

MYSTIC- benzalkonium chloride solution
Kay Chemical Company

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

Warnings

- **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 doctor 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 forearms
- Dispense a palmful of product to hands
- Scrub hands and forearms for 20 seconds
- Rinse thoroughly and dry

Other information

- for additional information, see Safety Data Sheet (SDS)

- for emergency medical information in USA 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/Caprates, Alcohol, PEG-12 Dimethicone, Potassium Citrate, fragrance, Blue 1

Questions? Call **1-800-532-7732**

Representative Label and Principal Display Panel

SSDC

Sustainable Solutions

MYSTIC™

Foaming Anti-Bacterial Hand Soap

Jabón para manos con espuma antibacterial

Benzalkonium chloride 0.5%

1112019

Net Content/Contenido Neto: 750mL/25 US fl. oz.

Distributed by:


SSDC Division, Kay Chemical Company

4050 Corporate Drive, #100

Grapevine, Texas 76051, USA 800.532.7732

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<p>Datos sobre la droga (continuado)</p> <ul style="list-style-type: none"> ■ Suspense el uso si ocurre irritación o enrojecimiento <p>Suspenda el uso y consulte a un médico</p> <ul style="list-style-type: none"> ■ Si ocurre irritación o enrojecimiento en la piel por más de 72 horas <p>Manténgase fuera del alcance de los niños. Si se ingiere, obtenga atención médica o comuníquese con el Centro de control de intoxicaciones local inmediatamente.</p>	<p>Datos sobre la droga (continuado)</p> <p>Instrucciones</p> <ul style="list-style-type: none"> ■ Mójese las manos y antebrazos ■ Coloque una pequeña cantidad del producto en las manos ■ Frote las manos y los antebrazos durante 20 segundos ■ Enjuague completamente y deje secar <p>Información adicional</p> <ul style="list-style-type: none"> ■ Para obtener más información, consulte la hoja de datos de seguridad (SDS) ■ Para obtener información médica de emergencia en los Estados Unidos, llame al 1-800-328-0026 	<p>Datos sobre la droga (continuado)</p> <p>Ingredientes inactivos agua, óxido de cocamina, hexilenglicol, PEG-180, glicerina, cocamidopropil PG-dimonio cloruro fosfato, fenoxietanol, poliquaternio-7, DIPA miristamida, ácido cítrico, metilgluceth-20, glyceryl caprylate/caprate, alcohol, PEG-12 dimeticona, hidróxido de potasio, fragancia, azul 1.</p> <p>¿Tiene Preguntas? Llame al 1-800-532-7732</p>	 <p>MYSTIC™ Foaming Anti-Bacterial Hand Soap Jabón para manos con espuma antibacterial Benzalkonium chloride 0.5%</p> <p>Net Contents/Contenido Neto: 750 mL/25 US fl. oz. Distributed by: SSDC Division, Kay Chemical Company 4050 Corporate Drive, #100 Greenville, Texas 76051, USA 800.532.7732 ©2020 Kay Chemical Company. All Rights Reserved 1112019 749431 749431/77303/0920</p>
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<p>Net Contents: 750 mL/25 US fl oz</p> <p>Drug Facts</p> <p>Active ingredient Benzalkonium chloride 0.5% Purpose Antiseptic handwash</p> <p>Uses ■ For handwashing to decrease bacteria on the skin</p> <p>Warnings</p> <ul style="list-style-type: none"> ■ For external use only Do not use ■ 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 	<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 forearms ■ Dispense a palmful of product to hands ■ Scrub hands and forearms for 20 seconds ■ Rinse thoroughly and dry 	<p>Drug Facts (continued)</p> <p>Other Information</p> <ul style="list-style-type: none"> ■ for additional information, see Safety Data Sheet (SDS) ■ for emergency medical information in USA call 1-800-328-0026 <p>Inactive ingredients Water (Aqua), Cocaine 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 1-800-532-7732</p>	<p>Contenido Neto: 750 mL/25 US fl oz</p> <p>Datos del Medicamento</p> <p>Ingrediente activo Cloruro de benzalconio 0.5% Propósito Jabón antiséptico para manos</p> <p>Uso ■ lavado de manos para disminuir las bacterias en la piel</p> <p>Advertencia</p> <ul style="list-style-type: none"> ■ Para uso externo solamente <p>No usar</p> <ul style="list-style-type: none"> ■ En los ojos <p>Al usar este producto</p> <ul style="list-style-type: none"> ■ Si ocurre el contacto con los ojos, enjuague inmediatamente y con abundante agua
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MYSTIC

benzalkonium chloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63146-304
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
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POTASSIUM HYDROXIDE (UNII: WZ H3C48M4T)	
PEG-12 DIMETHICONE (300 CST) (UNII: Z EL54N6W95)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
METHYL GLUCETH-20 (UNII: J3QD0LD11P)	
MYRISTIC DIISOPROPANOLAMIDE (UNII: 17DN142CTK)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 900000 MW) (UNII: B70CUU14M9)	
PHENOXYETHANOL (UNII: H1E492Z Z3T)	
MYRISTAMINE OXIDE (UNII: J086PM3RRT)	
COCAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE (UNII: H2KVQ74JM4)	

GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
WATER (UNII: 059QF0KO0R)	
COCAMINE OXIDE (UNII: QWA2IZI6FI)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63146-304-03	750 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/11/2016	
2	NDC:63146-304-10	1250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/11/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	02/11/2016	

Labeler - Kay Chemical Company (003237021)

Revised: 11/2022

Kay Chemical Company