

**ULTRA BLUE ANTIBACTERIAL FOAMING SKIN CLEANSER- benzalkonium chloride 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.

UltraBlue™ Antibacterial Foaming Skin Cleanser

Active Ingredient

Benzalkonium Chloride 0.13%

Purpose

Antibacterial

Warnings

- **For external use only. Do not ingest.**
- Avoid contact with eyes. If contact occurs, rinse thoroughly with water.
- Stop use and ask a doctor if irritation and redness develop.
- 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

- **?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, Phenoxyethanol, Cocamine Oxide, Propylene Glycol, Decyl Glucoside, PEG-4 Rapeseedamide, Cocamidopropyl Hydroxysultaine, Glycerin, Fragrance, Sodium Chloride, Tetrasodium EDTA, Citric Acid, Ethanol, Iodopropynyl Butylcarbamate, Benzyl Acetate, Sodium Glycolate, Sodium Hydroxide, Trisodium Nitrilotriacetate, Diethyl Phthalate, FD&C Blue #1.

Questions? 888-GO BETCO (888-462-3826)

Clario Ultra Blue Antibacterial Foaming Skin Cleanser

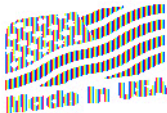
Purpose


Antibacterial

Clario Ultra Blue Antibacterial Foaming Skin Cleanser

KEEP OUT OF REACH OF CHILDREN

Clario Ultra Blue Antibacterial Foaming Skin Cleanser

<p>Drug Facts</p> <p>Active Ingredient Benzalkonium Chloride 0.13%</p> <p>Purpose Antibacterial</p> <p>Uses • Antibacterial hand cleaner. • Use in daycare centers, hospitals, nursing homes, physician offices, dental offices and clinics.</p> <p>Warnings • For external use only. Do not ingest. • Avoid contact with eyes. If contact occurs, rinse thoroughly with water. • Stop use and ask a doctor if irritation and redness develop. • 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.</p> <p>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.</p> <p>Inactive Ingredients Water, Phenoxyethanol, Cocamine Oxide, Propylene Glycol, Decyl Glucoside, PEG-4 Rapeseedamide, Cocamidopropyl Hydroxysultaine, Glycerin, Fragrance, Sodium Chloride, Tetrasodium EDTA, Citric Acid, Ethanol, Iodopropinyl Butylcarbamate, Benzyl Acetate, Sodium Glycolate, Sodium Hydroxide, Trisodium Nitrotriacetate, Diethyl Phthalate, FD&C Blue #1.</p> <p>Questions? 888-GO BETCO (888-462-3826) ©2018 Betco Corporation 400 Van Camp Road Bowling Green, Ohio 43402 Made in U.S.A. All Rights Reserved. Betco.com</p> 	<p>Datos del Producto</p> <p>Ingrediente Activo Cloruro de benzalconio 0.13%</p> <p>Usos • Limpiador de manos antibacterial. • Para uso en hogares para ancianos, consultorios médico</p> <p>Advertencias • Sólo para uso externo. No ingiera este j • Evite el contacto con los ojos. En caso de co • Deje de usarlo y consulte a un médico si la i desarrollan. • Si la irritación persiste durante más de 72 h • MANTENGA ESTE PRODUCTO FUERA DEL • En caso de ingestión, obtenga asistencia mé toxicología de inmediato.</p> <p>Instrucciones • Lea la etiqueta completa antes de • Aplique 2 dosis del producto en bien en todas las superficies • Enjuague con agua limpia</p>
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Clario
UltraBlue™
**Antibacterial Foaming
Skin Cleanser**
Luxury Foam Antibacterial Skin Cleanser
Espuma limpiadora antibacteriana de lujo para la piel

Master Label - 11/2018

bag-1000ml

ULTRA BLUE ANTIBACTERIAL FOAMING SKIN CLEANSER

benzalkonium chloride soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65601-759
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CO CAMINE O XIDE (UNII: QWA2IZI6FI)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

PEG-4 RAPESEEDAMIDE (UNII: 89575CN928)
CO CAMIDO PROPYL HYDRO XYSULTAINE (UNII: 62V75NI93W)
GLYCERIN (UNII: PDC6A3C0OX)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
EDETATE SODIUM (UNII: MP1J8420LU)
ALCOHOL (UNII: 3K9958V90M)
BENZYL ACETATE (UNII: 0ECG3V79ZJ)
SODIUM GLYCOLATE (UNII: B75E535IM)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
TRISODIUM NITRILOTRIACETATE (UNII: E3C8R2M0XD)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
N-ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE (C12-C18) (UNII: 9U1Q4T4ZYS)
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)
2,4-DIMETHYL-3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: 452GFV2AFS)
METHYL DIHYDROJASMONATE (SYNTHETIC) (UNII: 3GW44CIE3Y)
CAPRYLYL/CAPRYL OLIGOGLUCOSIDE (UNII: E00JL9G9K0)
MAGNESIUM NITRATE (UNII: 77CBG3UN78)
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)
GERANIOL (UNII: L837108USY)
LIME OIL (UNII: UZH29XGA8G)
2-METHYLUNDECANAL (UNII: S94QNS2VY5)
.BETA.-CITRONELLOL, (+/-)- (UNII: 565OK72VNF)
ALLYL CYCLOHEXANEPROPIONATE (UNII: H4W9H3L241)
GERANYL ACETATE (UNII: 3W81YG7P9R)
CITRONELLYL ACETATE (UNII: IZ420RT3OY)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)
CITRAL (UNII: T7EU0O9VPP)
FORMALDEHYDE (UNII: 1HG84L3525)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65601-759-29	1000 mL in 1 BAG; Type 0: Not a Combination Product	11/12/2012	
2	NDC:65601-759-57	550 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/12/2012	
3	NDC:65601-759-03	750 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/12/2012	
4	NDC:65601-759-04	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/12/2012	
5	NDC:65601-759-88	500 mL in 1 BOTTLE, PUMP; 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	part333E	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(65601-759) , label(65601-759)

Revised: 8/2020

Betco Corporation, Ltd