

HAND SANITIZER- alcohol gel
Dr.Sankunnis Ayurvedic Research Foundation 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.

Hand Sanitizer

Active Ingredient(s)

Alcohol 70% v/v.

Purpose

Antimicrobial

Use

Hand Sanitizer to help reduce bacteria that potentially could cause disease. Recommended for repeated use

Warnings

For external use only. Flammable. Keep away from heat or flame

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 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 your hands. Rub hands briskly until dry.
- No rinsing required
- No towels needed

Other information

- Do not store above 110F (43C)
- May discolor certain fabrics or surfaces

Inactive ingredients

Vitamin E, Demineralized Water, Glycerin

Package Label - Principal Display Panel



Sycuan
CASINO • RESORT

HAND
SANITIZER

Refreshing Gel

enhanced with

Vitamin E

3.38 FL OZ (100ML)

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
Ethanol Alcohol 70% v/v.....	Antimicrobial

Uses

- Hand sanitizer to help reduce bacteria on the skin that could cause disease.
- Recommended for repeated use.

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.

Directions

- Place enough product in your palm to thoroughly cover your hands.
- Rub hands briskly until dry
- No rinsing required
- No towels needed

Other information

- Do not store above 110°F (43°C)
- May discolor certain fabrics or surfaces

Inactive Ingredients

Vitamin E, Demineralized Water, Glycerin



DISTRIBUTED BY:
ZEN ENTERPRISES CORPORATION
3111 S. VALLEY VIEW BLVD #H105
LAS VEGAS, NV 89102





HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70 146-012
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
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70 146-012-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:70 146-012-02	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:70 146-012-03	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
4	NDC:70 146-012-04	5000 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Dr.Sankunnis Ayurvedic Research Foundation Pvt Ltd (650517704)

Establishment

Name	Address	ID/FEI	Business Operations
Dr.Sankunnis Ayurvedic Research Foundation Pvt Ltd		650517704	manufacture(70146-012)

Revised: 6/2020

Dr.Sankunnis Ayurvedic Research Foundation Pvt Ltd