

QSR- chloroxylonol 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

Chloroxylonol, 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 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

- Wet skin and spread a small amount on hands and forearms
- Scrub well, rinse thoroughly and 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), potassium cocoate, hexylene glycol, sodium sulfate, tetrasodium EDTA, sodium lauryl sulfate, hydroxyethylcellulose, glycerin, cocoglucoside, glyceryl oleate, citric acid, fragrance, methylchloroisoithiazolinone, methylisoithiazolinone, FD&C Red #40 (CI 16035), FD&C Yellow #5 (CI 19140), D&C Red #33 (CI 17200)

Questions? Call 1-800-529-5458

Principal display panel and representative label

NDC 63146-110-10 Kay

QSR

Antibacterial Hand Soap

KEEP OUT OF REACH OF CHILDREN • FOR INSTITUTIONAL USE ONLY

Chloroxylenol 0.5%

Net Contents: 42 USA 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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758210-01 • KUSA 758210/8001/0416

<p>Datos sobre la droga (continuado)</p> <p>Deje de usarlo y vea a un doctor si</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>Dircciones</p> <ul style="list-style-type: none"> Humedezca la piel y aplique una cantidad pequeña en las manos y los antebrazos Retregue bien, enjuague minuciosamente y seque <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>Inactive ingredients water (aqua), coconut soap, hexylene glycol, sodium lauryl sulfate, sodium sulfate, tetrasodium EDTA, hydroxyethyl cellulose, glycerine, coco glucoside, citric acid, fragrance, methylchloroisoithiazolinone, FD&C red 40 (CI 16035), FD&C yellow 5 (CI 19140), FD&C red 33 (CI 17200)</p> <p>¿Preguntas? Llame al 1-800-529-5458</p>	<p>Distributed by / Distribuido por: Kay Chemical Company • 8300 Capital Drive Greensboro, NC 27409-9790 USA Customer Service: (800) 529-5458 ©2016 Kay Chemical Company All rights reserved Todos los derechos reservados 758210-01 • KUSA 758210/8001/0416</p>	<p>NDC 63146-110-10</p> <p>QSR</p> <p>Antibacterial Hand Soap</p> <p>Jabón de manos antibacterial</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>Chloroxylenol 0.5%</p> <p>Net contents: 42 US fl oz (1250 mL)</p>
<p>Drug Facts</p> <p>Active ingredient Chloroxylenol 0.5% Purpose Antiseptic Handwash</p> <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 	<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 skin and spread a small amount on hands and forearms Scrub well, rinse thoroughly and 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 water (aqua), coconut soap, hexylene glycol, sodium lauryl sulfate, sodium sulfate, tetrasodium EDTA, hydroxyethyl cellulose, glycerine, coco glucoside, citric acid, fragrance, methylchloroisoithiazolinone, FD&C red 40 (CI 16035), FD&C yellow 5 (CI 19140), FD&C red 33 (CI 17200)</p> <p>Questions? Call 1-800-529-5458</p>	<p>Datos sobre la droga</p> <p>Ingredientes activos Chloroxylenol 0.5% Propósito jabón para manos antiséptico</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 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

QSR

chloroxylenol solution

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:63146-110

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Chloroxylenol (UNII: 0F32U78V2Q) (Chloroxylenol - UNII:0F32U78V2Q)	Chloroxylenol	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
POTASSIUM COCOATE (UNII: F8U72V8ZXP)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
SODIUM SULFATE (UNII: 0YPR65R21J)	
EDETATE SODIUM (UNII: MP1J8420LU)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
HYDROXYETHYL CELLULOSE (3000 MPA.S AT 1%) (UNII: 7Q6P4JN1QT)	
GLYCERIN (UNII: PDC6A3C0OX)	
COCO GLUCOSIDE (UNII: ICS790225B)	
GLYCERYL OLEATE (UNII: 4PC054V79P)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
METHYLCHLOROISOTHIAZOLINONE/METHYLISOTHIAZOLINONE MIXTURE (UNII: 1509QS218W)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63146-110-02	800 mL in 1 BAG; Type 0: Not a Combination Product	12/15/2009	
2	NDC:63146-110-01	3800 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/15/2009	
3	NDC:63146-110-10	1250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/21/2014	
4	NDC:63146-110-08	750 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/21/2014	05/21/2020

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	12/15/2009	

Labeler - Kay Chemical Company (003237021)

