ENVIRO CARE HAND SANITIZER I.S.- hand sanitizer liquid Iron Smoke Whiskey 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.

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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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)

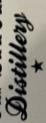
Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel



IRON SMOKE.



Enviro Care® Hand Sanitizer I.S.

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

NOTE: Made under emergency measures, not for consumption (not potable alcohol)

Active ingredient[s] Alcohol 80% v/v

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LIQUID

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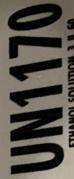
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Medical Emergency Telephone Number: 1-800-535-5053 (US), Outside US: 1-325-323-3500

Bottled by: Iron Smoke Distillery www.ironsmokedistillery.com Distributed by: Rochester Midland Corporation World Headquarters
155 Panagon Drive, Rochester, NY 14624 USA
www.rochestermidland.com

PC 12014057







Net Contents: 55 Gallons

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Enviro Care® Hand Sanitizer I.S.

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

NOTE: Made under emergency measures, not for consumption (not potable alcohol)

Net Contents: 1 U.S. Quart (.946 Liters)

Drug Facts

Active ingredient[s] Alcohol 80% v/v...

Purpose

Use[s]

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World Headquarters 155 Paragon Drive Rochester, NY 14624 USA www.rochestermidland.com

Distributed by: Rochester Midland Corporation

Bottled by: Iron Smoke Distillery 111 Parce Ave #5b, Fairport, NY 14450 www.ironsmokedistillery.com



NDC: 74051-001-01 NDC: 74051-001-02

ENVIRO CARE HAND SANITIZER I.S.

hand sanitizer liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74051-001	
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: PDC6 A3C0 OX)	1.45 mL in 100 mL		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL		

WATER (UNII: 059QF0KO0R)

ı	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:74051-001- 01	208197 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020		
	2 NDC:74051-001- 02	946 mL in 1 BOTTLE, SPRAY; 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 - Iron Smoke Whiskey LLC (034337219)

Establishment				
Name	Address	ID/FEI	Business Operations	
Iron Smoke Whiskey LLC		034337219	manufacture(74051-001)	

Revised: 3/2020 Iron Smoke Whiskey LLC