# 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**

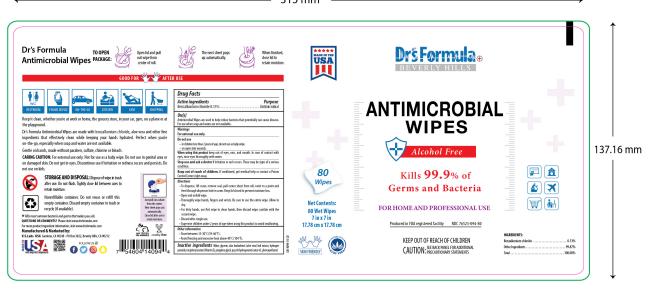
Water, Glycerin, Aloe barbadensis (aloe vera) leaf extract, Hydrogen Peroxide, Tocopheryl Acetate (Vitamin E), PEG-60 Hydrogenated Castor Oil, Propylene Glycol, Phenoxyethanol

## 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



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

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>BENZALKO NIUM CHLO RIDE</b> (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
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 PERO XIDE (UNII: BBX060AN9V)	0.125 g in 100 g	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	0.3 g in 100 g	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	0.01 g in 100 g	

Product Characteristics			
Color	white (Canister white with blue cap)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

ı	Packaging			
ı	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
ı	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)	

Revised: 11/2020 Valley of the Sun Cosmetics LLC