## HAND SANITIZER- alcohol liquid Badger State Ethanol, 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.

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#### Hand sanitizer

Alcohol 80 % v/v

## Antiseptic

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

For external use only. Flammable. Keep away from heat or flame

- In children less than 2 months of age
- On open skin wounds

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 40 C (104F)

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

#### **Hand Sanitizer**

Hand Sanitizer Non-sterile Solution

1 gal (3.78 L)

Lot#

Date:

Active ingredient(s)

Purpose

Alcohol 80% v/v..... Antiseptic

## Use(s)

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## Warnings

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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 eyes thoroughly with water.

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#### Directions

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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, water, denatonium benzoate

Hand Sanitizer Non-sterile Solution

2.5 gal (9.45 L)

Lot#

Date:

Active ingredient(s)

Purpose

Alcohol 80% v/v..... Antiseptic

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Inactive ingredients glycerin, hydrogen peroxide, water, denatonium benzoate

Hand Sanitizer Non-sterile Solution

5 gal (18.9 L)

Lot#

Date:

Active ingredient(s)

Purpose

Alcohol 80% v/v..... Antiseptic

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Inactive ingredients glycerin, hydrogen peroxide, water, denatonium benzoate

Hand Sanitizer
Non-sterile Solution

1000 ml

Active ingredient(s)

Purpose

Alcohol 80% v/v..... Antiseptic

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Inactive ingredients glycerin, hydrogen peroxide, water, denatonium benzoate

Hand Sanitizer
Non-sterile Solution

500 ml

Active ingredient(s)

Purpose

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Inactive ingredients glycerin, hydrogen peroxide, water, denatonium benzoate

Hand Sanitizer
Non-sterile Solution

1000 ml

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Inactive ingredients glycerin, hydrogen peroxide, water, denatonium benzoate

Badger State Ethanol, located in Monroe, WI, (608)329-3900

#### HAND SANITIZER

alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74210-0001
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

Strength

Packaging				
Marketing End Date	Marketing Start Date	Package Description	Item Code	#
	03/30/2020	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	NDC:74210-0001- 1	1
	03/30/2020	, , , , ,	NDC:74210-0001- 2	
	03/30/2020	1000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	NDC:74210-0001-5	3
	03/30/2020	3780 mL in 1 JUG; Type 0: Not a Combination Product	NDC:74210-0001-3	4
	03/30/2020	9450 mL in 1 JUG; Type 0: Not a Combination Product	NDC:74210-0001-	5
	03/30/2020	18900 mL in 1 CONTAINER; Type 0: Not a Combination Product	NDC:74210-0001-	6
	03/30/2020	Product  3780 mL in 1 JUG; Type 0: Not a Combination Product  9450 mL in 1 JUG; Type 0: Not a Combination Product  18900 mL in 1 CONTAINER; Type 0: Not a Combination	NDC:74210-0001- 3 NDC:74210-0001- 4	5

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

## Labeler - Badger State Ethanol, LLC (808674605)

Establishment			
Name	Address	ID/FEI	Business Operations
Badger State Ethanol, LLC		808674605	manufacture(74210-0001)

Revised: 4/2020 Badger State Ethanol, LLC