

**WINNING HANDS PREMIUM ANTIBACTERIAL- chloroxylenol soap**  
**Betco Corporation, Ltd.**

*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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**Winning Hands Premium Antibacterial**

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**☐Active Ingredient**

☐ Chloroxylenol 0.5%

**Winning Hands Premium Antibacterial**

**Uses**

- ☐☐Antibacterial hand cleaner.
- Use in daycare, hospitals, nursing homes, physicians offices, dental offices and clinics

**Winning Hands Premium Antibacterial**

**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.**

**Winning Hands Premium Antibacterial**

**Directions**

- ☐**Read the entire label before using this product.**
- ☐Dispense 1-2 pumps of product onto wet palm.
- Lather and rinse hands with clean water

**Winning Hands Premium Antibacterial**

**Inactive Ingredients**

☐Water, Sodium Lauryl Sulfate, Coco Diethanolamide, Cocamidopropyl Betaine, Phenoxyethanol, Sodium Laureth Sulfate, Allantoin, DMDM Hydantoin, Fragrance, Aloe Barbadosensis Leaf Juice, Glycerine, FD&C Yellow #5, FD&C Red #40.

**Winning Hands Premium Antibacterial**

**Questions or Comments?Phone: (800) 777-9343**

**MDS information:☐(800) 891-4965**

**Winning Hands Premium Antibacterial**

## Purpose

Antibacterial

## Winning Hands Premium Antibacterial

KEEP OUT OF REACH OF CHILDREN

## Winning Hands Premium Antibacterial

## Winning Hands Premium Antibacterial

## SKIN CLEANSER

Premium Antibacterial Skin Cleanser with Chloroxylenol (PCMX), Aloe and Allantoin

Net Contents: 30.4 fl. oz. (900 mL)

100 mL MORE!\*
100 mL MORE!\*
100 mL MORE!\*
100 mL MORE!\*

SKIN CLEANSER

**WINNING HANDS™  
PREMIUM  
ANTIBACTERIAL**

Premium Antibacterial Skin Cleanser with Chloroxylenol (PCMX), Aloe and Allantoin

Loción limpiadora antibacteriana de calidad superior para la piel con Cloroxileno (PCMX), aloe y alantoína

NET CONTENTS: 30.4 fl. oz. (900 mL)

73619-00

**Drug Facts**

<b>Active Ingredient</b> Chloroxylenol 3%	<b>Purpose</b> Antibacterial
<b>Uses</b> • Antibacterial hand cleanser. • Use in daycare, hospitals, nursing homes, physician offices, dental offices and clinics.	
<b>Warnings</b> • 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 rash develops. • If irritation persists for more than 72 hours, consult a physician. • KEEP OUT OF REACH OF CHILDREN.	
<b>Directions</b> • Read the entire label before using this product. • Dispense 1 - 2 pumps of product onto wet palms. • Rub and wash hands with clean water.	
<b>Inactive Ingredients</b> Water, Cocamid DEA, Sodium Lauryl Sulfate, Sodium Lauryl Sulfate, Phenoxyethanol, Cocamidopropyl Betaine, Citrus, Fragrance, Allantoin, Aloe Substantia, Leaf Juice, FD-C, Thymol, 40, FD-C, Tea Oil.	
<b>Questions or Comments?</b> Phone: (800) 777-8343 MSDS Information: Phone: (800) 891-4965	
<b>Información sobre el producto</b>	
<b>Principio activo</b> Cloroxileno 0.9%	<b>Objetivo</b> Antibacteriano
<b>Usos</b> • Limpador de manos antibacteriano. • Para usar en guarderías, hospitales, hogares para ancianos, consultorios médicos y odontológicos y clínicas.	
<b>Precauciones</b> • Solo para uso externo. • Evite el contacto con los ojos. • Lave las manos de 4 a 6 veces al día después de salir al exterior por un período prolongado. • Si los ojos se irritan o se inflaman, consulte a un médico. • Mantener fuera del alcance de los niños.	
<b>Instrucciones</b> • Lea toda la etiqueta antes de usar este producto. • Empuje la barra del dispensador 1 - 2 veces para el producto en manos mojadas. • Retire las manos para hacer espuma y enjuague con agua limpia.	
<b>Componentes Inactivos</b> Agua, Cocamid DEA, Lauril Sulfato de Sodio, Lauril Sulfato de Sodio, Fenoxietanol, Cocamidopropil Betaina, Citrus, Fragancia, Alantoína, Aloe Substantia, Leaf Juice, FD-C, Thymol, 40, FD-C, Tea Oil.	
<b>¿Preguntas o comentarios?</b> Teléfono: (800) 777-8343 <b>Información de la Hoja de Datos sobre Seguridad del Material (MSDS)</b> Teléfono: (800) 891-4965	

SKIN CLEANSER

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**LOADING INSTRUCTIONS:** 1. Open the dispenser. 2. Tear off the perforated tab on the front of this box. 3. Pull out the nozzle. 4. Check nozzle to properly align with slot near bottom of dispenser. 5. Close dispenser cover and pump to prime. 6. When empty remove box and nozzle from unit and replace.

**INSTRUCCIONES CARGANTES:** 1. Abra el dispensador. 2. Desgarrar la lengüeta perforada del frente de esta caja. 3. Extraiga la boquilla. 4. Oriente la boquilla para que quede alineada correctamente con la ranura próxima al fondo del dispensador. 5. Cierre la tapa del dispensador y bombe para cebarlo. 6. Cuando se vacíe, retire la caja y la boquilla de la unidad y vuelva a colocarla.

NDCS No. 736 1173811

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\*100 mL MORE THAN INDUSTRY STANDARD.

## WINNING HANDS PREMIUM ANTIBACTERIAL

chloroxylenol soap

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:6560 1-736
<b>Route of Administration</b>	Topical		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78 V2Q) (CHLOROXYLENOL - UNII:0F32U78 V2Q)	CHLOROXYLENOL	5.0 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
CO CAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

SODIUM LAURETH SULFATE (UNII: BPV390UAP0)

ALLANTOIN (UNII: 344S277G0Z)

ALOE VERA LEAF (UNII: ZY81Z83H0X)

GLYCERIN (UNII: PDC6A3C0OX)

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)

FD&C RED NO. 40 (UNII: WZB9127XOA)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65601-736-19	900 mL in 1 BAG		
2	NDC:65601-736-10	1100 mL in 1 BAG		
3	NDC:65601-736-04	3780 mL in 1 BOTTLE, PLASTIC		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/12/2012	

**Labeler** - Betco Corporation, Ltd. (005050158)

**Registrant** - Betco corporation, Ltd. (005050158)

### Establishment

Name	Address	ID/FEI	Business Operations
Betco Corpo, Ltd.		005050158	manufacture(65601-736)

Revised: 11/2012

Betco Corporation, Ltd.