

**PIRANHA BRAND FOAMING ANTIBACTERIAL HAND- foaming antibacterial hand soap 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 Foaming Antibacterial Hand**

Triclosan 0.5% w/w.....Antibacterial Agent

Water, Ammonium Lauryl Sulfate, Sodium Laureth Sulfate, Glycerin, Polyquaternium-7, Aloe Barbadensis Leaf, Tocopheryl Acetate, Disodium Cocamido MIPA-Sulfosuccinate, Tetrasodium EDTA, Fragrance, Citric Acid, Polyquaternium-10, DMDM Hydantoin, Yellow 5, Red 33.

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

**For external use only.**

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

**Stop use and ask a doctor if**, in rare instances, redness or irritation develop and persists for more than 72 hours.

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

For handwashing to decrease bacteria on skin.

To decrease bacteria on skin, apply small amount, covering hands with product for 30 seconds. Add water, lather, rinse.

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**FOAMING ANTIBACTERIAL  
HAND SOAP**

*with Aloe and Vitamin E*

**Item # BS1035**

**Drug Facts**

**Active Ingredient**

Triclosan 0.5% w/w .....Antibacterial Agent

**Purpose**

**Uses** ■ For handwashing to decrease bacteria on skin.

**Warnings**

■ **For external use only.** ■ **Avoid contact with eyes.** If contact occurs, flush with water.

■ **Stop use and ask a doctor if**, in rare instances, redness or irritation develop and persists for more than 72 hours.

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

### **Directions**

- To decrease bacteria on skin, apply small amount, covering hands with product for 30 seconds. Add water, lather, rinse.

**Inactive Ingredients** Water, Ammonium Lauryl Sulfate, Sodium Laureth Sulfate, Glycerin, Polyquaternium-7, Aloe Barbadensis Leaf, Tocopheryl Acetate, Disodium Cocamido MIPA-Sulfosuccinate, Tetrasodium EDTA, Fragrance, Citric Acid, Polyquaternium-10, DMDM Hydantoin, Yellow 5, Red 33.

LA707U-0813

**Ingrédient actif** Triclosane 0,5% 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** Appliquer une quantité suffisante, se couvrant les mains pendant 30 secondes. Ajouter d'eau, former une mousse et rincer/

**Ingrédients inactifs** Eau, sulfate laurylique d'ammonium, sulfate laureth de sodium, glycérine, polyquaternium-7, feuille d'aloès barbadine, acétate tocophérylique (vitamine E), sulfosuccinate-MIPA de cocamido disodique, tétrasodium d'EDTA parfum, acide citrique, polyquaternium-10, hydantoïne déminéralisée, jaune 5, rouge 33.

**Ingrediente Activo** Triclosano 0,5% w/w (Agente 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. **Modo de Empleo** Aplique una cantidad pequeña de producto sobre las manos, cubriendo las manos durante 30 segundos. Añada agua, forme espuma y enjuague. **Ingredientes Inactivos** Agua, lauril sulfato de amonio, lauret sulfato de sodio, glicerina, policuaternio-7, hoja de aloe barbadensis, acetato tocoferilico (vitamina E), sulfocuccinato-MIPA de cocamido disódico, EDTA de tetrasodio, perfume, ácido cítrico, policuaternio-10, hidantoína desmineralizada, amarillo 5, rojo 33.

**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

61625-689-41.jpg

## **PIRANHA BRAND FOAMING ANTIBACTERIAL HAND**

foaming antibacterial hand soap with aloe and vitamin e solution

### **Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:61625-689

Route of Administration TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	18.9 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
POLYQUATERNIUM-10 (1000 MPA.S AT 2 %) (UNII: GMR4PEN8PK)	
EDETATE SODIUM (UNII: MP1J8420LU)	
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ISO STEARAMIDOPROPYL MORPHOLINE LACTATE (UNII: 082Y3WQI5K)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61625-689-41	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	09/23/2013	

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

**Registrant** - Kutol Products Company, Inc. (004236139)

### Establishment

Name	Address	ID/FEI	Business Operations
Kutol Products Company, Inc.		004236139	manufacture(61625-689) , analysis(61625-689) , label(61625-689) , pack(61625-689)