

MYSTIC FOAMING HAND SANITIZER- 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 0.1%

Purpose

Antiseptic handwash

Uses

- For handwashing to decrease bacteria on the skin

Warnings

- **For external use only**

Do not use

- In eyes

When using this 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

- wash hands to remove soil
- dispense palmful
- spread to cover hands, rub in well
- air dry, do not rinse or towel dry

Other information

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

- for emergency medical information in USA call 1-800-391-1504

Inactive ingredients water (aqua), isopropyl alcohol, propylene glycol, FD&C Red 40, FD&C Blue 1

Questions?

Call **1-800-532-7732**

Representative label and principal display panel

NDC 63146-117-10

MYSTIC

Foaming Hand Sanitizer

Benzalkonium chloride 0.1%

Net Contents: 1250 mL/42.3 US fl oz

Distributed by: SSDC Division, Kay Chemical Company

4050 Corporate Drive, #100

Grapevine, Texas 76051, USA 800.532.7732

Datos sobre la droga (continuado)

Manténgase fuera del alcance de los niños. Si se ingiere, obtenga ayuda médica o póngase en contacto con un centro de envenenamiento inmediatamente.

Instrucciones

- Lávese las manos para remover la tierra
- Agregue una mano llena
- Extiéndalo hasta cubrir las manos y fróteselo bien
- No se enjuague las manos ni se las seque con una toalla; déjelas secar al aire ambiente

Información adicional

- Para informaciones adicionales, vea la hoja de datos de seguridad (SDS)
- **INFORMACIÓN DE EMERGENCIA SOBRE SALUD:** para obtener información médica de emergencia en los Estados Unidos, llame al 1-800-391-1504.

Datos sobre la droga (continuado)

Ingredientes inactivos agua, propileno glicol, alcohol isopropílico, CI 16035 (FD&C rojo 40), CI 42090 (FD&C azul 1).

¿Preguntas? llame al **1-800-532-7732**

SSDC
Sustainable Solutions

Distributed by:
SSDC Division, Kay Chemical Company
4160 Corporate Drive #100
Grapevine, TX 76051, USA 800.532.7732

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Made in the USA | Hecho en los Estados Unidos
This product may be patented | Este producto puede ser patentado
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NDC 63146-117-10

MYSTIC™
Foaming Hand Sanitizer
Sanitizante para las manos

Active Ingredient: Benzalkonium chloride 0.1%

SSDC

Net Contents/Contenido Neto:
1250 mL (42.3 US FL OZ)

1110491 765694/r301/0322

Drug Facts

Active ingredient Benzalkonium chloride 0.1% **Purpose** Antiseptic handwash

Uses

- For handwashing to decrease bacteria on the skin

Warnings

- For external use only

Do not use

- In eyes

When using this product

- If in eyes, rinse promptly and thoroughly with water

Drug Facts (continued)

- Discontinue use if irritation and redness develop

Stop use and ask a doctor if

- Skin irritation and redness persist 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

- Wash hands to remove soil
- Dispense palmful
- Spread to cover hands, rub in well
- Air dry, do not rinse or towel dry

Drug Facts (Continued)

Other information

- For additional information, see Safety Data Sheet (SDS)
- **EMERGENCY HEALTH INFORMATION:** In the US, call 1-800-391-1504.

Inactive ingredients water (aqua), isopropyl alcohol, propylene glycol, CI 16035 (FD&C red 40), CI 42090 (FD&C blue 1).

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

Datos sobre la droga

Ingrediente activo Cloruro de benzalkonium 0.1% **Propósito** Jabón antiséptico para manos

Usos

- Lavado de manos para disminuir las bacterias en la piel

Advertencia

- Para uso externo solamente

No lo use

- En los ojos

Cuando use este producto

- Si ocurriera irritación roja, descontinúe su uso
- Si en los ojos, láveselos rápida y completamente con abundante agua

Deje de usarlo y vea a un doctor si

- Si la irritación y rojedo, dura más de 72 horas

MYSTIC FOAMING HAND SANITIZER

benzalkonium chloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63146-117
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)		BENZALKONIUM CHLORIDE	1 mg in 1 mL	
Inactive Ingredients				
Ingredient Name		Strength		
Water (UNII: 059QF0KO0R)				
Isopropyl alcohol (UNII: ND2M416302)				
Propylene glycol (UNII: 6DC9Q167V3)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63146-117-03	750 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/29/2010	
2	NDC:63146-117-10	1250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/29/2010	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	11/29/2010		

Labeler - Kay Chemical Company (003237021)

Revised: 5/2023

Kay Chemical Company