

KEYSTONE- benzalkonium chloride solution

Ecolab Inc.

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.

Drug Facts

Active Ingredient

Benzalkonium chloride 0.5%

Purpose

Antiseptic handwash

Uses

- for handwashing to decrease bacteria on the skin

Warning

☐ **For external use only**

Do not use

- in eyes

When using the product

- if in eyes, rinse promptly and thoroughly with water
- discontinue use if irritation and redness develop

Stop use and ask a physician if skin irritation or redness occurs for more than 72 hours

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wet hands and apply foam
- scrub hands and forearms
- rinse thoroughly and dry

Other information

- for additional information, see Safety Data Sheet (SDS)
- for emergency medical information, in USA and Canada, call 1 800 328 0026

Inactive ingredients water (aqua), cocamine oxide, hexylene glycol, PEG-180, glycerin, cocamidopropyl PG-dimonium chloride phosphate, phenoxyethanol, polyquaternium-7, myristamide DIPA, myristamine oxide, citric acid, methyl gluceth-20, glyceryl caprylate/caprate, alcohol, PEG-12 dimethicone, potassium citrate, fragrance, blue 1

Questions? call **1-866-781-8787**

Representative Label and Principal Display Panel

KEYSTONE SYSCO

ADVANCED ANTIBACTERIAL FOAM HAND SOAP

Active ingredient: Benzalkonium chloride 0.5%

Sysco 5284789 6101971 ECOLAB®

Net Contents

750 mL (25.3 US FL OZ) 6101971

This product may be patented: www.ecolab.com/patents

For SDS information visit:

www.cleawnwithkeystone.com

Ecolab · 1 Ecolab Place · St. Paul MN 55102 USA

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Made in United States

www.ecolab.com · 773738/5401/1018

<p>Datos sobre la droga (continuado)</p> <p>Deje de usarlo y vea a un doctor si</p> <ul style="list-style-type: none"> la irritación y rosado, dura más de 72 horas <p>Manténgase fuera del alcance de los niños. Si se enferma, obtenga ayuda médica o póngase en contacto con un centro de envenenamiento inmediatamente.</p> <p>Instrucciones</p> <ul style="list-style-type: none"> manos húmedas y aplique la espuma refréguese las manos y los antebrazos enjuáguese completamente y séquese 	<p>Datos sobre la droga (continuado)</p> <p>Información adicional</p> <ul style="list-style-type: none"> para informaciones adicionales, vea la hoja de datos de seguridad para información médica de emergencia en los EEUU o Canadá, llame al 1 800 328 0026 <p>Ingredientes inactivos agua, óxido de cocamina, hexilenglicol, PEG-180, glicerina, cocamidopropil PG-dimonio cloruro fosfato, fenoxietanol, poliquaternario 7, DIPA miristamida, óxido de myristamine, ácido cítrico, metilgluceth-20, glicéridos caprílico / cáprico, alcohol, PEG-12 dimeticona, hidróxido de potasio, fragancia, FD & C azul 1.</p> <p>¿Preguntas? Llame al 1-866-781-8787</p>	<p>This product may be patented Este producto puede ser patentado: www.ecolab.com/patents</p> <p>For SDS information visit: www.cleawnwithkeystone.com</p> <p>Distributed by Sysco Corporation Ecolab · 1 Ecolab Place · St. Paul MN 55102 USA · tel: 1 800 35 CLEAN (352 5326) © 2018 Ecolab USA Inc. · All rights reserved Todos los derechos reservados Made in U.S.A. Hecho en EE.UU. www.ecolab.com · 773738/5401/1018</p>	
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<p>Drug Facts</p> <table border="1"> <tr> <th>Active ingredient</th> <th>Purpose</th> </tr> <tr> <td>Benzalkonium chloride 0.5%</td> <td>Antiseptic handwash</td> </tr> </table> <p>Uses</p> <ul style="list-style-type: none"> for handwashing to decrease bacteria on the skin <p>Warnings For external use only</p> <p>Do not use</p> <ul style="list-style-type: none"> in eyes <p>When using this product</p> <ul style="list-style-type: none"> if in eyes, rinse promptly and thoroughly with water discontinue use if irritation and redness develop 	Active ingredient	Purpose	Benzalkonium chloride 0.5%	Antiseptic handwash	<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> skin irritation or redness occurs for more than 72 hours <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> wet hands and apply foam scrub hands and forearms rinse thoroughly and dry <p>Other information</p> <ul style="list-style-type: none"> for additional information, see Safety Data Sheet (SDS) for emergency medical information in USA and Canada, call 1 800 328 0026 	<p>Drug Facts (continued)</p> <p>Inactive ingredients water (agua), cocamine oxide, hexylene glycol, PEG-180, glycerin, cocamidopropyl PG-dimonium chloride phosphate, phenoxethanol, polyquaternium-7, myristamide DIPA, myristamine oxide, citric acid, methyl gluceth-20, glyceryl caprylate/caprate, alcohol, PEG-12 dimethicone, potassium citrate, fragrance, blue 1.</p> <p>Questions? call 1-866-781-8787</p>	<p>Datos sobre la droga</p> <table border="1"> <tr> <th>Ingrediente activo</th> <th>Propósito</th> </tr> <tr> <td>Cloruro de benzalconio 0.5% ...</td> <td>Jabón antiséptico para manos</td> </tr> </table> <p>Usos</p> <ul style="list-style-type: none"> lavado de manos para disminuir las bacterias en la piel <p>Advertencia Para uso externo solamente</p> <p>No lo use</p> <ul style="list-style-type: none"> en los ojos <p>Cuando use este producto</p> <ul style="list-style-type: none"> si ocurriera irritación roja, descontinúe su uso si en los ojos, láveselos rápida y completamente con abundante agua 	Ingrediente activo	Propósito	Cloruro de benzalconio 0.5% ...	Jabón antiséptico para manos
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KEYSTONE			
benzalkonium chloride solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:47593-595
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
COCAMINE OXIDE (UNII: QWA2IZI6FI)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
GLYCERIN (UNII: PDC6A3C0OX)	
COCAMIDOPROPYL PROPYLENE GLYCOL-DIMONIUM CHLORIDE PHOSPHATE (UNII: H2KVQ74JM4)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600000 MW) (UNII: 0L414VCS5Y)	
MYRISTIC DIISOPROPANOLAMIDE (UNII: 17DN142CTK)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
METHYL GLUCETH-20 (UNII: J3QD0LD11P)	
GLYCERYL CAPRYLATE/CAPRATE (UNII: G7515SW10N)	
ALCOHOL (UNII: 3K9958V90M)	
PEG-12 DIMETHICONE (UNII: ZEL54N6W95)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47593-595-41	750 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/20/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/20/2018	

Labeler - Ecolab Inc. (006154611)

Revised: 10/2018

Ecolab Inc.