

ALCOHOL FREE FOAM SANITIZER- benzalkonium chloride soap
Afflink, 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.

Alcohol Free Foam Sanitizer

Alcohol Free Foam Sanitizer

☐Active Ingredient

Benzalkonium Chloride 0.13%

Alcohol Free Foam Sanitizer

Uses

- Use in a variety of public facilities.
- Use this product when soap and water are not available.

Alcohol Free Foam Sanitizer

Warnings

- **For external use only.**
- Avoid contact with eyes.
- Children under the age of 6 should be supervised by an adult when using this product.
- Discontinue use if irritation or redness develops.
- If irritation persists for more than 72 hours, consult a physician.
- **KEEP OUT OF REACH OF CHILDREN.**

Alcohol Free Foam Sanitizer

Directions

- ☐**Read the entire label before using this product.**
- ☐Dispense 1-2 pumps of product onto dry hands. Rub hands together to distribute product

Alcohol Free Foam Sanitizer

Inactive Ingredients

Deionized ☐Water, Sodium PCA, PEG/PPG-8/3 Laurate, Dimethicone, DMDM Hydantoin, PEG-3 Cocamide, Fragrance, Iodopropryl Btylcarbamate, D&C Green #5.

Alcohol Free Foam Sanitizer

Purpose

Antiseptic

Alcohol Free Foam Sanitizer

KEEP OUT OF REACH OF CHILDREN

Alcohol Free Foam Sanitizer

AFFEX Cleaning Solutions

Alcohol Free Foam Sanitizer

Non Alcohol hand Sanitizer

Mediucal Emergency:

(800)424-9300

NET CONTENTS: 1000 mL

ITEM #304-60

Drug Facts		Datos del Producto	
Active Ingredient Benzalkonium Chloride 0.13%	Purpose Antiseptic	Ingrediente Activo Cloruro de benzalconio 0.13%	Propósito Antiséptico
Uses • Use in a variety of public facilities. • Use this product when soap and water are not available.		Usos • Para usar en diversos establecimientos públicos. • Utilice este producto cuando el jabón y el agua no están disponibles.	
Warnings • For external use only. • Children under the age of 6 should be supervised by an adult when using this product. • Discontinue use if irritation or redness develops. • If irritation persists for more than 72 hours, consult a physician. • KEEP OUT OF REACH OF CHILDREN.		Advertencias • Sólo para uso externo. • Los niños menores de 6 años deben ser supervisados por un adulto cuando usen este producto. • Deje de usarlo si se desarrolla una irritación o enrojecimiento. • Si la irritación persiste durante más de 72 horas, consulte a un médico. • MANTENGA ESTE PRODUCTO FUERA DEL ALCANCE DE LOS NIÑOS.	
Directions • Read the entire label before using this product. • Dispense 1 - 2 pumps of product onto dry hands. Rub hands together to distribute product.		Instrucciones • Lea la etiqueta completa antes de usar este producto. • Empuje 1 - 2 veces para el producto en manos secas. Frótese las manos para distribuir el producto.	
Inactive Ingredients Deionized Water, Sodium PCA, PEG/PPG-8/3 Laurate, Dimethicone, DMDM Hydantoin, PEG-3 Cocamide, Fragrance, Iodopropinyl Butylcarbamate, D&C Green #5.		Ingredientes Inactivos Agua desionizada, PCA de sodio, PEG/PPG-8/3 Laurate, Dimeticono, DMDM Hidantoína, PEG-3 Cocamida, Fragancia, Iodopropinil butilcarbamatato, D&C Verde #5.	



AFFEX
CLEANING SOLUTIONS

**ALCOHOL FREE
FOAM SANITIZER**

Non Alcohol Hand Sanitizer
Sanitizador sin alcohol para las manos

Medical Emergency:
(800) 424-9300



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NET CONTENTS: 1000 mL
ITEM #304-60

Distributed By:
AFFLINK, LLC
1400 AFFLINK Place
Tuscaloosa, AL 35406-2289
(888) 395-2206
Made In U.S.A.
www.afflink.com/affex

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ALCOHOL FREE FOAM SANITIZER

benzalkonium chloride soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54057-304
Route of Administration	Topical		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
PEG-6 COCAMIDE (UNII: YZ6NLA4O1E)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54057-304-60	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	11/12/2012	

Labeler - Afflink, Inc. (023121150)**Registrant** - Betco corporation, Ltd. (005050158)**Establishment**

Name	Address	ID/FEI	Business Operations
Betco Corporation, Ltd.		005050158	manufacture(54057-304)

Revised: 12/2012

Afflink, Inc.