

HAND SANITIZER- alcohol gel
STANCOS PRIVATE LIMITED

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.

PRO-SAN Hand Sanitizer 60ml

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.

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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, trolamine, purified water USP, acrylates/c10-30 alkyl acrylate crosspolymer, Fragrance

Package Label - Principal Display Panel



PRO-SAN

Alcohol Antiseptic 80%
Topical Gel

HAND SANITIZER
Non-sterile Gel

WATERLESS HYGIENIC TREATMENT

EXCELLENT SKIN PROTECTION & HAND CARE

KILLS BACTERIA WITH PROLONGED PROTECTION

60 ml

Drug Facts	
Active ingredient[s] Ethyl Alcohol 80 % v/v	Purpose Antiseptic
Use[s] 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 <ul style="list-style-type: none"> • 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.	
Directions <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients Aqua, Glycerin, Acrylates/C10-30, Alkyl Acrylate Crosspolymer, Triethanolamine, Parfum	



A Product of:

PENTONOVA LTD - UK

Manufactured & Marketed by
Stancos (Pvt.) Ltd Under technical
assistance of PENTONOVA LTD - UK



Made in Pakistan

60 mL NDC: 79982-000-01

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79982-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	48 mL in 60 mL	
Inactive Ingredients				
Ingredient Name			Strength	
GLYCERIN (UNII: PDC6A3C0OX)			0.87 mL in 60 mL	
TROLAMINE (UNII: 9O3K93S3TK)			0.06 mL in 60 mL	
WATER (UNII: 059QF0K00R)			10.89 mL in 60 mL	
FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95)			0.03 mL in 60 mL	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)			0.15 mL in 60 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79982-000-01	60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/07/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	08/07/2020	

Labeler - STANCOS PRIVATE LIMITED (645478686)

Establishment

Name	Address	ID/FEI	Business Operations
STANCOS PRIVATE LIMITED		645478686	manufacture(79982-000)

Revised: 12/2020

STANCOS PRIVATE LIMITED