

**ANTISEPTATION- benzethonium chloride lotion**  
**A-Cute Derm, Incorporated**

*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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**DRUG FACTS**

Kills 99.9% of harmful germs in 30 seconds.

**Active Ingredients**

Benzethonium Chloride (0.2%)

**Purpose**

Antimicrobial

**Uses**

•Antiseptation™ is a unique, non-drying cleanser. •Designed for all skin types and pH balanced. •Excellent for postoperative care. •May be used as a topical antimicrobial to help protect against skin infection.

**Warnings**

•External use only. •Do not use in eyes. •In case of deep wounds or puncture wounds, consult a physician. •If irritation develops and persists for more than a few days, discontinue use and consult a physician.

**KEEP OUT OF REACH OF CHILDREN**

**Directions**

•Wet hands and other areas to be treated. •Place a small amount of gel in your hands and work into lather. •Apply lather to areas to be treated using a gentle, circular motion. •Rinse clean.

**Inactive ingredients**

Purified Water, Ammonium Lauryl Sulfate,  
Lauramidopropyl Betaine, Hydroxypropyl  
Bis-Hydroxyethyl-dimonium Chloride,  
Propylene Glycol, Hydroxypropylmethylcellulose,  
Sodium Chloride, Diazolidinyl  
Urea, PEG-4 Laurate, Methylparaben,  
Propylparaben, 3-iodo-2-propynylbutylcarbamate.

**Other Information**

•Alcohol Free •Moisturizes •Made in USA

**Questions or Comments**

A-Cute Derm, Inc.  
1810 Cravens Road  
Stafford, TX 77477  
800.922.2883  
M-F 8:30am-5:30pm  
info@a-cutederm.com  
www.a-cutederm.com

**Principal Display Panel**

ANTISEPTATION™

CLEANSING GEL

Kills 99.9% of Harmful

Germs In 30 Seconds

NDC# 61619-717-14

4.0 FL OZ (118.3 ml)

**Warnings**  
 •External use only. •Do not use in eyes.  
 •In case of deep wounds or puncture wounds, consult a physician. •If irritation develops and persists for more than a few days, discontinue use and consult a physician.

**KEEP OUT OF REACH OF CHILDREN**

**Directions**  
 •Wet hands and other areas to be treated. •Place a small amount of gel in your hands and work into lather. •Apply lather to areas to be treated using a gentle, circular motion. •Rinse clean.

**Other Information**  
 •Alcohol Free •Moisturizes •Made in USA

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**Drug Facts**  
 Kills 99.9% of harmful germs in 30 seconds.

Active Ingredients	%	Purpose
Benzethonium Chloride	0.20	Antimicrobial

**Inactive Ingredients**  
 Purified Water, Ammonium Lauryl Sulfate, Lauramidopropyl Betaine, Hydroxypropyl Bis-Hydroxyethyl-dimonium Chloride, Propylene Glycol, Hydroxypropylmethylcellulose, Sodium Chloride, Diazolidinyl Urea, PEG-4 Laurate, Methylparaben, Propylparaben, 3-iodo-2-propynylbutylcarbamate.

**Purpose**  
 •Antimicrobial Wash

**Uses**  
 •Antiseption™ is a unique, non-drying cleanser. •Designed for all skin types and pH balanced. •Excellent for postoperative care. •May be used as a topical antimicrobial to help protect against skin infection.

**ANTIMICROBIAL**

**ANTISEPTION™**  
**CLEANSING GEL**  
 Kills 99.9% of Harmful Germs In 30 Seconds  
 NDC# 61619-717-14  
 4.0 FL OZ (118.3 ml)



Marketed by  
 A-Cute Derm, Inc. Stafford, TX 77477  
 Item 7174 •V. 081415  
 Animal Cruelty Free •Made in U.S.A.



## ANTISEPTION

benzethonium chloride lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61619-717
<b>Route of Administration</b>	CUTANEOUS		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	2 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
HYDROXYPROPYL BIS-HYDROXYETHYLDIMONIUM CHLORIDE (UNII: 1EO3O1X7HG)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
PEG-4 LAURATE (UNII: AYF4VM3N1Z)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
LAURAMIDOPROPYL BETAINE (UNII: 23D6XVI233)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

**PROPYLENE GLYCOL** (UNII: 6DC9Q167V3)

**WATER** (UNII: 059QF0KO0R)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61619-717-14	118.294 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/05/2016	
2	NDC:61619-717-12	946.4 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/05/2016	
3	NDC:61619-717-07	29.6 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/05/2016	
4	NDC:61619-717-28	3800 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/05/2016	
5	NDC:61619-717-18	236.6 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/05/2016	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	02/05/2016	

**Labeler** - A-Cute Derm, Incorporated (809845803)

### Establishment

Name	Address	ID/FEI	Business Operations
Bio-Medical & Pharmaceutical Manufacturing Corporation		072186356	manufacture(61619-717)

Revised: 4/2016

A-Cute Derm, Incorporated