

GEL HAND SANITIZER- gel hand sanitizer gel

Streamline Polymers 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.

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) :

- 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. Polyquaternium 37 (0.67% v/v)
- d. Hydrogen peroxide (0.125% v/v).
- e. 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 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, hydrogen peroxide, Polyquaternium 37, purified water USP

Gel Hand Sanitizer 3780 mL - Poly 37

Drug Facts	
Active ingredient	Purpose
Ethyl Alcohol 70% v/v	Antiseptic
Use[s]	
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available	
Warnings	
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• on children less than 2 months of age • on open skin wounds	
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Directions	
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Other information	
• Store between 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F)	
Inactive ingredients: Water, Glycerin, Polyquaternium 37, Hydrogen Peroxide	

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Manufactured and Distributed by Streamline Polymers

Streamline Polymers 16950 Wallisville Rd., Houston, TX 77049

3780 mL NDC: 74793-0003-1

GEL HAND SANITIZER

gel hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74793-0003
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
POLYQUATERNIUM 37 (200 MPA.S) (UNII: 67C1D6YV24)	0.67 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74793-0003-1	3780 mL in 1 JUG; Type 0: Not a Combination Product	06/08/2020	



GEL HAND SANITIZER

1 Gallon / 3.78L

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Streamline Polymers 16550 Wallisville Rd. Houston, TX 77019



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/08/2020	

Labeler - Streamline Polymers LLC (117054225)

Registrant - Streamline Polymers LLC (117054225)

Establishment

Name	Address	ID/FEI	Business Operations
Streamline Polymers LLC		117054225	manufacture(74793-0003)

Revised: 1/2022

Streamline Polymers LLC