

## **HAND SANITIZER- alcohol gel**

### **HS HomeWorx LLC**

*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.*

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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 75% v/v. Purpose: Antiseptic

### **Purpose**

Antiseptic

### **Use**

to help reduce bacteria on skin.

### **Warnings**

For external use only. Flammable. Keep away from fire, flame and high heat.

When using this product avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

Avoid contact with broken skin. Do not ingest or inhale.

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

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

## Directions

- Dispense into hands, rub thoroughly until dry.

## Other information

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

## Inactive ingredients

Water (Aqua), Glycerin, Butylene Glycol, Fragrance (Parfum), Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Aloe Barbadensis Leaf Extract, Artemisia Argyi Leaf Extract, Cnidium Monnieri Fruit Extract, Sargassum Fusiforme Extract

## Package Label - Principal Display Panel

236 mL NDC: 81282-047-01

**SCENTWORX**  
BY HARRY SLATKIN

**ICED VANILLA FROSTING**

ANTI-BACTERIAL  
HAND SANITIZER  
Kills Germs and Bacteria

Infused with Aloe

**FESTIVE & INDULGENT**  
**ICED VANILLA FROSTING**

**Drug Facts**

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Alcohol 75% V/V	Antiseptic

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**Warnings**  
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Made in China  
Distributed by ScentWorx LLC  
New York, NY 10021

\$6.50

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## HAND SANITIZER

alcohol gel

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:81282-047

**Route of Administration**

TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL
WATER (UNII: 059QF0KOOR)	22 mL in 100 mL
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	1 mL in 100 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81282-047-01	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/01/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/01/2021	

**Labeler** - HS HomeWorx LLC (080653110)

### Establishment

Name	Address	ID/FEI	Business Operations
Cosbe Laboratory Inc		543033650	manufacture(81282-047)

Revised: 5/2021

HS HomeWorx LLC