

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 Sulfate, 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

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Warnings

- For external use only. • Avoid contact with eyes.
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- **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.
- Place enough product on your palm to thoroughly cover your hands.
- Rinse with clean water.

Inactive Ingredients

Water, Cocamidopropyl Betaine, Sodium Lauryl Ether Sulfate, Ethylene Glycol Phenyl Ether, Cocamide MIPA, Ethanol, Glycerin, Propylene Glycol, Glycol Distearate, Fragrance, Sodium Chloride, Methylchlorisothiazolinone, Lauramide MIPA, Sodium Hydroxide, Disodium Cocamide MIPA-Sulfosuccinate, Methylisothiazolinone, D&C Green #5, FD&C Yellow #5.

Questions? 888-GO BETCO (888-462-3826)

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Datos del Producto

Ingrediente Activo

Cloroxilenol 0.375%

Usos

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

Advertencias

- Sólo para uso externo.
- Evite el contacto con los ojos.
- En caso de contacto con los ojos, enjuáguese con agua.
- 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 ALCAHOCE.**
- En caso de ingestión, obtenga asistencia médica o llame al Centro de Control de Venenos inmediatamente.

Instrucciones

- Lea la etiqueta completa antes de usar.
- Poner suficiente cantidad del producto en la palma de la mano.
- Enjuague con agua limpia.

Clarifo.

Antibacterial Lotion Skin Cleanser

Pearlescent Antibacterial Skin Cleanser
with Chloroxylenol (PCMX) with emollients
Limpiador anacarado antibacteriano para la piel
con Cloroxilenol (PCMX) con emoliente



RB10141

Drug Facts Active Ingredient Chloroxylenol 0.375% Purpose Antibacterial Uses • Antibacterial hand cleanser. • Use in daycares, 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. • Place enough product on your palm to thoroughly cover your hands. • Rub with clean water. Inactive Ingredients Water, Cocamidopropyl Betaine, Sodium Lauryl Ether Sulfate, Ethylene Glycol Phenyl Ether, Cocamide MP14, Ethanol, Glycerin, Propylene Glycol, Glycol Distearate, Fragrance, Sodium Chloride, Methylchloroisothiazolinone, Laureamide MIPA, Sodium Hydroxide, Disodium Cocamide MP14-Sulfosuccinate, Methylisothiazolinone, DSC Green #5, FD&C Yellow #5.	Datos del Producto Ingrediente Activo Cloroxileno 0.375% Propósito Antibactericida Usos • Limpiador de manos antibactericida. • Para usar en guarderías, 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, enjuáguese los ojos con agua. • Deje de usarlo si se 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. • Poner suficiente cantidad del producto en la palma de la mano para cubrir las manos completamente. • Enjuague con agua limpia. ©2020 Betco Corporation 400 Van Camp Road Bowling Green, Ohio 43402 Made in U.S.A. All Rights Reserved. Betco.com
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Questions? 888-GO BETCO (888-462-3826)

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SKIN CLEANSER 141

16.9 fl. oz. (1.16 qt.)

Drug Facts Active Ingredient Chloroxylenol 0.375% Purpose Antibacterial Uses • Antibacterial hand cleanser. • Use in daycares, 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. • Place enough product on your palm to thoroughly cover your hands. • Rub with clean water. Inactive Ingredients Water, Cocamidopropyl Betaine, Sodium Lauryl Ether Sulfate, Ethylene Glycol Phenyl Ether, Cocamide MP14, Ethanol, Glycerin, Propylene Glycol, Glycol Distearate, Fragrance, Sodium Chloride, Methylchloroisothiazolinone, Laureamide MIPA, Sodium Hydroxide, Disodium Cocamide MP14-Sulfosuccinate, Methylisothiazolinone, DSC Green #5, FD&C Yellow #5.	Datos del Producto Ingrediente Activo Cloroxileno 0.375% Propósito Antibactericida Usos • Limpiador de manos antibactericida. • Para usar en guarderías, 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, enjuéguese los ojos con agua. • Deje de usarlo si se 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. • Poner suficiente cantidad del producto en la palma de la mano para cubrir las manos completamente. • Enjuague con agua limpia.
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Questions? 888-GO BETCO (888-462-3826)

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SKIN CLEANSER 141

1 gal. (3.78 L)



Antibacterial Lotion Skin Cleanser

Pearlized Antibacterial Skin Cleanser with Chloroxylonol (PCMX) with emollients
Limpiador perlizado antibacteriano para la piel con Cloroxilenol (PCMX) con emoliente

**SKIN
CLEANSER
141**

55 gal. (208 L)

Drug Facts

Active Ingredient	Purpose
Chloroxylonol 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.**
- Place enough product on your palm to thoroughly cover your hands.
- Rinse with clean water.

Inactive Ingredients

Water, Cocamidopropyl Betaine, Sodium Lauryl Ether Sulfate, Ethylene Glycol Phenyl Ether, Cocamide MIPA, Ethanol, Glycerin, Propylene Glycol, Glycol Distearate, Fragrance, Sodium Chloride, Methylchloroisothiazolinone, Lauramide MIPA, Sodium Hydroxide, Disodium Cocamido MIPA-Sulfosuccinate, Methylisothiazolinone, D&C Green #5, FD&C Yellow #5.

Questions? 888-GO BETCO (888-462-3826)

Datos del Producto

Ingrediente Activo	Propósito
Cloroxilenol 0.375%	Antibacterial

Usos

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

Advertencias

- **Sólo para uso externo.**
- Evite el contacto con los ojos.
- En caso de contacto, enjuáguese los ojos con agua.
- Deje de usarlo si se 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.**
- Poner suficiente cantidad del producto en la palma de la mano para cubrir las manos completamente.
- Enjuague con agua limpia.

SDS No. 141



RLB8963V1

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0614120

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
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ALCOHOL (UNII: 3K9958V90M)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
MAGNESIUM NITRATE (UNII: 77CBG3UN78)	
DIMETHYL BENZYL CARBINYL BUTYRATE (UNII: 3Q0C60547R)	
ETHYL BUTYRATE (UNII: UFD2LZ005D)	
SODIUM FERROCYANIDE (UNII: 5HT6X21AID)	
ETHYL ACETOACETATE (UNII: IZP61H3TB1)	
LAURIC ISOPROPANOLAMIDE (UNII: 82DUX3RRVU)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
.GAMMA.-DECALACTONE (UNII: 7HLS05KP9O)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
ETHYL METHYLPHENYLGLYCIDATE (UNII: UD51D5KR4A)	
CHLOROACETIC ACID (UNII: 5GD84Y125G)	
IONONE (UNII: QP734LIN1K)	
BENZYL BENZOATE (UNII: N863NB338G)	
MYRCENE (UNII: 3M39CZS25B)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
METHYL ANTHRANILATE (UNII: 981I0C1E5W)	
DIMETHYL BENZYL CARBINYL ACETATE (UNII: 6Y9488RL8H)	
CALCIUM SILICATE (UNII: S4255P4G5M)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYL ALCOHOL (UNII: Y4S76JWI15)	
ETHYLENE OXIDE (UNII: JJH7GNN18P)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
DIOXANE (UNII: J8A3S10O7S)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
SODIUM ALUMINIUM SILICATE (UNII: 058TS43PSM)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	

PHENOXYETHANOL (UNII: HIE492ZZ3T)				
COCO MONOISOPROPANOLAMIDE (UNII: 21X4Y0VTB1)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
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	07/15/2020
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	
7	NDC:65601-708-88	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/11/2020	
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: 9/2020

Betco Corporation, Ltd.