SIENA HAND SANITIZER- alcohol gel
Hilal Care Pvt Ltd

Siena Hand Sanitizer Fresh

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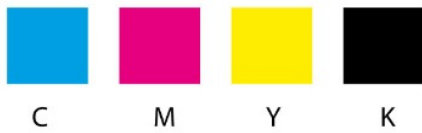
Other information
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

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

Package Label - Principal Display Panel

C   M   Y   K

Pantone 285 C

HilalCare logo
Pantone 2935 C

30mm

30mm

70mm

70mm

Special Gold

99.9%
Effective

Siena®

HAND
SANITIZER

Fresh

Alcohol Antiseptic 80%
Topical Gel

net. Vol. 60ml (2.028 fl. oz.)

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 throughly cover your hands • Rub hands together briskly until dry.

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

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

Hilal®

25ºC
77ºF

4M

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.

8 961101 783938

60 mL NDC: 81338-003-01

Sticker Size 53x66.5mm

C	M	Y	K

Pantone 285 C	HilalCare logo Pantone 2935 C

Special Gold

Back

Siena® HAND SANITIZER

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 throughly cover your hands • Rub hands together briskly until dry.

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

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

25ºC 77ºF

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

Hilal®

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

MADE IN PAKISTAN.

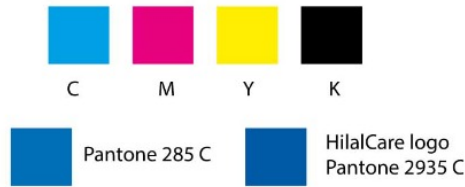8 961101784096

Front

99.9% Effective

Siena®

HAND SANITIZER

Fresh

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

275 ml NDC 81338-003-02

Sticker Size 54.6 x 84.4mm

C · M · Y · K

Pantone 285 C

HilalCare logo
Pantone 2935 C

Special Gold

Front

99.9% Effective

Siena®

HAND SANITIZER

Fresh

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

Back

HAND SANITIZER

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 throughly cover your hands • Rub hands together briskly until dry.

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

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

25°C 77°F
4M

8 961101 784638

Hilal®

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 81338-003-03

SIENA HAND SANITIZER
alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81338-003
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 FRESH CITRUS FLORAL ORC1501495 (UNII: OU4GI2R2WB)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81338-003-01	60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/23/2021	
2	NDC:81338-003-02	275 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/23/2021	
3	NDC:81338-003-03	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/23/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/23/2021	

Labeler - Hilal Care Pvt Ltd (645791893)

Establishment

Name	Address	ID/FEI	Business Operations
STANCOS PRIVATE LIMITED		645478686	manufacture(81338-003)

Revised: 3/2021

Hilal Care Pvt Ltd