

SURYA HENNA HAND SANITIZER- ethyl alcohol gel

Surya Nature Inc

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.

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 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

USE: Apply a small amount of SURYA HENNA HAND SANITIZER in the hands palm, massaging lightly, until completely absorbed.

NO RINSE REQUIRED.

Warnings

Flammable. Keep away from fire or flame.

For external use only.

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask a doctor if irritation or rash appears and lasts Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Do not use

When using this product do not use in or near the eyes.

In case of contact, rinse eyes thoroughly with water.

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or redness develops.

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 redness develops.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Directions • apply palmful to hands • rub hands together vigorously until dry
• supervise children in the use of this product.

Other information

- Other Information
 - Store below 110 ° F (43 ° C).
 - May discolor certain fabrics or surfaces.

Inactive ingredients

Inactive ingredients: Alcohol, Aqua, Glycerin (Vegetal), Carbomer, Aminomethyl Propanol, Aloe Barbadensis Leaf Extract (Aloe Vera), Lawsonia Inermis Leaf Extract (Henna), Chamomilla Recutita Flower Extract (Camomila), Denatonium Benzoate

Package Label - Principal Display Panel

SURYA  Brasil

SURYA HENNA HAND SANITIZER

ALCOHOL GEL 70° INPM



EXTRA HYDRATION
WITH:


Henna

Chamomile Aloe Vera



7.78 fl.oz (230 ml)

Read instructions before using

SURYA HENNA HAND SANITIZER alcohol-based developed for hand hygiene. Henna, Chamomile and Aloe Vera natural emollients with moisturizing properties provide softness and velvet touch.

Free from synthetic fragrance or perfume.

Drug Facts

Active Ingredients	Purpose
Ethyl Alcohol 70%.....	Antiseptic

USE: Apply a small amount of SURYA HENNA HAND SANITIZER in the hands palm, massaging lightly, until completely absorbed.
NO RINSE REQUIRED.

WARNING: Flammable. Keep away from fire or flame.
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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions • apply palmful to hands • rub hands together vigorously until dry • supervise children in the use of this product.

Other Information

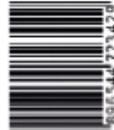
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Manufactured by: Vedic Hindus Ind.
Com. Imp. e Exp. Ltda.
Rua Dr. Paulo Leite de Oliveira, 170 –
São Paulo/SP - Brasil CEP: 05551-020
CNPJ: 48.875.587/0001-09 - Ind. Bras.
Aut. Func.: 2.01.259-1 SAC:
0800-770-7411

Imported and distributed by Surya Nature Inc.
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SH4254REV00



SURYA HENNA HAND SANITIZER

ALCOHOL GEL 70° INPM



EXTRA HYDRATION WITH:



2.03 fl.oz (60 ml)

Read instructions before using

230 mL NDC: 75252-720-10

60mL NDC: 75252-720-20

SURYA HENNA HAND SANITIZER alcohol-based developed for hand hygiene. Henna, Chamomile and Aloe Vera natural emollients with moisturizing properties provide softness and velvet touch. Free from synthetic fragrance or perfume.

Drug Facts	
Active Ingredients	Purpose
Ethyl Alcohol 70%.....	Antiseptic
USE: Apply a small amount of SURYA HENNA HAND SANITIZER in the hands palm, massaging lightly, until completely absorbed. NO RINSE REQUIRED.	
WARNING: Flammable. Keep away from fire or flame. For external use only.	
When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.	
Stop use and ask a doctor if irritation or redness develops.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions • apply palmful to hands • rub hands together vigorously until dry • supervise children in the use of this product.	
Other Information • Store below 110 ° F (43 ° C). • May discolor certain fabrics or surfaces.	
Inactive ingredients: Alcohol, Aqua, Glycerin (Vegetal), Carbomer, Aminomethyl Propanol, Aloe Barbadosis Leaf Extract (Aloe Vera), Lawsonia Inermis Leaf Extract (Henna), Chamomilla Recutita Flower Extract (Camomila), Denatonium Benzoate.	

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SURYA HENNA HAND SANITIZER

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75252-720
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL	
Inactive Ingredients			
Ingredient Name	Strength		
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)			
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.15 mL in 100 mL		
LAWSONIA INERMIS LEAF (UNII: E5818YZ355)	0.01 mL in 100 mL		
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)			
GLYCERIN (UNII: PDC6A3C0OX)	2 mL in 100 mL		

WATER (UNII: 059QF0K00R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.02 mL in 100 mL
CHAMOMILE (UNII: FGL3685T2X)	0.01 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75252-720-10	230 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/15/2020	
2	NDC:75252-720-20	60 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/15/2020	

Labeler - Surya Nature Inc (884726055)

Registrant - Surya Nature Inc (884726055)

Revised: 5/2020

Surya Nature Inc