

**AQUARELLE- benzalkonium chloride cloth**  
**HIGIENE + SALUD, S.A. DE C.V.**

*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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Benzalkonium Chloride 0.125%

Antibacterial

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For external use only

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Over large areas of the body if you are allergic to any of the ingredients.

Do not get into eyes.

If contact occurs, rinse thoroughly with water.

If irritation or rash develops and continues for more than 72 hours.

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If swallowed, get medical help or contact a Poison Control Center right away.

- Thoroughly wipe hands and face as desired.
- allow to dry without wiping.
- Discard wipe in trash receptacle after use. Do not flush.

Store at room temperature. Cold weather may cloud this product. It's antiseptic properties are not affected.

Water, Propylene Glycol, Polysorbate 20, Sodium Cocoamphoacetate, Fragrance, Methylchloroisothiazolinone/ Methylisothiazolinone, Aloe Extract, Tetrasodium EDTA, Citric Acid, Vitamin E.

Dosage: Swab - Administration: Topical

- **Convenient**

Easy to use & carry anywhere!

- **Clean-up**

Use to wash up quickly when soap and water are not available.

- **Moisturize**

Contains soothing Aloe to help moisturize your skin and leave it feeling soft and smooth.



## AQUARELLE

benzalkonium chloride cloth

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52629-801
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.125 mg in 100 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	98.54 mg in 100 mg
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	0.05 mg in 100 mg
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	0.3 mg in 100 mg
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8)	0.01 mg in 100 mg
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	0.5 mg in 100 mg
<b>SODIUM COCOAMPHOACETATE</b> (UNII: W7Q5E87674)	0.2 mg in 100 mg
<b>METHYLCHLOROISOTHIAZOLINONE</b> (UNII: DEL7T5QRPN)	0.1 mg in 100 mg
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	0.03 mg in 100 mg
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	0.018 mg in 100 mg

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52629-801-03	16 in 1 BOX	07/01/2020	
1		1 in 1 PACKAGE		
1		0.3 mg in 1 POUCH; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/01/2020	

**Labeler** - HIGIENE + SALUD, S.A. DE C.V. (814608832)

**Registrant** - HIGIENE + SALUD, S.A. DE C.V. (814608832)

### Establishment

Name	Address	ID/FEI	Business Operations
HIGIENE + SALUD, S.A. DE C.V.		814608832	manufacture(52629-801) , pack(52629-801) , label(52629-801)

