

MEDI-HANDS- chloroxylenol soap
Topmost Chemical & Paper Corporation

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.

Medi-Hands

Medi-Hands

☐Active Ingredient

Chloroxylenol 0.375%

Medi-Hands

Uses

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

Medi-Hands

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.**

Medi-Hands

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

Medi-Hands

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.

Medi-Hands

Purpose

Antibacterial

Medi-Hands

Medi-Hands

KEEP OUT OF REACH OF CHILDREN

Medi-Hands

Pearlized Antibacterial Skin Cleanser with PCMX

Distributed by:

TOPMOST CHEMICAL & PAPER CORP.

3394 Winchester Rd. Memphis, TN 38118

(901) 363-7278

14104-00_Topmost_MediHands

Drug Facts	
Active Ingredient Chloroxylenol 0.375%	Purpose Antibacterial
Uses <ul style="list-style-type: none">Antibacterial hand cleanser.Use in daycare, hospitals, nursing homes, physician offices, dental offices and clinics.	
Warnings <ul style="list-style-type: none">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 <ul style="list-style-type: none">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 MPA, Phenoxylethanol, Ethanol, Sodium Lauryl Sulfate, Glycol Distearate, Sodium Chloride, Glycerin, Propylene Glycol, Lauramide MIPA, Fragrance, Disodium Cocamidoisopropyl Sulfosuccinate, Sodium Hydroxide, Magnesium Nitrate, Etharylated Alcohol, Methylchloroisothiazolinone, Magnesium Chloride, D&C Green #5, FD&C Yellow #5, Methylisothiazolinone.	

Datos del Producto	
Ingrediente Activo Cloroxileno 0.375%	Propósito Antibacterial
Usos <ul style="list-style-type: none">Limpiador de manos antibacterial.Para usar en guarderías, hospitales, hogares para ancianos, consultorios médicos y odontológicos y clínicas.	
Precauciones <ul style="list-style-type: none">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 <ul style="list-style-type: none">Lea toda la etiqueta antes de usar este producto.Aplique 2 dosis del producto en la palma de la mano y frótese bien en todas las superficies de ambas manos.Enjuague con agua limpia.	



Made in U.S.A.
SDS No. 141 TM
R.88815



DISTRIBUTED BY:
TOPMOST CHEMICAL & PAPER CORP.
3394 Winchester Rd. • Memphis, TN 38118
(901) 363-7278 • www.topmostchemical.com

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MEDI-HANDS

chloroxylenol soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68978-141
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)	

COCO DIETHANOLAMIDE (UNII: 92005F972D)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
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:68978-141-04	3780 mL in 1 JUG; Type 0: Not a Combination Product	05/03/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/06/2014	

Labeler - Topmost Chemical & Paper Corporation (086944576)

Registrant - Betco corporation, Ltd. (005050158)

Establishment

Name	Address	ID/FEI	Business Operations
Betco Corpo, Ltd.		005050158	manufacture(68978-141) , pack(68978-141) , label(68978-141)

Revised: 5/2019

Topmost Chemical & Paper Corporation