

DERMAFOAM PREMIUM ANTIBACTERIAL- benzalkonium chloride soap

Superior Chemical

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.

DermaFoam Premium Antibacterial

DermaFoam Premium Antibacterial Active Ingredients

☐Active Ingredient

☐ Benzalkonium Chloride 0.13%

DermaFoam Premium Antibacterial Indications

Uses

- ☐☐Antibacterial skin cleanser.
- Use in a variety of public facilities including daycare centers, hospitals, nursing homes, physicians offices.

DermaFoam Premium Antibacterial Warnings

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.

DermaFoam Premium Antibacterial Dosage

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.

DermaFoam Premium Antibacterial Inactive Ingredients

Inactive Ingredients

☐Water, Potassium Cocoate, Propylene Glycol, Glycerin, Tetrasodium EDTA, Fragrance, Bronopol, Sodium Citrate, Magnesium Nitrate, Sodium Hydroxyacetate, Ethanol, Aloe Barbadensis Leaf Juice, Trisodium Nitritoacetate, FD&C Yellow #5, Sodium Hydroxide, Methylchloroisothiazolinone,

Magnesium Chloride, Methylisothiazolinone, FD&C Red #40.

DermaFoam Premium Antibacterial Purpose

Purpose

Antibacterial

DermaFoam Premium Antibacterial Keep our of Reach of Children

KEEP OUT OF REACH OF CHILDREN

DermaFoam Premium Antibacterial

Drug Facts	Drug Facts (continued)
Active Ingredient Benzalkonium Chloride 0.13%	Purpose Antibacterial
Uses <ul style="list-style-type: none">• Antibacterial skin cleanser.• Use in a variety of public facilities including daycare centers, hospitals, nursing homes, physicians offices.	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.
Warnings <ul style="list-style-type: none">• For external use only. • Avoid contact with eyes.• 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.	Inactive Ingredients Water, Potassium Cocoate, Propylene Glycol, Glycerin, Tetrasodium EDTA, Fragrance, Bronopol, Sodium Citrate, Magnesium Nitrate, Sodium Hydroxyacetate, Ethanol, Aloe Barbadensis Leaf Juice, Trisodium Nitriloacetate, FD&C Yellow #5, Sodium Hydroxide, Methylchlorisothiazolinone, Magnesium Chloride, Methylisothiazolinone, FD&C Red #40.
	Questions/Comments: 800-242-7694



NORTH WOODS®
4415 S. Taylor Drive • Sheboygan, WI 53081
800-242-7694 • www.northwoodstm.com

NET CONTENTS:
1 L (33.8 fl. oz.) 1.05 qt.

Made in USA 04/17 7637

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DERMAFOAM PREMIUM ANTIBACTERIAL			
benzalkonium chloride soap			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53125-709
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
WATER (UNII: 059QF0KO0R)	
COCAMIDOPROPYLAMINE OXIDE (UNII: M4SL82J7HK)	
N-ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE (C12-C18) (UNII: 9U1Q4T4ZYS)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
MAGNESIUM NITRATE (UNII: 77CBG3UN78)	
ALCOHOL (UNII: 3K9958V90M)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GERANIOL (UNII: L837108USY)	
2-TERT-BUTYLCYCLOHEXYLOXYBUTANOL (UNII: 1DR20642YH)	
ALLYL HEPTANOATE (UNII: AU4CYG9V68)	
CITRAL (UNII: T7EU0O9VPP)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
2-TERT-BUTYLCYCLOHEXYL ACETATE (UNII: 364FV60913)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
DIHYDROMYRCENOL (UNII: 46L1B02ND9)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53125-709-29	1000 mL in 1 BAG; Type 0: Not a Combination Product	07/19/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/19/2017	

Labeler - Superior Chemical (023335086)**Registrant** - Betco Corporation, Ltd. (024492831)

Establishment

Name	Address	ID/FEI	Business Operations
Betco Corporation, Ltd.		024492831	manufacture(53125-709) , label(53125-709)

Revised: 7/2020

Superior Chemical