PYROXY GEL-70 BASE POLY CLEAR- 70% gel hand sanitizer - base poly clear 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.

Pyrock Gel 70B - New Polymer

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, triethanolamine

Package Label - Principal Display Panel





Hand Sanitizer

Kills 99.99% of common germs and bacteria



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



5 Gallons (640 oz)



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

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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









Hand Sanitizer

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



330 Gallons (42,240 oz)



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275 Gallons (35,200 oz)



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55 Gallons (7,040 oz)



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6,700 Gallons (857,600 oz)



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1 Gallon (128 oz)



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Active: Ethyl Alcohol......70% v/v
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0.25 Liter (250 mL)



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+

1 Liter (1,000 mL)



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

NDC 78517-711-91

PYROXY GEL-70 BASE POLY CLEAR

70% gel hand sanitizer - base poly clear gel

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Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78517-711
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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			
CARBOMER 1342 (UNII: 809Y72KV36)	0.4 mL in 100 mL			
GLYCERIN (UNII: PDC6A3C0OX)	0.3 mL in 100 mL			
WATER (UNII: 059QF0KO0R)	29.05 mL in 100 mL			
CUPRIC BIS(TRIETHANOLAMINE) (UNII: YBM44X0B6H)	0.25 mL in 100 mL			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78517- 711-67	25362259 mL in 1 TANK; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78517- 711-33	1249185.9 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78517- 711-27	1040988.2 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	
4	NDC:78517- 711-55	208197.65 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
5	NDC:78517- 711-01	3785.41 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
6	NDC:78517- 711-91	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
7	NDC:78517- 711-92	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
8	NDC:78517- 711-95	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(78517-711)	

Revised: 1/2022 Pyrock Chemical