

## **HAND SANITIZER- ethyl alcohol gel**

### **Black Irish Products**

*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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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)**

Ethyl Alcohol 75% 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**

Water, Carbool Aqua SF1, Hydrogen Peroxide 3%, Glycerol, Fragrance, AMP PC2000

### **Package Label - Principal Display Panel**

946 mL NDC: 80589-001-06

DEMAND BETTER



community  
focused



sustainably  
produced



made in  
the USA

fresh lemon scent

# BLK METTLE HAND SANITIZER

kills 99.99% of germs | 75% alcohol

32 fl oz | 946 ml

Drug Facts	
<b>Active ingredient(s)</b>	<b>Purpose</b>
Ethyl alcohol 75% w/v	Antiseptic
<b>Uses(s)</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>on 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 15-30 °C (59-86 °F)</li> <li>Avoid freezing and excessive heat above 40 °C (104 °F)</li> </ul>	
<b>Inactive ingredients</b> Water, Carbopol Aqua SF1, Hydrogen Peroxide 3%, Glycerol, Fragrance, AMP PC2000	
<b>Questions?</b> Visit <a href="http://www.penta5usa.com">www.penta5usa.com</a> or call toll free 1-800-511-5869	

NOT FOR HUMAN CONSUMPTION



Manufactured by Black Irish Products and distributed by Lancaster Packaging LLC, 560 Main St, Hudson MA 01749

532 mL NDC 80589-001-07

DEMAND BETTER



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made in  
the USA

fresh lemon scent

# BLK METTLE HAND SANITIZER

kills 99.99% of germs | 75% alcohol

18 fl oz | 532 ml

Drug Facts	
<b>Active ingredient(s)</b>	<b>Purpose</b>
Ethyl alcohol 75% w/v	Antiseptic
<b>Uses</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>on 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 15-30 °C (59-86 °F)</li> <li>Avoid freezing and excessive heat above 40 °C (104 °F)</li> </ul>	
<b>Inactive ingredients</b> Water, Carbopol Aqua SF1, Hydrogen Peroxide 3%, Glycerol, Fragrance, AMP PC2000	
<b>Questions?</b> Visit <a href="http://www.penta5usa.com">www.penta5usa.com</a> or call toll free 1-800-511-5869	

NOT FOR HUMAN CONSUMPTION



Manufactured by Black Irish Products and distributed by Lancaster Packaging LLC, 560 Main St, Hudson MA 01749

236 mL NDC 80589-001-08

**DEMAND BETTER**



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produced



made in  
the USA

fresh lemon scent

# BLK METTLE

## HAND SANITIZER

kills 99.99% of germs | 75% alcohol

8 fl oz | 236 ml

Drug Facts	
<b>Active ingredient(s)</b>	<b>Purpose</b>
Ethyl alcohol 75% w/v	Antiseptic
<b>Uses</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.	
Do not use	
<ul style="list-style-type: none"> <li>on 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 15-30 °C (59-86 °F)</li> <li>Avoid freezing and excessive heat above 40 °C (104 °F)</li> </ul>	
<b>Inactive ingredients</b> Water, Carbopol Aqua SF1, Hydrogen Peroxide 3%, Glycerol, Fragrance, AMP PC2000	
<b>Questions?</b> Visit <a href="http://www.penta5usa.com">www.penta5usa.com</a> or call toll free 1-800-511-5869	

NOT FOR HUMAN CONSUMPTION

**FPO UPC**

Manufactured by Black Irish Products and distributed by Lancaster Packaging LLC, 560 Main St, Hudson MA 01749

## HAND SANITIZER

ethyl alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80589-001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95)	
.ALPHA.,.BETA.-METHYLENE ADENOSINE 5'-DIPHOSPHATE (UNII: 0T2A54390E)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	

## Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	LEMON	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80589-001-06	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/29/2020	
2	NDC:80589-001-07	532 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/29/2020	
3	NDC:80589-001-08	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/29/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/29/2020	

**Labeler** - Black Irish Products (131420039)

## Establishment

Name	Address	ID/FEI	Business Operations
Redi-2-PaQ Home Products, LLC.		081148102	manufacture(80589-001)

## Establishment

Name	Address	ID/FEI	Business Operations
Black Irish Products		131420039	label(80589-001)

Revised: 6/2021

Black Irish Products