

**CARROLLCLEAN- chloroxylenol (pcmx) soap**  
**CarrollCLEAN LCC**

*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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**Pink Antimicrobial Soap**

**Active ingredient**

Chloroxylenol 0.25% w/v

**Purpose**

Antimicrobial

**Uses**

- hand washing in public washrooms, work areas, healthcare facilities, office buildings, food service facilities, and wherever cleanliness and antimicrobial properties are desired.

**Warnings**

**For external use only**

**When using this product**

- do not use in or near eyes

**Keep out of reach of children**

In case of accidental ingestion, seek medical attention or contact a poison control center immediately.

**Directions**

- apply small amount of product to hands
- hold hands under water and work cleaner into lather
- rinse with water and wipe clean

**Other information**

- store at room temperature

**Inactive ingredients:**

Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Sodium Chloride, Dimethylol-5,5-dimethylhydantoin, Linear Ethoxylated Alcohol, Propylene Glycol, Polyethylene Glycol Distereate, Fragrance, Tetrasodium EDTA, Methylchloroisoithiazolinone (and) Methyllisoithiazolinone, Isopropyl Myristate, Citric acid, FD & C Red #40, D & C Red #33

**Package label**



# Clean N Fresh

Antimicrobial Pink Hand Soap

<b>Drug Facts</b>	
<b>Active Ingredient</b> Chloroxylenol (PCMX)	<b>Purpose</b> Antimicrobial
<b>Uses</b> Hand washing in public washrooms, work sites, health-care facilities, office buildings, food service facilities, and wherever clean hands and effective disinfection are desired.	
<b>Warnings</b> For external use only. <b>When using this product:</b> Do not use in or near eyes. Keep out of reach of children. In case of accidental ingestion, seek medical attention or contact a poison control center immediately.	
<b>Directions:</b> Apply small amount of product to hands. Rub hands under water and work cleaner into lather. Rinse thoroughly with water.	
<b>Other information</b> Store at room temperature.	
<b>Inactive Ingredients:</b> Water, Sodium Cocoyl Sulfate, Cocamidopropyl Betaine, Sodium Citrate, Dimethyl S-Dimethylthiazolyl, Carbonyl Diethylamine, Sodium Chloride, Propylene Glycol, Methylisothiazolinone, Fragrance, Tetrasodium EDTA, Methylparaben, Methylchloroisothiazolinone, Isopropyl Myristate, Citric Acid, D-C Red #3, D-C Red #40.	

Net 3750/375  
04491-0214-2

<b>Información sobre la Droga</b>	
<b>Ingrediente Activo</b> Chloroxylenol (PCMX)	<b>Propósito</b> Antimicrobial
<b>Uso</b> Para lavado de manos en baños públicos, áreas de trabajo, instalaciones para el cuidado de la salud, edificios de oficinas, instalaciones para servicios de comida, y en donde se desee obtener propósitos antimicrobiales de limpieza.	
<b>Advertencias</b> <b>Para su externa aplicación:</b> Cuidado con los ojos. No lo use en o cerca de los ojos. <b>Precaución para los niños de los niños:</b> Manténgalo fuera del alcance de los niños. Si ocurre un accidente, busque atención médica o llame a un centro de control de intoxicaciones o al servicio de emergencia.	
<b>Instrucciones de Uso:</b> Aplique una pequeña cantidad de producto en sus manos. Manténgalo en sus manos debajo del chorro de agua y frote sus manos para formar espuma. Rinselas con agua abundante.	
<b>Otra información</b> Almacenar a temperatura ambiente.	
<b>Ingredientes Inactivos:</b> Agua, Sulfato de Lauril Sódico, Cocamidopropil Betaina, Cloruro de Sodio, Dimetil S-Dimetilthiazolil, Carbonyl Diethylamine, Cloruro de Sodio, Propileno Glicol, Metilisotiazolinona, Fragancia, EDTA Tetrasódico, Metilparabeno, Metilcloroisotiazolinona, Isopropil Miristato, Ácido cítrico, D-C Rojo # 3, D-C Rojo # 40.	

KEEP OUT OF REACH OF CHILDREN  
**CAUTION:**  
See back panel for additional precautions.  
**ITEM# 524**

Manufactured by  
**CARROLLCLEAN**  
2300 W. Kingsley Rd. • Garland, Texas 75041 • 800.527.5722  
www.CARROLLCLEAN.com



Medical Emergency 1-800-535-5053

NET CONTENTS: 1 U.S. GALLON/3.78 LITERS

**LABEL SOLUTIONS INC.**  
Premium Labels that make your brand stick  
10000 W. Kingsley Rd. • Garland, TX 75041 • 800.527.5722  
www.LabelSolutionsInc.com

**PROOF APPROVAL FORM**

Date: 05.07.2020 11:35 AM  
Description: 1 Gal Clean N Fresh Antimicrobial Pink Hand Soap\_PROOF  
Material: White Semi-Gloss Perm w/ Lam  
Size: 4.875 x 17.875 in  
Colors:

**SIGN AND RETURN TODAY!**

Colors on this proof are not guaranteed. PMS or Process Color matches. Color/Proof Color/Order for final approval colors. PMS printed on order. PMS use are not guaranteed to be exactly like please test color before printing final request.

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**YOU MUST SIGN THIS APPROVAL BEFORE WE CAN PROCEED WITH YOUR ORDER.**

OK to print as is  
 OK to print with corrections  
 Make corrections and Re-Proof

Signed: \_\_\_\_\_  
Date: \_\_\_\_\_

## CARROLLCLEAN

chloroxylenol (pcmx) soap

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73708-524
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	0.282 mg in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.221 mL in 100 mL
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	0.0004 mL in 100 mL
FD&C RED NO. 40 (UNII: WZB9127XOA)	0.0002 mL in 100 mL
DMDM HYDANTOIN (UNII: BYR0546TOW)	0.334 mL in 100 mL
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	0.317 mL in 100 mL
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	7.85 mL in 100 mL
C9-11 PARETH-8 (UNII: 80E6PSE1XL)	0.242 mL in 100 mL
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	0.005 mL in 100 mL
METHYLCHLOROISOTHIAZOLINONE/METHYLISOTHIAZOLINONE MIXTURE (UNII: 15O9QS218W)	0.099 mL in 100 mL
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	0.026 mL in 100 mL
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	4.132 mL in 100 mL
EDETATE SODIUM TETRAHYDRATE (UNII: L13NHD21X6)	0.038 mL in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	2.146 mL in 100 mL
WATER (UNII: 059QF0KO0R)	84.307 mL in 100 mL

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73708-524-28	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/16/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/16/2020	

**Labeler** - CarrollCLEAN LCC (081222623)

**Registrant** - CarrollCLEAN LCC (081222623)

## Establishment

Name	Address	ID/FEI	Business Operations
CarrollCLEAN LCC		081222623	manufacture(73708-524)

Revised: 9/2020

CarrollCLEAN LCC