

HAND SANITIZER- alcohol liquid
Ole Smoky Distillery, 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.

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

18927.1 ml NDC: 74290-001-01



HAND SANITIZER

Alcohol Antiseptic 80%
Topical Solution

Hand Sanitizer
Non-sterile Solution

5 Gallons

Drug Facts

Active ingredient[s]

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

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
- 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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Other information

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

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

PRODUCED BY
OLE SMOKY DISTILLERY, LLC
GATLINBURG, TENNESSEE

750 ml NDC: 74290-001-04

Ole Smoky
Tennessee

HAND SANITIZER

750ml DO NOT DRINK

Alcohol Antiseptic 80%
Topical Solution
Hand Sanitizer
Non-sterile Solution

Drug Facts	Purpose
Active ingredient[s] 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	<i>For external use only. Flammable. Keep away from heat or flame.</i>
Do not use	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Store between 15-30C (59-86F)• Avoid freezing and excessive heat above 40C (104F)
Inactive ingredients	glycerin, hydrogen peroxide, purified water USP

PRODUCED & BOTTLED BY
OLE SMOKY DISTILLERY, LLC
GATLINBURG, TENNESSEE
www.OleSmoky.com

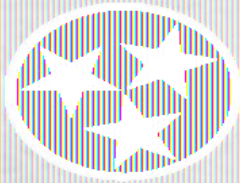


DO NOT DRINK



HAND
SANITIZER
DO NOT
DRINK

50 ml NDC: 74290-001-02



DO NOT DRINK



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HAND
SANITIZER

50ml DO NOT DRINK

Alcohol Antiseptic: 80%
Topical Solution
Hand Sanitizer
Non-sterile Solution

Active Ingredients Alcohol 80% w/v	Active Ingredients Alcohol 80% w/v
Uses Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	Uses 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 If you use this product keep out of eyes, ears, and mouth. In case of contact with eyes, nose or eyes thoroughly with water. Stop use and ask a doctor if irritation or rash occurs. There 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.	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 If you use this product keep out of eyes, ears, and mouth. In case of contact with eyes, nose or eyes thoroughly with water. Stop use and ask a doctor if irritation or rash occurs. There 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.	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).	Other Information - Store between 15-30C (59-86F) - Avoid freezing and excessive heat above 40C (104F).
Inactive ingredients glycerol, hydrogen peroxide, purified water USP	Inactive ingredients glycerol, hydrogen peroxide, purified water USP

NDC 74290-001-02
PRODUCED & BOTTLED BY
OLE SMOKY DISTILLERY, LLC
GATLINBURG, TENNESSEE
PH: 865-436-6995 customer@oddistillery.com



59.1471 ml NDC: 74290-001-03



HAND SANITIZER

Alcohol Antiseptic 80%
Topical Solution
Hand Sanitizer
Non-sterile Solution

2 FL OZ (59mL)

Drug Facts

<i>Active ingredient[s]</i>	<i>Purpose</i>
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
- ♦ 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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Other information

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

Inactive ingredients chloroform, butylparaben

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

PRODUCED BY
OLE SMOKY DISTILLERY, LLC
GATLINBURG, TENNESSEE

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74290-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74290-001-01	18927.1 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74290-001-02	50 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74290-001-03	59.1471 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
4	NDC:74290-001-04	750 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	04/13/2020	

Marketing Information

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

Labeler - Ole Smoky Distillery, LLC (117474396)

Revised: 4/2020

Ole Smoky Distillery, LLC