

**BAC STOP4A HAND SANITIZER- alcohol solution**  
**ENVIRO TECH CHEMICAL SERVICES, 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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**Active Ingredient**

Alcohol 80% v/v.

**Purpose**

Antiseptic

**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.

**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**

Label 59 mL

**Bac Stop 4A**  
**Alcohol Antiseptic**  
**80% Topical Solution**

**Hand Sanitizer**  
**Non-sterile Solution**

**2 fl oz/59 ml**

**Drug Facts**

**Active ingredient**

Alcohol 80% v/v.....

**Purpose**

Antiseptic

**Use**

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**Inactive ingredients** glycerin, hydrogen peroxide, purified water USP

118 mL Label

**Bac Stop 4A**  
**Alcohol Antiseptic**  
**80% Topical Solution**

**Hand Sanitizer**  
**Non-sterile Solution**

**4 fl oz/118 ml**

**Drug Facts**

**Active ingredient**

Alcohol 80% v/v.....

**Purpose**

Antiseptic

**Use**

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**Warnings**

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- Store between 15-30C (59-86F)
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**Inactive ingredients** glycerin, hydrogen peroxide, purified water USP

177 mL Label

**Bac Stop 4A**  
**Alcohol Antiseptic**  
**80% Topical Solution**

**Hand Sanitizer**  
**Non-sterile Solution**

**6 fl oz/177 ml**

**Drug Facts**

**Active ingredient**

Alcohol 80% v/v.....

**Purpose**

Antiseptic

**Use**

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**Warnings**

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**Other information**

- Store between 15-30C (59-86F)
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**Inactive ingredients** glycerin, hydrogen peroxide, purified water USP

236 mL Label

**Bac Stop 4A**  
**Alcohol Antiseptic**  
**80% Topical Solution**

**Hand Sanitizer**  
**Non-sterile Solution**

**8 fl oz/236 ml**

**Drug Facts**

**Active ingredient**

Alcohol 80% v/v.....

**Purpose**

Antiseptic

**Use**

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**Warnings**

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**Do not use**

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**Directions**

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**Other information**

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**Inactive ingredients** glycerin, hydrogen peroxide, purified water USP

473 mL Label

**Bac Stop 4A**  
**Alcohol Antiseptic**  
**80% Topical Solution**

**Hand Sanitizer**  
**Non-sterile Solution**

**16 fl oz/473 ml**

**Drug Facts**

**Active ingredient**

Alcohol 80% v/v.....

**Purpose**

Antiseptic

**Use**

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**Other information**

- Store between 15-30C (59-86F)
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**Inactive ingredients** glycerin, hydrogen peroxide, purified water USP

946 mL Label

**Bac Stop 4A**  
**Alcohol Antiseptic**  
**80% Topical Solution**

**Hand Sanitizer**  
**Non-sterile Solution**

32 fl oz/946 ml

**Drug Facts**

**Active ingredient**

Alcohol 80% v/v.....

**Purpose**

Antiseptic

**Use**

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**Other information**

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**Inactive ingredients** glycerin, hydrogen peroxide, purified water USP

3785 mL (1 gallon) Label



**Bac Stop 4A**  
**Alcohol Antiseptic**  
**80% Topical Solution**

**Hand Sanitizer**  
**Non-sterile Solution**

1 gallon/3.785 L

<b>Drug Facts</b>	
<b>Active ingredient</b> Alcohol 80% v/v	<b>Purpose</b> Antiseptic
<b>Use</b> Hand sanitizer 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.	
<b>Do not use</b> <ul style="list-style-type: none"> <li>in children less than 2 months of age</li> <li>on open skin wounds</li> </ul>	
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> <ul style="list-style-type: none"> <li>Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
<b>Other information</b> <ul style="list-style-type: none"> <li>Store between 15-30C (59-86F)</li> <li>Avoid freezing and excessive heat above 40C (104F)</li> </ul>	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	

## BAC STOP4A HAND SANITIZER

alcohol solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66284-002
<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)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	

### Packaging

Marketing Start      Marketing End



#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66284-002-01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/23/2020	
2	NDC:66284-002-02	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/23/2020	
3	NDC:66284-002-03	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/23/2020	
4	NDC:66284-002-04	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/23/2020	
5	NDC:66284-002-05	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/23/2020	
6	NDC:66284-002-06	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/23/2020	
7	NDC:66284-002-07	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/23/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/23/2020	

**Labeler** - ENVIRO TECH CHEMICAL SERVICES, INC. (805860483)

### Establishment

Name	Address	ID/FEI	Business Operations
ENVIRO TECH CHEMICAL SERVICES, INC.		805860483	manufacture(66284-002)

Revised: 4/2020

ENVIRO TECH CHEMICAL SERVICES, INC.