

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.

Medicated Lotion Skin Cleanser

Medicated Lotion Skin Cleanser

☐Active Ingredient

☐☐Chloroxylenol 0.5%

Knuckle Under Medicated

Uses

- ☐☐For use in a variety of industrial setting including manufacturing, machine shops, maintenance areas and automotive shops.

Knuckle Under Medicated

Warnings

- **For external use only.**
- Avoid contact with eyes.
- If contact occurs, rinse thoroughly with water.
- Discontinue use is 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.

Knuckle Under Medicated

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.

Knuckle Under Medicated

Inactive Ingredients

☐Water, sodium tallate, Sodium Laureth Sulfate, Triisopropanolamine, Alcohol, Tetrasodium EDTA, Sodium Chloride, Coco MIPA, Fragrance, Cocamidopropyl Betaine, Glycerin, Methyl Chlorosiothiazolinone, D&C Green #5, FD&C Yellow #5.

Knuckle Under Medicated

Purpose

Antibacterial

Knuckle Under Medicated

KEEP OUT OF REACH OF CHILDREN

Medicated Lotion Skin Cleanser



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Medicated Lotion Skin Cleanser

Antibacterial Hand Cleaner for Industrial Applications
Limpia manos antibacteriano para aplicaciones industriales

**HAND
CLEANER
765**

55 gal. (208 L)

Drug Facts		Datos del Producto	
Active Ingredient	Purpose	Ingrediente Activo	Propósito
Chloroxylenol 0.5%	Antibacterial	Cloroxileno 0.5%	Antibacterias
Uses • For use in a variety of industrial settings including manufacturing, machine shops, maintenance areas and automotive shops.		Usos • Para usar en una variedad de ambientes industriales, incluidas fábricas, talleres mecánicos, áreas de mantenimiento y talleres de automóviles.	
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.		Advertencias • Para uso externo únicamente. • 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.	
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.		Instrucciones • Lea toda la etiqueta antes de usar este producto. • Aplique 2 dosis del producto en la palma de la mano y fréguelo bien en todas las superficies de ambas manos. • Enjuague con agua limpia.	
Inactive Ingredients Water, Sodium Tallowate, Sodium Laureth Sulfate, Trisopropylamine, Ethanol, Tetrasodium EDTA, Sodium Chloride, Coco MIPA, Fragrance, Cocamidopropyl Betaine, Glycerin, Methyl Chloroisothiazolinone, Methyl Isothiazolinone, D&C Green #5, FD&C Yellow #5.		Ingredientes Inactivos Agua, Lauril Eter Sulfato De Sodio, Tallato Sódico, Etanol, Tetrasodio Edta, Hidruóxido De Sodio, Coco, N - (2-hidroxi)propil, Fragancia, Disopropilammina, Etanol, Cocamidopropil Betaina, Alcoholes Etoxilados, Cloruro De Sodio, Sodio Hidroxicelato, Trisodio Nitroisocelato, D&C Verde #5, FD&C Amarillo #5.	

SDS No. 765



RE8611

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SKIN CLEANSER

chloroxylenol soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65601-865
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM ALUMINIUM SILICATE (UNII: 058TS43PSM)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TRISODIUM NITRILOTRIACETATE (UNII: E3C8R2M0XD)	
METHYL ALCOHOL (UNII: Y4S76JWH15)	
WATER (UNII: 059QF0K00R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
EDETATE SODIUM (UNII: MP1J8420LU)	
TALL OIL ACID (UNII: H9HR63474M)	
ALCOHOL (UNII: 3K9958V90M)	
COCO MONOISOPROPANOLAMIDE (UNII: 21X4Y0VTB1)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
DIISOPROPANOLAMINE (UNII: 0W44HYL8T5)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
CALCIUM SILICATE (UNII: S4255P4G5M)	
FORMALDEHYDE (UNII: 1HG84L3525)	
DIOXANE (UNII: J8A3S10O7S)	
SODIUM FERROCYANIDE (UNII: 5HT6X21AID)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
SODIUM GLYCOLATE (UNII: B75E535IMJ)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65601-865-04	3780 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/2016	
2	NDC:65601-865-06	3780 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/12/2012	
3	NDC:65601-865-55	208000 mL in 1 DRUM; 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(65601-865) , label(65601-865) , pack(65601-865)

Revised: 7/2020

Betco Corporation, Ltd.