HAND SANITIZER- alcohol liquid Whiskey Acres Distilling Company

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



4 oz/118.294 mL 74148-111-01

Active Ingredients: 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.

Do not use on children less than 2 months of age or 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. Inactive ingredients: glycerin, hydrogen peroxide, purified water USP

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16 oz/473.176mL 74148-111-02

Active Ingredients: 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.

Do not use on children less than 2 months of age or 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. Inactive ingredients: glycerin, hydrogen peroxide, purified water USP

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32 oz/946.353mL 74148-111-03

Active Ingredients: 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.

Do not use on children less than 2 months of age or 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. Inactive ingredients: glycerin, hydrogen peroxide, purified water USP

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64 oz/1892.71mL 74148-111-04

Active Ingredients: 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.

Do not use on children less than 2 months of age or 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. Inactive ingredients: glycerin, hydrogen peroxide, purified water USP

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128 oz/3785.41mL 74148-111-05

Active Ingredients: 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.

Do not use on children less than 2 months of age or 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. Inactive ingredients: glycerin, hydrogen peroxide, purified water USP

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640 oz/18927.1mL 74148-111-06

Active Ingredients: 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.

Do not use on children less than 2 months of age or 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. Inactive ingredients: glycerin, hydrogen peroxide, purified water USP

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10 oz/296.735mL 74148-111-09

Active Ingredients: 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.

Do not use on children less than 2 months of age or 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. Inactive ingredients: glycerin, hydrogen peroxide, purified water USP

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270 gal/1022L 74148-111-07

Active Ingredients: 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.

Do not use on children less than 2 months of age or 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. Inactive ingredients: glycerin, hydrogen peroxide, purified water USP

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55 gal/208L 74148-111-08

Active Ingredients: 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.

Do not use on children less than 2 months of age or 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. Inactive ingredients: glycerin, hydrogen peroxide, purified water USP

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Produced by Whiskey Acres Distilling Co. DeKalb, IL

Alcohol Antiseptic 80% Topical Solution

HAND SANITIZER alcohol liquid Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:74148-111 Route of Administration TOPICAL Active Ingredient/Active Moiety

Basis of Strength

ALCOHOL

Strength

80 mL in 100 mL

Ingredient Name

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)

Inactive Ingredients				
Ingredient Name	Strength			
GLYCERIN (UNII: PDC6A3C0OX)				
HYDROGEN PERO XIDE (UNII: BBX060AN9V)				
WATER (UNII: 059QF0KO0R)				

Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:74148-111- 02	473.176 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020				
2	NDC:74148-111-01	118.294 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020				
3	NDC:74148-111- 03	946.353 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020				
4	NDC:74148-111- 04	1892.71 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020				
5	NDC:74148-111- 05	3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020				
6	NDC:74148-111- 06	18927.1 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020				
7	NDC:74148-111- 07	1022 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020				

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

Labeler - Whiskey Acres Distilling Company (075741260)

Establishment						
Name	Address	ID/FEI	Business Operations			
Whiskey Acres Distilling Company		075741260	manufacture(74148-111)			

Revised: 4/2020 Whiskey Acres Distilling Company