

## **ANTIMICROBIAL FOAM- triclosan 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.*

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### **Antimicrobial Foam**

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##### **☐Active Ingredient**

☐☐Triclosan 0.30%

#### **Antimicrobial Foam**

##### **Uses**

- ☐☐Antibacterial hand cleaner.
- Use in a variety of public facilities including daycare centers, hospitals, nursing homes, physicians offices.

#### **Antimicrobial Foam**

##### **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.**

#### **Antimicrobial Foam**

##### **Directions**

- ☐**Read the entire label before using this product.**
- ☐Dispense 0.8 mL of product onto wet palm.
- Rub hands together to distribute product, then rinse hands with clean.

#### **Antimicrobial Foam**

##### **Inactive Ingredients**

☐Water, Potassium cocoate (contains coconut), Propylene Glycol, Glycerine, DMDM Hydantoin, Fragrance, FD&C Yellow #5, Aloe Barbadensis Leaf Juice. FD&C Red #40.

#### **Antimicrobial Foam**

##### **Purpose**

☐Antibacterial

#### **Antimicrobial Foam**

KEEP OUT OF REACH OF CHILDREN

**Antimicrobial Foam**

**AFFEX CLEANING SOLUTIONS**

Antimicrobial Foam Soap

Foaming Skin Cleanser with Triclosan


MEDICAL EMERGENCY:

(800)424-9300

NET CONTENTS: 1000 mL


ITEM #305-60

<p><b>Drug Facts</b></p> <table border="1"> <tr> <td><b>Active Ingredient</b></td> <td><b>Purpose</b></td> </tr> <tr> <td>Triclosan 0.3%</td> <td>Antibacterial</td> </tr> </table> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>Antibacterial hand cleaner.</li> <li>Use in a variety of public facilities including daycare centers, hospitals, nursing homes, physicians offices.</li> </ul> <p><b>Warnings</b></p> <ul style="list-style-type: none"> <li>For external use only.</li> <li>Avoid contact with eyes.</li> <li>Children under the age of 6 should be supervised by an adult when using this product.</li> <li>Discontinue use if irritation or redness develops.</li> <li>If irritation persists for more than 72 hours, consult a physician.</li> <li><b>KEEP OUT OF REACH OF CHILDREN.</b></li> </ul> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>Read the entire label before using this product.</li> <li>Dispense 1 - 2 pumps of product onto wet hands.</li> <li>Rub hands together to distribute product, then rinse hands with clean water.</li> </ul> <p><b>Inactive Ingredients</b></p> <p>Water, Potassium Cocoate (contains coconut), Propylene Glycol, Glycerin, Tetrasodium EDTA, Fragrance, DMDM Hytaintoin, FD&amp;C Yellow #5, Aloe Barbadensis Leaf Juice, FD&amp;C Red #40.</p>		<b>Active Ingredient</b>	<b>Purpose</b>	Triclosan 0.3%	Antibacterial	<p><b>Datos del Producto</b></p> <table border="1"> <tr> <td><b>Ingrediente Activo</b></td> <td><b>Propósito</b></td> </tr> <tr> <td>Triclosan 0.3%</td> <td>Antibacterial</td> </tr> </table> <p><b>Usos</b></p> <ul style="list-style-type: none"> <li>Limpiador de manos antibacterial.</li> <li>Para usar en diversos establecimientos públicos, incluidas guarderías infantiles, hospitales, hogares para ancianos, consultorios médicos.</li> </ul> <p><b>Advertencias</b></p> <ul style="list-style-type: none"> <li>Sólo para uso externo.</li> <li>Evite el contacto con los ojos.</li> <li>Los niños menores de 6 años deben ser supervisados por un adulto cuando usen este producto.</li> <li>Deje de usarlo si se desarrolla una irritación o enrojecimiento.</li> <li>Si la irritación persiste durante más de 72 horas, consulte a un médico.</li> <li><b>MANTENGA ESTE PRODUCTO FUERA DEL ALCANCE DE LOS NIÑOS.</b></li> </ul> <p><b>Instrucciones</b></p> <ul style="list-style-type: none"> <li>Lea la etiqueta completa antes de usar este producto.</li> <li>Empuje 1 - 2 veces para el producto en las manos mojadas.</li> <li>Frótese las manos para distribuir el producto y luego enjuágueselas con agua limpia.</li> </ul> <p><b>Ingredientes Inactivos</b></p> <p>Agua, Cocoate de Potasio (contiene coco), Propileno Glicol, Glicerina, Tetrasodio EDTA, Fragancia, DMDM Hidantoina, FD&amp;C Amarillo #5, Jugo de hojas de Aloe Barbadensis (Aloe vera), FD&amp;C Rojo #40.</p>		<b>Ingrediente Activo</b>	<b>Propósito</b>	Triclosan 0.3%	Antibacterial
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**AFFEX**<sup>®</sup>  
CLEANING SOLUTIONS  
**ANTIMICROBIAL  
FOAM SOAP**  
Foaming Skin Cleanser with Triclosan  
Espuma limpiadora para la piel con Triclosan

**Medical Emergency:**  
**(800) 424-9300**



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**NET CONTENTS: 1000 mL**  
**ITEM #305-60**

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

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**ANTIMICROBIAL FOAM**

tricolan soap

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54057-305
<b>Route of Administration</b>	Topical		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	3.0 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
POTASSIUM COCOATE (UNII: F8U72V8ZXP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE SODIUM (UNII: MP1J8420LU)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALOE VERA Leaf (UNII: ZY81Z83H0X)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54057-305-60	1000 mL in 1 BAG		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	11/12/2012	

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

Name	Address	ID/FEI	Business Operations
Betco Corpo, Ltd.		005050158	manufacture(54057-305) , label(54057-305) , pack(54057-305)

Revised: 12/2012

Afflink, Inc.