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

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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, Cocamidopropropyl 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

Master Label - 08/2017

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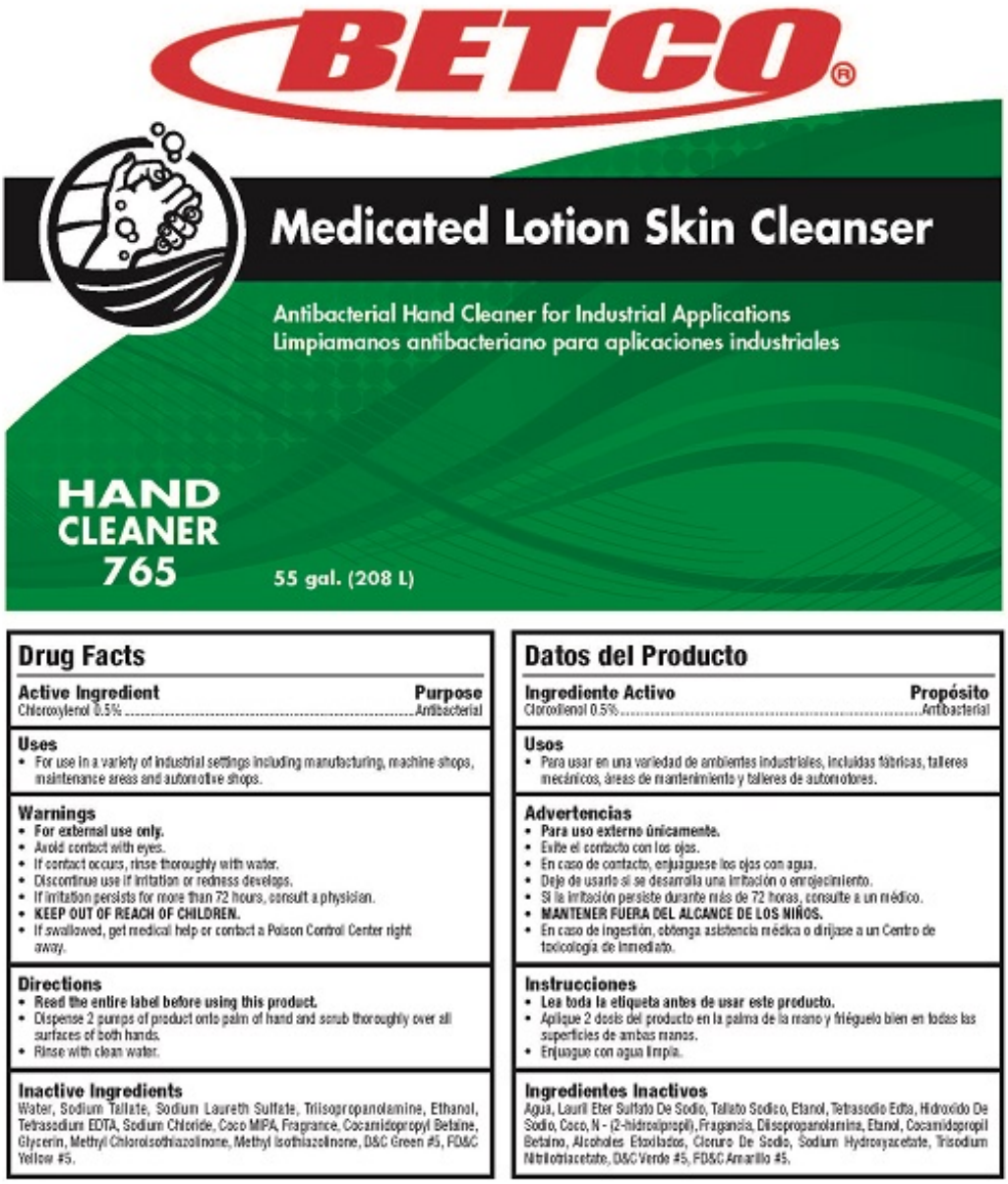

SKIN CLEANSER

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: Y4S76JWI15)	
WATER (UNII: 059QF0KO0R)	
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: B75E535IMI)	
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.