

## **AMERICAN BEAUTY ADVANCED HAND SANITIZER- alcohol gel**

**American Beauty Manufacturing 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.*

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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)

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (65%, 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. Hydroxypropyl Cellulose (1.00% w/w).
- d. Alpha-Tocopherol Acetate (0.05% w/w).
- e. Isopropyl Myristate (0.50% v/v)
- f. 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 65% v/v. Purpose: Antiseptic

### **Purpose**

Antiseptic, Hand Sanitizer

### **Use**

Hand Sanitizer to help reduce bacteria that potentially can 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 with eyes, flush thoroughly with water.

Avoid contact with broken skin.

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

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 together until dry
- No rinsing or towels required

## Inactive ingredients

water, glycerin, hydroxypropylcellulos, isopropyl myristate, tocopheryl acetate

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

Call 918-516-8340 Monday to Friday 8:00am to 5:00pm CST

contact@americanbeautymfg.com

Do not store above 110°F (43°C)

May discolor certain fabrics or surfaces

## Package Label - Principal Display Panel

3.78L NDC: 76907-401-01

**AMERICAN BEAUTY**

**Advanced Hand Sanitizer Gel**

**Kills 99.99% of Germs**      **Leaves hands feeling clean and soft**

- Take a coin sized drop on your palm.
- Spread sanitizer and rub palms together
- Rub tips of each hand with palm of other hand.
- Rub hands together until they are dry.

**1 GAL (128 fl oz) 3.78L**

**Drug Facts**

**Active Ingredients**      **Purpose**  
Ethyl alcohol 65% w/v...      Antimicrobial

**Uses**  
•Hand Sanitizer to help reduce bacteria on 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 with eyes, flush thoroughly with water.  
Avoid contact with broken skin.  
Stop use and ask a doctor if irritation or redness develop.  
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 together until dry.  
•No rinsing or towels required

**Other Information**  
•Do not store above 110°F (43°C)  
•May discolor certain fabrics or surfaces

**Inactive Ingredients**  
water, glycerin, hydroxypropylcellulos, isopropyl myristate, tocopheryl acetate

**Questions or comments**  
Call 918-516-8340 Monday to Friday 8:00am to 5:00pm CST  
contact@americanbeautymfg.com

Manufactured by:-  
AMERICAN BEAUTY MANUFACTURING, INC.  
1623 EAST APACHE STREET  
TULSA, OK 74106

Made in USA

## AMERICAN BEAUTY ADVANCED HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76907-401
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	2461 mL in 3785 mL

### Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	19 mL in 3785 mL
GLYCERIN (UNII: PDC6A3C0OX)	55 mL in 3785 mL
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	2 mL in 3785 mL
WATER (UNII: 059QF0K00R)	1267 mL in 3785 mL
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	34 g in 3785 mL

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76907-401-01	3785 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	11/02/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/02/2020	

**Labeler** - American Beauty Manufacturing Inc (785139648)

## Establishment

Name	Address	ID/FEI	Business Operations
Enter Establishment Name		785139648	manufacture(76907-401)

Revised: 12/2020

American Beauty Manufacturing Inc