

ANTIBACTERIAL SKIN CLEANSER- 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.

Antibacterial Skin Cleanser

Active Ingredient

Chloroxylenol 0.375%

Uses

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

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.**
- If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- ☐☐**Read the entire label before using this product.**
- ☐☐Dispense 2 pumps of product onto palm of hand and scrub thoroughly over all surfaces of both hands.
- Rinse with clean water.

Inactive Ingredients

☐Water, Sodium Laureth 1Sulfate, Cocamidopropyl betadine, Phenoxyethanol, Coco MIPA, Glycol Stearate, DMDM Hydantoin, Propylene Glycol, Sodium Chloride, Fragrance, Glycerin, Ethanol, D&C Green #5, FD&C Yellow #5.

Purpose

Antibacterial

Winning Hands Antibacterial

KEEP OUT OF REACH OF CHILDREN

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Drug Facts

Active Ingredient
Chloroxylenol 0.375%

Purpose
Antibacterial

Uses

- Antibacterial hand cleanser
- Use in hospitals, hospitals, nursing homes, physician offices, dental offices and clinics.

Warnings

- For external use only.
- Avoid contact with eyes.
- If contact occurs, rinse thoroughly with water.
- Discontinue use if irritation or redness develops.
- Apply only products for more than 72 hours, consult a physician.
- KEEP OUT OF REACH OF CHILDREN.**
- If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Read the entire label before using this product.
- Dispense 2 pumps of product onto palm of hand and scrub thoroughly over all surfaces of both hands.
- Rinse with clean water.

Inactive Ingredients
Water, Sodium Lauryl Sulfate, Cocamidopropyl Betaine, Coco MIPA, Phenoxethylalcohol, Ethanol, Sodium Lauryl Sulfate, Glycol Distearate, Sodium Chloride, Glycerin, Propylene Glycol, Lantamide MPA, Fragrance, Disodium Cocoyl Sulfosuccinate, Sodium Hydroxide, Magnesium Nitrate, Disodium Alkyl Sulfosuccinate, Magnesium Chloride, D&C Green #5, FD&C Yellow #5, Methylchlorzoxinone.

Datos del Producto

Ingrediente Activo
Chloroxylenol 0.375%

Propósito
Antibacterial

Usos

- Limpador de manos antibacterial.
- Para usar en hospitales, hospitales, hogares para ancianos, consultorios médicos y odontológicos y clínicas.

Advertencias

- Solo para uso externo.
- Evite el contacto con los ojos.
- En caso de contacto, enjuague los ojos con agua.
- Deje de usarlo si no desarrolla una irritación o enrojecimiento.
- Si la irritación persiste durante más de 72 horas, consulte a un médico.
- MANTENER FUERA DEL ALCANCE DE LOS NIÑOS.**
- En caso de ingestión, obtenga asistencia médica o diríjase a un Centro de toxicología de inmediato.

Instrucciones

- Lea toda la etiqueta antes de usar este producto.
- Aplique 2 dosis del producto en la palma de la mano y límpielo bien en todas las superficies de ambas manos.
- Enjuague con agua limpia.

SDS No. 149



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**Antibacterial
Skin Cleanser**

Pearlized Antibacterial
Limpador perlizado

**SKIN
CLEANSER
141**

1 gal. (3.78 L)

Betco Master - 08/2017





Antibacterial Lotion Skin Cleanser

Pearlized Antibacterial Skin Cleanser with Chloroxylenol (P)
Limpiador perlizado antibacteriano para la piel con Cloro

**SKIN
CLEANSER**
141

2 L (67.6 fl. oz.) 2.11 qt.

Drug Facts

Active Ingredient

Chloroxylenol 0.375%

Purpose

Antibacterial

Uses

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

Warnings

- For external use only.
- Avoid contact with eyes.
- If contact occurs, rinse thoroughly with water.
- Discontinue use if irritation or redness develops.
- If irritation persists for more than 72 hours, consult a physician.
- **KEEP OUT OF REACH OF CHILDREN.**
- If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Read the entire label before using this product.
- Dispense 2 pumps of product onto palm of hand and scrub thoroughly over all surfaces of both hands.
- Rinse with clean water.

Inactive Ingredients

Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Coco NIPA, Phenoxyethanol, Ethanol, Sodium Lauryl Sulfate, Glycol Distearate, Sodium Chloride, Glycerin, Propylene Glycol, Lauramide MIPA, Fragrance, Disodium Cocamidoisopropyl Sulfosuccinate, Sodium Hydroxide, Magnesium Nitrate, Ethoxylated Alcohols, Methylchloroisothiazolinone, Magnesium Chloride, D&C Green #5, FD&C Yellow #5, Methylisothiazolinone.

SDS No. 141



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RLB8962

Datos del Producto

Ingrediente Activo

Cloroxileno 0.375%

Usos

- Limpiador de manos antibacteriano. • Para hospitales, hogares para ancianos, consulto odontológicos y clínicas.

Advertencias

- **Sólo para uso externo.**
- Evite el contacto con los ojos.
- En caso de contacto, enjuáguese los ojos con agua limpia.
- Deje de usarlo si se desarrolla una irritación.
- Si la irritación persiste durante más de 72 horas, consulte a un médico.
- **MANTENER FUERA DEL ALCANCE DE LOS NIÑOS.**
- En caso de ingestión, obtenga asistencia médica en el Centro de toxicología de inmediato.

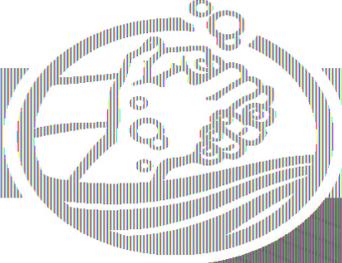
Instrucciones

- Lea toda la etiqueta antes de usar este producto.
- Aplique 2 dosis del producto en la palma de la mano de cada mano.
- Enjuague con agua limpia.

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Betco Master - 08/20



Antibacterial Lotion Skin Cleanser

Pearlized Antibacterial Skin Cleanser with Chloroxylenol
Limpiador perlizado antibacteriano para la piel con C

**SKIN
CLEANSER
141**

55 gal. (208 L)

Drug Facts

Active Ingredient	Purpose
Chloroxylenol 0.375%	Antibacterial

Uses

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

Warnings

- For external use only.
- Avoid contact with eyes.
- If contact occurs, rinse thoroughly with water.
- Discontinue use if irritation or redness develops.
- If irritation persists for more than 72 hours, consult a physician.
- **KEEP OUT OF REACH OF CHILDREN.**
- If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Read the entire label before using this product.
- Dispense 2 pumps of product onto palm of hand and scrub thoroughly over all surfaces of both hands.
- Rinse with clean water.

Inactive Ingredients
Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Coco MIPA, Phenoxyethanol, Ethanol, Sodium Lauryl Sulfate, Glycol Distearate, Sodium Chloride, Glycerin, Propylene Glycol, Lauramide MIPA, Fragrance, Disodium Cocamidoisopropyl Sulfosuccinate, Sodium Hydroxide, Magnesium Nitrate, Ethoxylated Alcohols, Methylchloroisoithiazolinone, Magnesium Chloride, D&C Green #5, FD&C Yellow #5, Methylisothiazolinone.

Datos del Producto

Ingrediente Activo
Cloroxileno 0.375%

Usos

- Limpiador de manos antibacterial.
- Para usar en guarderías, hospitales, hogares y odontológicos y clínicas.

Advertencias

- Sólo para uso externo.
- Evite el contacto con los ojos.
- En caso de contacto, enjuáguese los ojos co
- Deje de usarlo si se desarrolla una irritación
- Si la irritación persiste durante más de 72 h
- **MANTENER FUERA DEL ALCANCE DE LOS**
- En caso de ingestión, obtenga asistencia mé toxicología de inmediato.

Instrucciones

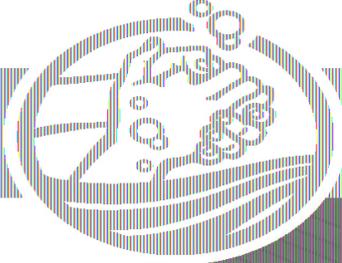
- Lea toda la etiqueta antes de usar este
- Aplique 2 dosis del producto en la palma de superficies de ambas manos.
- Enjuague con agua limpia.

SDS No. 141



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Antibacterial Lotion Skin Cleanser

Pearlized Antibacterial Skin Cleanser with Chloroxylenol
Limpiador perlizado antibacteriano para la piel con C

**SKIN
CLEANSER
141**

55 gal. (208 L)

Drug Facts

Active Ingredient	Purpose
Chloroxylenol 0.375%	Antibacterial

- Uses**
- Antibacterial hand cleaner.
 - Use in daycare, hospitals, nursing homes, physician offices, dental offices and clinics.

- Warnings**
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 - If contact occurs, rinse thoroughly with water.
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 - **KEEP OUT OF REACH OF CHILDREN.**
 - If swallowed, get medical help or contact a Poison Control Center right away.

- Directions**
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 - Rinse with clean water.

Inactive Ingredients
 Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Coco MIPA, Phenoxyethanol, Ethanol, Sodium Lauryl Sulfate, Glycol Distearate, Sodium Chloride, Glycerin, Propylene Glycol, Lauramide MIPA, Fragrance, Disodium Cocamidoisopropyl Sulfosuccinate, Sodium Hydroxide, Magnesium Nitrate, Ethoxylated Alcohols, Methylchloroisothiazolinone, Magnesium Chloride, D&C Green #5, FD&C Yellow #5, Methylisothiazolinone.

Datos del Producto

Ingrediente Activo
Cloroxileno 0.375%

- Usos**
- Limpiador de manos antibacterial.
 - Para usar en guarderías, hospitales, hogares y odontológicos y clínicas.

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 - Si la irritación persiste durante más de 72 h
 - **MANTENER FUERA DEL ALCANCE DE LOS**
 - En caso de ingestión, obtenga asistencia mé toxicología de inmediato.

- Instrucciones**
- Lea toda la etiqueta antes de usar este
 - Aplique 2 dosis del producto en la palma de superficies de ambas manos.
 - Enjuague con agua limpia.

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ANTIBACTERIAL SKIN CLEANSER

chloroxylenol soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65601-708
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	3.75 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCO MONOISOPROPANOLAMIDE (UNII: 21X4Y0VTB1)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALCOHOL (UNII: 3K9958V90M)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65601-708-04	3780 mL in 1 JUG; Type 0: Not a Combination Product	02/01/2016	
2	NDC:65601-708-19	900 mL in 1 BAG; Type 0: Not a Combination Product	02/01/2016	
3	NDC:65601-708-41	2000 mL in 1 BAG; Type 0: Not a Combination Product	02/01/2016	
4	NDC:65601-708-55	207900 mL in 1 DRUM; Type 0: Not a Combination Product	02/01/2016	
5	NDC:65601-708-10	1100 mL in 1 BAG; Type 0: Not a Combination Product	02/01/2016	
6	NDC:65601-708-29	1000 mL in 1 BAG; Type 0: Not a Combination Product	11/12/2012	

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. (024492831)

Registrant - Betco corporation, Ltd. (024492831)

Establishment

Name	Address	ID/FEI	Business Operations
Betco Corporation, Ltd.		024492831	manufacture(65601-708) , pack(65601-708) , label(65601-708)

Revised: 3/2019

Betco Corporation, Ltd.