

**LAGARDE- chloroxylonol solution**  
**Kay Chemical Co.**

*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.*

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**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 hands and forearms
- Apply 5 ml (teaspoonful) or palmful to hands and forearms
- Scrub thoroughly for 20 seconds
- Rinse and repeat

**Other information**

- for additional information, see Material Safety Data Sheet (MSDS)

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

## Inactive ingredients

water (aqua), potassium cocoate, hexylene glycol, sodium sulfate, tetrasodium EDTA, sodium lauryl sulfate, hydroxyethylcellulose, glycerin, cocoglucoside, glyceryl oleate, citric acid, fragrance, methylchlorisothiazolinone, methylisothiazolinone, FD&C Red #40, FD&C Yellow #5, D&C Red #33

## Principal display panel and representative label

**NDC 63149-121-01**

**LAGARDE™**

**Antibacterial Hand Soap**

**Active ingredient**

Chloroxylenol 0.5%

**SSDC Sustainable Solutions**

**1 US gallon (3.78 liters)**

**Distributed by:** SSDC Division, Kay Chemical Company

4050 Corporate Drive, #100 • Grapevine, Texas 76051, USA • 800.532.7732

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**1111917**

747932-01 747932/7300/0613

<p>NDC 63146-121-01</p> <p><b>Drug Facts</b></p> <p><b>Active ingredient</b> Chloroxylenol 0.5%</p> <p><b>Purpose</b> Antiseptic handwash</p> <p><b>Uses</b> For handwashing to decrease bacteria on the skin</p> <p><b>Warnings</b> For external use only</p> <p><b>Do not use</b> In eyes</p> <p><b>When using this product</b> If in eyes, rinse promptly and thoroughly with water Discontinue use if irritation and redness develop</p> <p><b>Stop use and ask a doctor if</b> Skin irritation or redness occurs for more than 72 hours</p> <p><b>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</b></p> <p><b>Directions</b> Wet hands and forearms Apply 5 mL (one teaspoon) or palmful to hands and forearms Scrub thoroughly for 20 seconds Rinse and repeat</p> <p><b>Other information</b> For additional information, see Material Safety Data Sheet (MSDS) For emergency medical information in USA, call 1-800-391-1504</p> <p><b>Inactive ingredients</b> water (aqua), potassium cocoate, hexylene glycol, sodium sulfate, tetrasodium EDTA, sodium lauryl sulfate, hydroxyethylcellulose, glycerin, cocoglucoside, glyceryl oleate, citric acid, fragrance, methylchlorisothiazolinone, methylisothiazolinone, FD&amp;C Red #40, FD&amp;C Yellow #5, D&amp;C Red #33</p> <p><b>Questions?</b> call 1-800-532-7732</p>	<p><b>INSTRUCTION</b> Do not dilute. Pour directly into built-in soap dispenser.</p>	<p>NDC 63146-121-01</p> <p><b>LAGARDE™</b></p> <p><b>Antibacterial Hand Soap</b></p> <p>Jabón antibacterial de manos</p> <p><b>Active ingredient</b> Chloroxylenol 0.5%</p> <p><b>SSDC</b> Sustainable Solutions</p> <p>1 US gallon (3.78 liters)</p> <p><b>1111917</b></p> <p><small>Distributed by: SSDC Division, Kay Chemical Company 4050 Corporate Drive, #100 • Grapevine, Texas 76051, USA • 800.532.7732 ©2013 Kay Chemical Company • All Rights Reserved 747932-01 747932/7300/0613</small></p>
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## LAGARDE

chloroxylenol solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63146-121
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>CHLOROXYLENOL</b> (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	0.5 mg in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POTASSIUM COCOATE</b> (UNII: F8U72V8ZXP)	
<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)	
<b>SODIUM SULFATE</b> (UNII: 0YPR65R21J)	
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>HYDROXYETHYL CELLULOSE (2000 CPS AT 1%)</b> (UNII: S38J6RZN16)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>COCO GLUCOSIDE</b> (UNII: ICS790225B)	
<b>GLYCERYL OLEATE</b> (UNII: 4PC054V79P)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>METHYLCHLOROISOTHIAZOLINONE</b> (UNII: DEL7T5QRPN)	
<b>METHYLISOTHIAZOLINONE</b> (UNII: 229D0E1QFA)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:63146-121-01	3780 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/31/2016	
2	NDC:63146-121-02	800 mL in 1 POUCH; Type 0: Not a Combination Product	05/31/2016	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333E	05/31/2016	

**Labeler** - Kay Chemical Co. (003237021)