

SUPREME- chloroxylenol soap
Brookmeade Hardware & Supply Co.

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.

Supreme

Supreme

☐Active Ingredient

Chloroxylenol 0.375%

Supreme

Uses

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

Supreme

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.**

Supreme

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

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Inactive Ingredients

☐Water, Sodium Lauryl Sulfate, Cocamide DEA, Cocamidopropyl betadine, Phenoxyethanol, Sodium Laureth Sulfate, Propylene Glycol, Fragrance, DMDM Hydantoin, Glycol Stearate, Lauramide DEA, Glycerine, Tocopheryl Acetate, D&C Green #5, FD&C Yellow #5.

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Purpose

Antibacterial

Supreme

KEEP OUT OF REACH OF CHILDREN

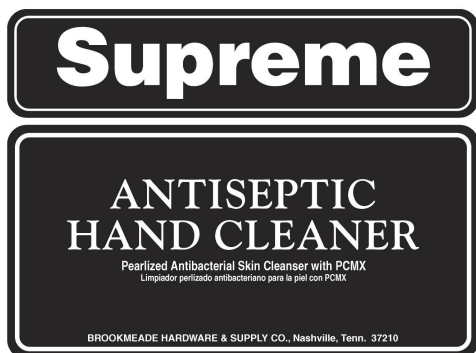
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Supreme

Antiseptic Hand Cleaner

Pearlized Antibacterial Skin Cleanser with PCMX

BROOKMEADE HARDWARE & SUPPLY CO., Nashville, Tenn. 37210



Drug Facts	
Active Ingredient Chloroxylenol 0.375%	Purpose Antibacterial
Uses	
<ul style="list-style-type: none"> Antibacterial hand cleaner. Use in daycares, hospitals, nursing homes, physician offices, dental offices and clinics. 	
Warnings	
<ul style="list-style-type: none"> 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. 	
Directions	
<ul style="list-style-type: none"> Read the entire label before using this product. Dispense 2 - 4 mL of product onto wet palms. Lather and rinse hands with clean water. 	
Inactive Ingredients	
Water, Sodium Lauryl Sulfate, Cocamide DEA, Cocamidopropyl Betaine, Phenoxyethanol, Sodium Laureth Sulfate, Propylene Glycol, Fragrance, DMDM Hydantoin, Glycol Stearate, Laureamide, DEA, Glycerin, D&C Green #5, FD&C Yellow #5.	

Información sobre el producto	
Principio activo Cloroxileno 0.375%	Objetivo Antibacteriano
Usos	
<ul style="list-style-type: none"> Limpiador de manos antibacteriano. Para usar en guarderías, hospitales, hogares para ancianos, consultorios médicos y odontológicos y clínicas. 	
Precauciones	
<ul style="list-style-type: none"> Solo para uso externo. Evite el contacto con los ojos. Los niños menores de 6 años deben ser supervisados por un adulto cuando usen este producto. 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. 	
Instrucciones	
<ul style="list-style-type: none"> Lea toda la etiqueta antes de usar este producto. Aplique 2 a 4 mL del producto en las palmas de las manos mojadas. Frotase las manos para hacer espuma y enjuáguelas con agua limpia. 	
Componentes	Inactivos
Aguá, Lauril Sulfato de Sodio, Cocamida DEA, Cocamidopropil Betaina, Fenoxietanol, Eter de Lauril Sulfato de Sodio, Propileno Glicol, Fragancia, DMDM Hidantoina, Glicol Estearato, Lauramida, DEA, Glicerina, D&C Verde #5, FD&C Amarillo #5.	

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BROOKMEADE HARDWARE & SUPPLY CO.
 1910A Airland Drive • Nashville, Tenn. 37210
 (800) 251-1142
 MAINTENANCE & JANITORIAL SUPPLIES

NET CONTENTS: 1 Gallon (3.78 L)

1114106

SUPREME

chloroxylenol soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68304-141
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 LAURYL SULFATE (UNII: 368GB5141J)	
CO CO DIETHANOLAMIDE (UNII: 92005F972D)	
CO CAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
PHENOXYETHANOL (UNII: H1E492ZZ3T)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
LAURIC DIETHANOLAMIDE (UNII: I29I2VHG38)	
GLYCERIN (UNII: PDC6A3C0OX)	
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:68304-141-04	3780 mL in 1 JUG		

Marketing Information

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

Labeler - Brookmeade Hardware & Supply Co. (034842716)

Registrant - Betco corporation, Ltd. (005050158)

Establishment

Name	Address	ID/FEI	Business Operations
Betco Corpo, Ltd.		005050158	manufacture(68304-141) , pack(68304-141) , label(68304-141)

Revised: 2/2013

Brookmeade Hardware & Supply Co.