

**ANTIMICROBIAL WIPES ALCOHOL FREE- benzalkonium chloride cloth**  
**Valley of the Sun Cosmetics 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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**Antimicrobial Wipes**

**Active Ingredients**

Benzalkonium Chloride 0.13%

**Purpose**

Antimicrobial

**Uses**

Antimicrobial Wipes are used to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

**Warnings**

For external use only.

**Do not Use**

- in children less than 2 years of age, do not use as baby wipe.
- 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 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**

- To dispense, lift cover, remove seal, pull center sheet from roll, twist to a point and feed through dispenser hole in cover. Keep lid closed to prevent moisture loss.
- Open and unfold wipe
- Thoroughly wipe hands, fingers and wrists. Be sure to use the entire wipe. Allow to dry.
- For dirty hands, use first wipe to clean hands, then discard wipe; sanitize with the second wipe.
- Discard after single use
- Supervise children under 2 years of age when using this product to avoid swallowing

## Other information

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

## Inactive ingredients

Water, Glycerin, Aloe barbadensis (aloe vera) leaf extract, Hydrogen Peroxide, Tocopheryl Acetate (Vitamin E), PEG-60 Hydrogenated Castor Oil, Propylene Glycol, Phenoxyethanol

## Label and product picture

80 wipes in 1 canister, NDC: 76523-094-80

Antimicrobial Wipes 80 sheets-Drs Formula- 11-12-2020 (No Fragrance)

← 315 mm →

↑ 137.16 mm ↓

Label Specs: 4 color  
Coating: Laminate  
Material: White BOPP Adhesive  
Label Size: 12.4" x 5.4"



## ANTIMICROBIAL WIPES ALCOHOL FREE

benzalkonium chloride cloth

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76523-094
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
WATER (UNII: 059QF0KO0R)	97.14 g in 100 g
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.15 g in 100 g
GLYCERIN (UNII: PDC6A3C0OX)	1.45 g in 100 g
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.3 g in 100 g
PEG-60 HYDROGENATED CASTOR OIL (UNII: 02NG325BQG)	0.4 g in 100 g
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 g in 100 g
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.3 g in 100 g
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.01 g in 100 g

**Product Characteristics**

<b>Color</b>	white (Canister white with blue cap)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76523-094-80	100 g in 1 CANISTER; Type 0: Not a Combination Product	11/12/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/12/2020	

**Labeler** - Valley of the Sun Cosmetics LLC (176470664)**Registrant** - Valley of the Sun Cosmetics LLC (176470664)**Establishment**

Name	Address	ID/FEI	Business Operations
Valley of the Sun Cosmetics LLC		176470664	manufacture(76523-094)

