

## **PYROXY LIQUID-80B- alcohol 80% liquid**

### **Pyrock Chemical**

*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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### **Pyroxy Liquid-80B - 80%**

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.

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**

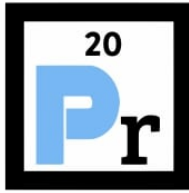
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

### **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

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

Front 3785.41 ml - NDC 78517-801-01



**PYROCK  
CHEMICAL.**



**PYROXY LIQUID-80**

# Hand Sanitizer

**Kills 99.99%**  
of common  
germs and  
bacteria

**80% Liquid Formula**

Active: Ethyl Alcohol.....80% v/v

Inactive: Glycerin, Purified Water, Hydrogen Peroxide



**1 Gallons (128 oz)**

MADE IN  
**FDA**  
REGISTERED FACILITY

## Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 80% v/v.....	Antiseptic

Use[s] : Hand Sanitizer to help reduce bacteria on the skin

### 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 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, Purified Water, Hydrogen Peroxide

### Other information

- Store at temperature below 110° F (43° C)
- May discolor certain fabrics or surfaces



Manufactured by:  
PYROCK CHEMICAL  
(877) 959-4998  
Sales@PyRockChemical.com or  
Info@PyRockChemical.com

**NDC 78517-801-01**



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CHEMICAL.**



**PYROXY LIQUID-80**

# Hand Sanitizer

**Kills 99.99%**  
of common  
germs and  
bacteria

**80% Liquid Formula**

Active: Ethyl Alcohol.....80% v/v

Inactive: Glycerin, Purified Water, Hydrogen Peroxide



**5 Gallons (640 oz)**

MADE IN  
**FDA**  
REGISTERED FACILITY

## Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 80% v/v.....	Antiseptic

Use[s] : Hand Sanitizer to help reduce bacteria on the skin

### 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 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, Purified Water, Hydrogen Peroxide

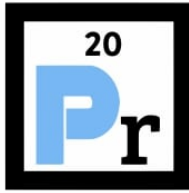
### Other information

- Store at temperature below 110° F (43° C)
- May discolor certain fabrics or surfaces



Manufactured by:  
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**NDC 78517-801-95**



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CHEMICAL.**



**PYROXY LIQUID-80**

# Hand Sanitizer

**Kills 99.99%**  
of common  
germs and  
bacteria

**80% Liquid Formula**

Active: Ethyl Alcohol.....80% v/v

Inactive: Glycerin, Purified Water, Hydrogen Peroxide



**55 Gallons (7,040 oz)**

MADE IN  
**FDA**  
REGISTERED FACILITY

## Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 80% v/v.....	Antiseptic

Use[s] : Hand Sanitizer to help reduce bacteria on the skin

### 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 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, Purified Water, Hydrogen Peroxide

### Other information

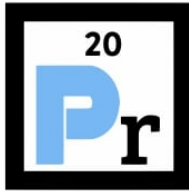
- Store at temperature below 110° F (43° C)
- May discolor certain fabrics or surfaces



Manufactured by:  
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**NDC 78517-801-55**





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CHEMICAL.**



**PYROXY LIQUID-80**

# Hand Sanitizer

**Kills 99.99%**  
of common  
germs and  
bacteria

**80% Liquid Formula**

Active: Ethyl Alcohol.....80% v/v

Inactive: Glycerin, Purified Water, Hydrogen Peroxide

0.25 Liter (250 mL)



MADE IN  
**FDA**  
REGISTERED FACILITY

## Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 80% v/v.....	Antiseptic

Use[s] : Hand Sanitizer to help reduce bacteria on the skin

### 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 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, Purified Water, Hydrogen Peroxide

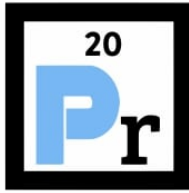
### Other information

- Store at temperature below 110° F (43° C)
- May discolor certain fabrics or surfaces



Manufactured by:  
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**NDC 78517-801-92**



**PYROCK  
CHEMICAL.**



**PYROXY LIQUID-80**

# Hand Sanitizer

**Kills 99.99%**  
of common  
germs and  
bacteria

**80% Liquid Formula**

Active: Ethyl Alcohol.....80% v/v

Inactive: Glycerin, Purified Water, Hydrogen Peroxide



**275 Gallons (35,200 oz)**

MADE IN  
**FDA**  
REGISTERED FACILITY

## Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 80% v/v.....	Antiseptic

Use[s] : Hand Sanitizer to help reduce bacteria on the skin

### 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 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, Purified Water, Hydrogen Peroxide

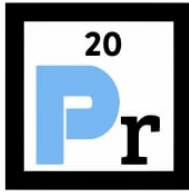
### Other information

- Store at temperature below 110° F (43° C)
- May discolor certain fabrics or surfaces



Manufactured by:  
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**NDC 78517-801-27**



**PYROCK  
CHEMICAL.**



**PYROXY LIQUID-80**

# Hand Sanitizer

**Kills 99.99%**  
of common  
germs and  
bacteria

**80% Liquid Formula**

Active: Ethyl Alcohol.....80% v/v

Inactive: Glycerin, Purified Water, Hydrogen Peroxide



**330 Gallons (42,240 oz)**

MADE IN  
**FDA**  
REGISTERED FACILITY

## Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 80% v/v.....	Antiseptic

Use[s] : Hand Sanitizer to help reduce bacteria on the skin

### 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 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, Purified Water, Hydrogen Peroxide

### Other information

- Store at temperature below 110° F (43° C)
- May discolor certain fabrics or surfaces



Manufactured by:  
PYROCK CHEMICAL  
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**NDC 78517-801-33**



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**PYROXY LIQUID-80**

# Hand Sanitizer

**Kills 99.99%**  
of common  
germs and  
bacteria

**80% Liquid Formula**

Active: Ethyl Alcohol.....80% v/v

Inactive: Glycerin, Purified Water, Hydrogen Peroxide

**1 Liter (1000 mL)**



MADE IN  
**FDA**  
REGISTERED FACILITY

## Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 80% v/v.....	Antiseptic

Use[s] : Hand Sanitizer to help reduce bacteria on the skin

### 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 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, Purified Water, Hydrogen Peroxide

### Other information

- Store at temperature below 110° F (43° C)
- May discolor certain fabrics or surfaces



Manufactured by:  
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**NDC 78517-801-91**

Front 25362259 ml - NDC 78517-801-67





**PYROCK  
CHEMICAL.**



**PYROXY LIQUID-80**

# Hand Sanitizer

**Kills 99.99%**  
of common  
germs and  
bacteria

**80% Liquid Formula**

Active: Ethyl Alcohol.....80% v/v

Inactive: Glycerin, Purified Water, Hydrogen Peroxide



**6700 Gallons (857,600 oz)**

MADE IN  
**FDA**  
REGISTERED FACILITY

## Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 80% v/v.....	Antiseptic

Use[s] : Hand Sanitizer to help reduce bacteria on the skin

### 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 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, Purified Water, Hydrogen Peroxide

### Other information

- Store at temperature below 110° F (43° C)
- May discolor certain fabrics or surfaces



Manufactured by:  
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**NDC 78517-801-67**

# PYROXY LIQUID-80B

alcohol 80% liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78517-801
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:78517-801-33	1249185.9 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78517-801-27	1040988.2 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78517-801-55	208197.65 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
4	NDC:78517-801-67	25362259 mL in 1 TANK; Type 0: Not a Combination Product	03/30/2020	
5	NDC:78517-801-01	3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:78517-801-92	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
7	NDC:78517-801-91	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
8	NDC:78517-801-95	18927.05 mL in 1 PAIL; Type 0: Not a Combination Product	03/30/2020	

## Marketing Information

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

**Labeler** - Pyrock Chemical (117537129)

# Establishment

Name	Address	ID/FEI	Business Operations
Reflow Supply Chain Solutions LLC		117537129	manufacture(78517-801)

Revised: 1/2022

Pyrock Chemical