

KAY- 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 and 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)
- **Medical emergency:** (877) 231-2615 or call collect 0 (952) 853-1713

Inactive ingredients water (aqua), isopropyl alcohol, propylene glycol, CI 16035 (FD&C Red 40), CI 42090 (FD&C Blue 1)

Questions? Call 1-800-529-5458

Principal Display panel and representative label

NDC 63146-109-10

KAY

Foaming Hand Sanitizer

KEEP OUT OF REACH OF CHILDREN - FOR INSTITUTIONAL USE ONLY

Benzalkonium chloride 0.1%

Net contents: 42 US fl oz (1250 ml)

Distributed by:

Kay Chemical Company • 8300 Capital Drive

Greensboro, NC 27409-9790 USA

Customer Service: (800) 529-5458

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<p>Datos sobre la droga (continuado)</p> <p>Deje de usarlo y vea a un doctor al</p> <ul style="list-style-type: none"> Hay irritación de piel por más de 72 horas <p>Mantener 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>Direcciones</p> <ul style="list-style-type: none"> Lava las manos y remueve la suciedad Aplice sobre la palma y frote en toda la mano Extiéndolo hasta cubrir las manos y fróteselo bien Séqueles al aire, no enjuagar, no utilizar toalla <p>Información adicional</p> <ul style="list-style-type: none"> para más información, consulte la FICHA DE DATOS DE SEGURIDAD (SDS) Emergencia médica: (877) 231-2615 o por cobro revertido al 0 (952) 853-1713 	<p>Datos sobre la droga (continuado)</p> <p>Ingredientes inactivos</p> <p>agua, alcohol isopropílico, glicol de propileno, CI 16035 (FD&C Rojo 40), CI 42090 (FD&C Azul 1)</p> <p>¿Preguntas? Llame al 1-800-529-5458</p>	<p>Distributed by / Distribuido por:</p> <p>Kay Chemical Company • 8300 Capital Drive Greensboro, NC 27409-9790 USA Customer Service: (800) 529-5458 ©2018 Kay Chemical Company All rights reserved / Todos los derechos reservados 757547-02 • KUSA 757547/8002/0618</p> <p>In Australia:</p> <p>Kay Chemical Company, c/o Ecolab Pty Limited 2 Drake Avenue, Macquarie Park NSW 2113 (Tel) # 02 8870 8100</p>	<p>NDC 63146-109-10</p> <p>KAY</p> <p>Foaming Hand Sanitizer</p> <p>Sanitizante de manos en espuma</p> <p>KEEP OUT OF REACH OF CHILDREN • FOR INSTITUTIONAL USE ONLY MANTENGASE FUERA DEL ALCANCE DE LOS NIÑOS • SOLO PARA USO INSTITUCIONAL</p> <p>Benzalkonium chloride 0.1% Clorido de Benzalkonium 0.1%</p> <p>Net contents: 42 US fl oz (1250 ml)</p>
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<p>Drug Facts</p> <p>Active ingredient Benzalkonium chloride 0.1%..... Antiseptic Handwash</p> <p>Purpose Antiseptic Handwash</p> <p>Uses</p> <ul style="list-style-type: none"> For handwashing to decrease bacteria on the skin <p>Warnings</p> <p>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 	<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"> Wash hands to remove soil Dispense palmful Spread to cover hands, rub in well Air dry, do not rinse or towel dry <p>Other information</p> <ul style="list-style-type: none"> For additional information, see Safety Data Sheet (SDS) Medical Emergency: (877) 231-2615 or call collect 0 (952) 853-1713 	<p>Drug Facts (continued)</p> <p>Inactive ingredients</p> <p>water (aqua), isopropyl alcohol, propylene glycol, CI 16035 (FD&C Red 40), CI 42090 (FD&C Blue 1)</p> <p>Questions? Call 1-800-529-5458</p>	<p>Datos sobre la droga</p> <p>Ingredientes activos Clorido de Benzalkonium 0.1%..... Antiséptico de manos</p> <p>Propósito Antiséptico de manos</p> <p>Uso</p> <ul style="list-style-type: none"> Para lavar las manos y disminuir la cantidad de bacterias en la piel <p>Advertencias</p> <p>Para uso externo solamente</p> <p>No lo use</p> <ul style="list-style-type: none"> En ojos <p>Cuando use este producto</p> <ul style="list-style-type: none"> Si ocurre el contacto con los ojos, enjuague inmediata y abundantemente con agua Suspenda el uso si ocurre irritación o enrojecimiento
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KAY
benzalkonium chloride solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63146-109
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:63146-109-03	750 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/22/2008	
2	NDC:63146-109-06	1200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/22/2011	
3	NDC:63146-109-10	1250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/10/2014	
4	NDC:63146-109-08	750 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/10/2014	05/21/2020

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	02/22/2008	

Labeler - Kay Chemical Company (003237021)

Revised: 7/2019

Kay Chemical Company