

SIENA HAND SANITIZER- alcohol gel
Hilal Care Pvt Ltd

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.

Siena Hand Sanitizer

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.

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

- 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



Special Gold

Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 80% v/v	Antiseptic

Uses • Hand sanitizer to help reduce bacteria on skin that cause diseases • May be used repeatedly.

Warnings • *Flammable, Keep away from fire or flames.*

For external use only.

When using this product Avoid contact with eyes. In case of irritation or redness of skin, discontinue use and consult a doctor.

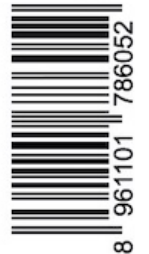
Directions • Place enough product in your palm to thoroughly cover your hands • Rub hands together briskly until dry.

Other information
 • Store between 15-30°C (59-86°F)
 • Avoid freezing and excessive heat above 40°C (104°F).

Inactive Ingredients:
 Aqua, Glycerin, Acrylates/C10-30, Alkyl Acrylate Crosspolymer, Triethanolamine, Parfum.



MANUFACTURED FOR
 HILAL CARE (PVT) LTD.
 510 CLIFTON CENTRE,
 BLOCK 5, CLIFTON,
 KARACHI 75600,
 PAKISTAN.
 MADE IN PAKISTAN.
 SIENA IS A REGISTERED
 TRADE MARK OF
 HILAL CARE (PVT) LTD.



60 mL NDC: 81338-001-01

Siena® HAND SANITIZER

Drug Facts	
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Ethyl Alcohol 80% v/v	Antiseptic
Uses • Hand sanitizer to help reduce bacteria on skin that cause diseases • May be used repeatedly.	
Warnings • <i>Flammable, Keep away from fire or flames.</i>	
For external use only.	
When using this product Avoid contact with eyes. In case of irritation or redness of skin, discontinue use and consult a doctor.	
Directions • Place enough product in your palm to thoroughly cover your hands • Rub hands together briskly until dry.	
Other information • Store between 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F).	
Inactive Ingredients: Aqua, Glycerin, Acrylates/C10-30, Alkyl Acrylate Crosspolymer, Triethanolamine, Parfum.	

SIENA IS A REGISTERED TRADE MARK OF HILAL CARE (PVT) LTD.

 MANUFACTURED FOR HILAL CARE (PVT) LTD. 510 CLIFTON CENTRE, BLOCK 5, CLIFTON, KARACHI 75600, PAKISTAN. MADE IN PAKISTAN.

    25°C / 77°F

8 961101 786069 

99.9% Effective

Siena®

HAND SANITIZER

Pure

Alcohol Antiseptic 80% Topical Gel
net. Vol. 275ml (2.028 fl. oz.)

275 ml NDC 81338-001-02

99.9% Effective

Siena®

HAND SANITIZER

Pure

Alcohol Antiseptic 80% Topical Gel
net. Vol. 500ml (2.028 fl. oz.)

Special Gold

HAND SANITIZER

Drug Facts	
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Ethyl Alcohol 80% v/v	Antiseptic
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For external use only.	
When using this product Avoid contact with eyes. In case of irritation or redness of skin, discontinue use and consult a doctor.	
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Other information • Store between 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F).	
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    25°C / 77°F

8 961101 786076 

 MANUFACTURED FOR HILAL CARE (PVT) LTD. 510 CLIFTON CENTRE, BLOCK 5, CLIFTON, KARACHI-75600, PAKISTAN. MADE IN PAKISTAN.

SIENA IS A REGISTERED TRADE MARK OF HILAL CARE (PVT) LTD.

500 ml NDC 81338-001-03

SIENA HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81338-001
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
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81338-001-01	60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	12/21/2020	
2	NDC:81338-001-02	275 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	12/21/2020	
3	NDC:81338-001-03	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	12/21/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/21/2020	

Labeler - Hilal Care Pvt Ltd (645791893)

Establishment

Name	Address	ID/FEI	Business Operations
STANCOS PRIVATE LIMITED		645478686	manufacture(81338-001)