

**NE MEXICO AGING LONG TERM SERVICES DEPARTMENT HAND SANITIZER-  
benzalkonium chloride gel  
Sombra Cosmetics**

*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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**New Mexico Aging Long-Term Services Department Alcohol Free Hand Sanitizer**

**Active Ingredients**

Benzalkonium Chloride 0.15%

**Uses**

To decrease bacteria and viruses on the skin that could cause disease. Recommended for repeated use.

**Warnings**

For external use only: hands.

**Do Not Use**

avoid contact with broken skin. Do not inhale or ingest. Children under 6, use only under adult supervision. Not recommended for infants.

**When Using**

When using this product, keep out of the eyes. In case of contact with eyes, flush thoroughly with water.

**Stop Use**

Stop use if irritation and redness develop or if condition persists for more than 72 hours.

**Keep out of reach of children**

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

**Directions**

Wet hands thoroughly with product and allow to dry without wiping. For children under 6,

use only under adult supervision.

## Storage and Handling


Store away from oxidizing agents. Do not store above 100 C.

## Inactive ingredients

Purified water, glycerin, cyamopsis tetragonoloba (Guar) gum, citrus limon (lemon) peel oil, hamamelis virginiana (witch hazel) leaf extract, camellia sinensis (green tea) leaf extract, champhilla recutita (matricaria) flower extract, rosa damascena (rose) flower waterr, aloe barbadensis leaf juice, yucca schidigera stem extract, filipendula ulmaria (queen of the prairie) extract, phenoxyethanol, caprylyl glyol, citric acid

## Purpose

Anitmicrobial

<b>Drug Facts</b> NDC 61577-4200-8		<b>Drug Facts (continued)</b>
<b>Active Ingredients:</b> Benzalkonium Chloride 0.15% <b>Purpose:</b> Antimicrobial		<b>Stop use and ask a doctor if</b> ■ irritation and redness develop ■ condition persists for more than 72 hours.
<b>Uses:</b> To decrease bacteria and viruses on the skin that could cause disease ■ recommended for repeated use.		<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.
<b>Warnings:</b> <b>For external use only: hands</b>		<b>Directions</b> ■ wet hands thoroughly with product and allow to dry without wiping ■ for children under 6, use only under adult supervision.
<b>When using this product</b> ■ keep out of the eyes. In case of contact with eyes, flush thoroughly with water ■ avoid contact with broken skin ■ do not inhale or ingest. ►	<b>Alcohol-Free Hand Sanitizer</b>	<b>Inactive Ingredients:</b> Purified Water, Glycerin, Cyamopsis Tetragonoloba (Guar) Gum, Citrus Limon (Lemon) Peel Oil, Hamamelis Virginiana (Witch Hazel) Leaf Extract, Camellia Sinensis (Green Tea) Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Rosa Damascena (Rose) Flower Water, Aloe Barbadensis Leaf Juice, Yucca Schidigera Stem Extract, Filipendula Ulmaria (Queen of the Prairie) Extract, Phenoxyethanol, Caprylyl Glycol, Citric Acid.
Made in the USA • 1-800-432-2080 www.nmaging.state.nm.us Manufactured for NM Aging & Long Term Services Department		with Natural Skin Conditioners
		Net Wt. 8 fl. oz. (236.6 ml)

# NE MEXICO AGING LONG TERM SERVICES DEPARTMENT HAND SANITIZER

benzalkonium chloride gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61577-4200
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.15 g in 100 g
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### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>GUAR GUM</b> (UNII: E89I1637KE)	
<b>LEMON OIL</b> (UNII: I9GRO824LL)	
<b>WITCH HAZEL</b> (UNII: 101I4J0U34)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>ROSA DAMASCENA FLOWER</b> (UNII: JWB78P295A)	
<b>CHAMOMILE</b> (UNII: FGL3685T2X)	
<b>YUCCA SCHIDIGERA STEM</b> (UNII: N59C6T6D72)	
<b>FILIPENDULA RUBRA WHOLE</b> (UNII: MT26BL24AZ)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-4200-8	237 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/03/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/03/2021	

**Labeler** - Sombra Cosmetics (097464309)

### Establishment

Name	Address	ID/FEI	Business Operations
Sombra Cosmetics		097464309	manufacture(61577-4200)

Revised: 9/2021

Sombra Cosmetics