

PURFREE HAND SANITIZER- alcohol gel
STERILCO SP Z O O

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.

Hand Sanitiser PurFree

Alcohol 75% v/v. Purpose: Antiseptic

Antiseptic, Hand Sanitizer

to help reduce bacteria on the skin. For use when soap and water are not available.

For external use only. Flammable. Keep away from sources of heat or fire.

-on children less than 2 months of age.

-on open skin wounds.

Avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Stop using and ask a doctor if irritation or redness develops and lasts.

Keep out of reach of children.

In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

-put enough product in your palm to cover hands and rub hands together until dry.

-children under 6 years old should be supervised when using this product.

-store at a temperature below 110°F (43°C).

-may discolor certain fabrics and surfaces.

water, Glycerin, Propylene Glycol, Menthol, Carbomer, Aminomethyl Propanol.



Hand Sanitizer

With Cooling Menthol & Moisturizers

75% Ethyl Alcohol

16 FL OZ (473ml)

Hand Sanitizer

Drug Facts

Active ingredient	Purpose
Ethyl alcohol 75%	Antiseptic

Use: to help reduce bacteria on the skin. For use when soap and water are not available.

Warnings:
For external use only. Flammable. Keep away from sources of heat or fire.

Do not use:
-on children less than 2 months of age.
-on open skin wounds.

When using this product:
-Avoid contact with eyes. If contact occurs, rinse thoroughly with water.
-Stop using and ask a doctor if irritation or redness develops and lasts.
-Keep out of reach of children.
-In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions:
-put enough product in your palm to cover hands and rub hands together until dry.
-children under 6 years old should be supervised when using this product.

Other information:
-store at a temperature below 110°F (43°C).
-may discolor certain fabrics and surfaces.

Inactive ingredients: Water, Glycerin, Propylene Glycol, Menthol, Carbomer, Aminomethyl Propanol.

Produced in the European Union
Distributed by PurFree LLC
888 Biscayne Blvd, Suite 5502, Mami, FL 33132
(800) 558-1763
www.purfree.com



Hand Sanitizer

With Cooling Menthol & Moisturizers

75% Ethyl Alcohol

1.32 GALLONS (5L)



Hand Sanitizer

Drug Facts

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Ethyl alcohol 75%	Antiseptic

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PURFREE HAND SANITIZER
alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78717-001
Route of Administration	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
MENTHOL (UNII: L7T10EIP3A)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78717-001-01	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/27/2020	
2	NDC:78717-001-02	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/27/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/27/2020	

Labeler - STERILCO SP Z O O (851443421)

Establishment

Name	Address	ID/FEI	Business Operations
STERILCO SP Z O O		851443421	manufacture(78717-001)

Revised: 4/2021

STERILCO SP Z O O