

PIRANHA BRAND FOAMING ALCOHOL HAND SANITIZER- foaming hand sanitizer 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 Alcohol Hand Sanitizer

Ethyl Alcohol 62% v/v.....Antibacterial Agent

Water, AMP-C8-18 Perfluoroalkylethyl Phosphate, Glycerin.

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

For external use only.

FLAMMABLE. Keep away from heat or flames.

Avoid contact with eyes. If eye 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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**FOAMING ALCOHOL
HAND SANITIZER
Item # BS1034**

Drug Facts

Active Ingredient

Ethyl Alcohol 62% v/v.....Antibacterial Agent

Purpose

Uses

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

Warnings

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Directions

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Inactive Ingredients Water, AMP-C8-18 Perfluoroalkylethyl Phosphate, Glycerin.

LA7075-0813

Ingrediente activo Alcool éthylique 62% v/v (Agent antibactérien) **Utilisations** Pour le lavage des mains, afin de réduire les bactéries sur la peau. **Avertissements** **INFLAMMABLE. Ne pas mettre a proximite d'un feu ou d'une flamme.** 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. **Ingédients inactifs** Eau, phosphate de perfluoroalkyléthyle AMP-C8-18, glycérine.

Ingrediente Activo Alcohol etílico 62% v/v (Agent antibacterial) **Usos** Se usa para el lavado de manos a fin de disminuir las bacterias en la piel. **Advertencias INFLAMABLE. Mantener alejado del fuego o llama.** 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. **Ingredientes Inactivos** Agua, AMP-C8-18 perfluoroalquiletil fosfato, glicerina.

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

61625-688-41.jpg

PIRANHA BRAND FOAMING ALCOHOL HAND SANITIZER

foaming hand sanitizer solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61625-688
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
AMINOMETHYLPROPANOL (PERFLUORO-C6-C12 ETHYL)PHOSPHATE (UNII: QCD5R22RNT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61625-688-41	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	06/27/2013	

Labeler - Bio Shine, Inc. (801231184)

Registrant - Kutol Products Company, Inc. (004236139)

Establishment

Name	Address	ID/FEI	Business Operations
Kutol Products Company, Inc.		004236139	manufacture(61625-688) , analysis(61625-688) , label(61625-688) , pack(61625-688)