

**PIRANHA BRAND ALCOHOL FREE FOAMING INSTANT HAND SANITIZER WITH ALOE AND VITAMIN E- foaming instant hand sanitizer with aloe and vitamin e solution**

**Bio Shine, Inc.**

*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.*

**Piranha Brand Alcohol Free Foaming Instant Hand Sanitizer with Aloe and Vitamin E**

Benzethonium Chloride 0.2% w/w.....Antibacterial Agent

Water, Fragrance, Aloe Barbadensis Leaf, Tocopheryl Acetate, Cocamidopropyl Betaine, Propylene Glycol, Phenoxyethanol, PEG-7 Glyceryl Cocoate, Tetrasodium EDTA.

Hand sanitizer to help reduce bacteria on the skin that could cause disease. Recommended for repeated use.

**For external use only.**

**Avoid contact with eyes.** If contact occurs, flush with water.

**Stop use if**, in rare instances, redness or irritation develop. If condition persists for more than 72 hours, consult a physician.

**Keep out of reach of children.** If swallowed, contact a physician or poison control center.

To decrease bacteria on skin, apply small amount to palm. Briskly rub, covering hands with product until dry.

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**ALCOHOL FREE FOAMING  
INSTANT HAND SANITIZER**

*with Aloe and Vitamin E*

**Item # BS1033**

***Drug Facts***

***Active Ingredient***

Benzethonium Chloride 0.2% w/w .....Antibacterial Agent

***Purpose***

***Uses*** ■ Hand sanitizer to help reduce bacteria on the skin that could cause disease. Recommended for repeated use.

## Warnings

- **For external use only.** ■ **Avoid contact with eyes.** If contact occurs, flush with water.
- **Stop use if**, in rare instances, redness or irritation develop. If condition persists for more than 72 hours, consult a physician.
- **Keep out of reach of children.** If swallowed, contact a physician or poison control center.

## Directions

- To decrease bacteria on skin, apply small amount to palm. Briskly rub, covering hands with product until dry.

**Inactive Ingredients** Water, Fragrance, Aloe Barbadensis Leaf, Tocopheryl Acetate, Cocamidopropyl Betaine, Propylene Glycol, Phenoxyethanol, PEG-7 Glyceryl Cocoate, Tetrasodium EDTA.

LA707V-0813

**Ingrédient actif** Chlorure de benzéthonium 0,2% w/w (Agent antibactérien) **Utilisations** Pour le lavage des mains, afin de réduire les bactéries sur la peau. **Avertissements** Pour usage externe seulement. Ne pas mettre dans les yeux. En cas d'irritation ou de rougeur, arrêtez l'utilisation. Si les symptômes persistent plus 72 heures, consultez un médecin. En cas d'ingestion, consultez un médecin ou un centre antipoison. Garder hors de portée des enfants. **Mode d'emploi** Pour réduire les bactéries sur la peau, appliquer une petite quantité sur la paume. Appliquer et faire pénétrer dans la peau en frottant. **Ingrédients inactifs** Eau, parfum, aloès barbadine, acétate tocophérylique (vitamine E), bétaine cocamidopropylique, propylèneglycol, phénoxyéthanol, PEG-7 cocoate glycérylique, tétrasodium d'EDTA.

**Ingrédiente Activo** Cloruro de bencetonium 0,2%w/w (Agent antibacterial) **Usos** Se usa para el lavado de manos a fin de disminuir las bacterias en la piel. **Advertencias** Solamente para uso externo. No lo utilice en los ojos. En casos raros de irritación y enrojecimiento, suspenda el uso. Si el estado persiste durante más de 72 horas consulte con un médico. Si se ingiere llame a un médico o a un centro de control de venenos. Mantenga fuera del alcance de niños. **Mode de Empleo** Para disminuir las bacterias en la piel, aplique una pequeña cantidad en la palma. Frote cubriendo las manos con brio hasta que el producto se seque. **Ingrédients Inactivos** Agua, perfume, áloe barbadino, acetato tocoferílico (vitamina E), betaina cocamidopropilica, propilén glicol, fenoxietanol, PEG-7 cocoato gliceril, tetrasodio de EDTA.

**Net Contents:**

**33.8 Fl. Oz.**

MADE IN USA

Manufactured for:

**Bio-Shine Inc.**

190 Summerhill Rd. / Spotswood, NJ 08884  
(888) 246-7446 / (732) 251-9506

61625-682-41.jpg

## PIRANHA BRAND ALCOHOL FREE FOAMING INSTANT HAND SANITIZER WITH ALOE AND VITAMIN E

foaming instant hand sanitizer with aloe and vitamin e solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61625-682
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZETHONIUM CHLORIDE</b> (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	7.56 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>PEG-7 GLYCERYL COCOATE</b> (UNII: VNX7251543)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61625-682-41	1000 mL in 1 BAG		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/17/2013	

**Labeler** - Bio Shine, Inc. (801231184)

### Establishment

Name	Address	ID/FEI	Business Operations
Kutol Products Company, Inc.		004236139	manufacture(61625-682) , analysis(61625-682) , label(61625-682) , pack(61625-682)