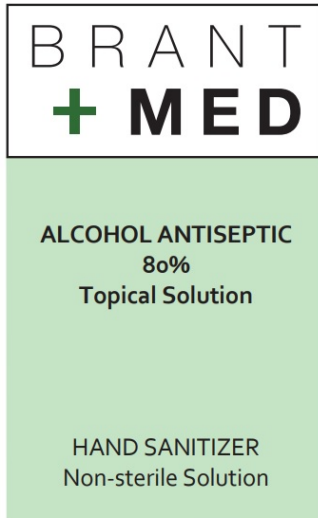
NDC 79362-246-02

LOT:                      EXP:



**BRANTMED INC.**  
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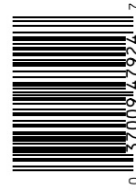
<b>Drug Facts</b>	<b>Purpose</b>
<b>Active ingredient(s)</b>	Antiseptic
Alcohol 60% (v/v)	
Use: Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Use(s)</b>	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame.	
Do not use	
• in children less than 2 months of age	
• 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.	
<b>Directions</b>	
• 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.	
<b>Other information</b>	
• Avoid freezing and excessive heat above 40°C (104°F)	
• Avoid use if you are pregnant or breastfeeding.	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	



500 mL

NDC 79362-246-03

LOT: EXP:



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**Made in Canada**

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

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79362-246
<b>Route of Administration</b>	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)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	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.