PYROXY GEL-70 BASE- 70% gel hand sanitizer - base gel 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.

Pyroxy Gel-70 Base

The hand sanitizer is manufactured in response to the COVID-19 pandemic

- a. Alcohol (ethanol) (70%, 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 (2.01% v/v).
- c. Carbomber (1.33% v/v).
- d. Deionized or reverse osmosis water

Active Ingredient(s)

Alcohol 70% 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, purified water, carbomer

Package Label - Principal Display Panel

18927.05 mL NDC: 78517-701-95





Hand Sanitizer

Kills 99.99% of common germs and bacteria



Active: Ethyl Alcohol......70% v/v Inactive: Glycerin, Purified Water, Carbomer



5 Gallons (640 oz)



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

Warnings

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Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
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Inactive ingredients: Glycerin, Purified Water, Carbomer

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 78517-701-95

1249185.9 mL NDC: 78517-701-33





Hand Sanitizer

Kills 99.99% of common germs and bacteria



Active: Ethyl Alcohol......70% v/v Inactive: Glycerin, Purified Water, Carbomer



330 Gallons (42,240 oz)



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

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Inactive ingredients: Glycerin, Purified Water, Carbomer

Other information

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NDC 78517-701-33

1040988.2 mL NDC: 78517-701-27





Hand Sanitizer

Kills 99.99% of common germs and bacteria



Active: Ethyl Alcohol......70% v/v Inactive: Glycerin, Purified Water, Carbomer



275 Gallons (35,200 oz)



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

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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.

Inactive ingredients: Glycerin, Purified Water, Carbomer

Other information

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NDC 78517-701-27

208197.65 mL NDC: 78517-701-55





Hand Sanitizer

Kills 99.99% of common germs and bacteria



Active: Ethyl Alcohol......70% v/v
Inactive: Glycerin, Purified Water, Carbomer



55 Gallons (7,040 oz)



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

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Directions

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Inactive ingredients: Glycerin, Purified Water, Carbomer

Other information

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NDC 78517-701-55

25362259 mL NDC: 78517-701-67





Hand Sanitizer

Kills 99.99% of common germs and bacteria



Active: Ethyl Alcohol......70% v/v Inactive: Glycerin, Purified Water, Carbomer



6,700 Gallons (857,600 oz)



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

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Directions

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Inactive ingredients: Glycerin, Purified Water, Carbomer

Other information

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NDC 78517-701-67

3785.41 mL NDC: 78517-701-01





Hand Sanitizer

Kills 99.99% of common germs and bacteria



Active: Ethyl Alcohol......70% v/v Inactive: Glycerin, Purified Water, Carbomer



1 Gallon (128 oz)



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

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Directions

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Inactive ingredients: Glycerin, Purified Water, Carbomer

Other information

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NDC 78517-701-01

250 mL NDC: 78517-701-92





Hand Sanitizer

Kills 99.99% of common germs and bacteria



Active: Ethyl Alcohol......70% v/v Inactive: Glycerin, Purified Water, Carbomer



0.25 Liter (250 mL)



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

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When using this product

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 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, Carbomer

Other information

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





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NDC 78517-701-92

1000 ml NDC: 78517-701-91





Hand Sanitizer

Kills 99.99% of common germs and bacteria



Active: Ethyl Alcohol......70% v/v
Inactive: Glycerin, Purified Water, Carbomer



1 Liter (1,000 mL)



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

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When using this product

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Inactive ingredients: Glycerin, Purified Water, Carbomer

Other information

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NDC 78517-701-91

PYROXY GEL-70 BASE

70% gel hand sanitizer - base gel

Product	Inform	ation
Product		auvii

Product Type HUMAN OTC DRUG Item Code (Source) NDC:78517-701

Route of Administration TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
SODIUM ACRYLOYLDIMETHYLTAURATE-ACRYLAMIDE COPOLYMER (1:1; 90000-150000 MPA.S) (UNII: 5F4963KLHS)	1.34 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	2.06 mL in 100 mL
WATER (UNII: 059QF0KO0R)	26.6 mL in 100 mL

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78517- 701-67	25362259 mL in 1 TANK; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78517- 701-33	1249185.9 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78517- 701-27	1040988.2 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	
4	NDC:78517- 701-55	208197.65 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
5	NDC:78517- 701-01	3785.41 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
6	NDC:78517- 701-91	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
7	NDC:78517- 701-92	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
8	NDC:78517- 701-95	18927.05 mL in 1 PAIL; 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 - Pyrock Chemical (117537129)

Establishment			
Name	Address	ID/FEI	Business Operations
Reflow Supply Chain Solutions LLC		117537129	manufacture(78517-701)

Revised: 1/2022 Pyrock Chemical