

**KLEAN-HANDS- klean-hands liquid**  
**Rite-Kem Incorporated**

*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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**Antimicrobial Hand Soap**

Chloroxylenol 0.3%

Antimicrobial Hand Soap

Handwash to help decrease bacteria on the skin. Recommended for repeated use

For external use only

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Wet hands

Apply a small amount of product and work into a lather

Rinse well and dry hands completely

Chloroxylenol 0.3%

Dodecylbenzene sulfonic acid, triethanolamine salt, Cocoamidopropyl betaine, Glycerol, 1,3-propanediol, Ammonium lauryl sulfate, Coconut monoethanolamide, Sodium Chloride, Fragrance, Dye, Water

**Label**

Klean-Hands Antimicrobial Hand soap

Formulated for food service and health care professionals who wash hands frequently and require the protection of an antimicrobial soap.

FDA registered

Made in USA

- \* Utilize the quickacting antimicrobial agent (PCMX) to kill germs
- \* Pleasing agent
- \* Powerful degreasers
- \* Soothing to the skin
- \* Ideal schools, health clubs, offices and recreation areas
- \* Rich Lather

- \* High foam enhances cleaning
- \* Performs equally well in hard and soft water
- \* Conditions as it cleans

Sold by: Rite-Kem Inc., 703 Westmoreland Drive, Tupelo, MS 38801

Ph.: 662-840-6060

NDC: 73943-948-xx

## Klean-Hands

Antimicrobial Hand Soap

Formulated for food service and health care professionals who wash hands frequently and require the protection of an antimicrobial soap.

**FDA Registered**



- Utilizes the quick-acting antimicrobial agent (PCMX) to kill germs
  - Pleasing scent
  - Powerful degreasers
  - Soothing to the skin.
- Ideal schools, health clubs, offices and recreation areas
  - Rich Lather
  - High foam enhances cleaning
- Performs equally well in hard and soft water
  - Conditions as it cleans

55 Gallon (208.2 L)

Drug Facts	
<b>Active ingredient</b> Chloroxylenol 0.3% <b>Purpose</b> Antibacterial Hand Soap	<b>Directions of Use</b> <ul style="list-style-type: none"> <li>• Wet hands</li> <li>• Apply a small amount of product and work into a lather</li> <li>• Rinse well and dry hands completely</li> </ul>
<b>Uses</b> <ul style="list-style-type: none"> <li>• Handwash to help decrease bacteria on the skin</li> <li>• Recommended for repeated use</li> </ul>	<b>Inactive ingredients</b> Dodecylbenzene sulfonic acid, Triethanolamine salt, Cocoadopropyl betaine, Glycerol, 1,3-propanediol, Ammonium lauryl sulfate, Coconut monoethanolamide, Sodium Chloride, Fragrance, Dye, Water
<b>Warnings</b> For external use only	
<ul style="list-style-type: none"> <li>• When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.</li> <li>• Stop use and ask a doctor if irritation or rash appears and lasts</li> <li>• Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</li> </ul>	

Sold By Rite-Kem, Inc. | 703 Westmoreland Drive  
662-840-6060 | Tupelo, MS 38801  
NDC 73943-948-04



WWW.RITE-KEM.COM

## Klean-Hands

Antimicrobial Hand Soap

Formulated for food service and health care professionals who wash hands frequently and require the protection of an antimicrobial soap.

**FDA Registered**



- Utilizes the quick-acting antimicrobial agent (PCMX) to kill germs
  - Pleasing scent
  - Powerful degreasers
  - Soothing to the skin.
- Ideal schools, health clubs, offices and recreation areas
  - Rich Lather
  - High foam enhances cleaning
- Performs equally well in hard and soft water
  - Conditions as it cleans

5 Gallon (18.93 L)

Drug Facts	
<b>Active ingredient</b> Chloroxylenol 0.3% <b>Purpose</b> Antibacterial Hand Soap	<b>Directions of Use</b> <ul style="list-style-type: none"> <li>• Wet hands</li> <li>• Apply a small amount of product and work into a lather</li> <li>• Rinse well and dry hands completely</li> </ul>
<b>Uses</b> <ul style="list-style-type: none"> <li>• Handwash to help decrease bacteria on the skin</li> <li>• Recommended for repeated use</li> </ul>	<b>Inactive ingredients</b> Dodecylbenzene sulfonic acid, Triethanolamine salt, Cocoadopropyl betaine, Glycerol, 1,3-propanediol, Ammonium lauryl sulfate, Coconut monoethanolamide, Sodium Chloride, Fragrance, Dye, Water
<b>Warnings</b> For external use only	
<ul style="list-style-type: none"> <li>• When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.</li> <li>• Stop use and ask a doctor if irritation or rash appears and lasts</li> <li>• Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</li> </ul>	

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NDC 73943-948-03



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# Klean-Hands

Antimicrobial Hand Soap

Formulated for food service and health care professionals who wash hands frequently and require the protection of an antimicrobial soap.

**FDA Registered**



- Utilizes the quick-acting antimicrobial agent (PCMX) to kill germs
  - Pleasant scent
  - Powerful degreasers
  - Soothing to the skin.
- Ideal schools, health clubs, offices and recreation areas
  - Rich Lather
  - High foam enhances cleaning
- Performs equally well in hard and soft water
  - Conditions as it cleans

128 ounces (3785.4mL)

Drug Facts	
<b>Active ingredient</b> Chloroxylenol 0.3% <b>Purpose</b> Antibacterial Hand Soap	<b>Directions of Use</b> <ul style="list-style-type: none"> <li>Wet hands</li> <li>Apply a small amount of product and work into a lather</li> <li>Rinse well and dry hands completely</li> </ul>
<b>Uses</b> <ul style="list-style-type: none"> <li>Handwash to help decrease bacteria on the skin</li> <li>Recommended for repeated use</li> </ul>	<b>Inactive ingredients</b> Dodecylbenzene sulfonic acid, Triethanolamine salt, Cocoadopropyl betaine, Glycerol, 1,3-propanediol, Ammonium lauryl sulfate, Coconut monoethanolamide, Sodium Chloride, Fragrance, Dye, Water
<b>Warnings</b> For external use only <ul style="list-style-type: none"> <li>When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.</li> <li>Stop use and ask a doctor if irritation or rash appears and lasts</li> <li>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</li> </ul>	

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662-840-6060 | Tupelo, MS 38801  
NDC 73943-948-02



# Klean-Hands

Antimicrobial Hand Soap

Formulated for food service and health care professionals who wash hands frequently and require the protection of an antimicrobial soap.

**FDA Registered**



- Utilizes the quick-acting antimicrobial agent (PCMX) to kill germs
  - Pleasant scent
  - Powerful degreasers
  - Soothing to the skin.
- Ideal schools, health clubs, offices and recreation areas
  - Rich Lather
  - High foam enhances cleaning
- Performs equally well in hard and soft water
  - Conditions as it cleans

8 ounces (236.6mL)

Drug Facts	
<b>Active ingredient</b> Chloroxylenol 0.3% <b>Purpose</b> Antibacterial Hand Soap	<b>Directions of Use</b> <ul style="list-style-type: none"> <li>Wet hands</li> <li>Apply a small amount of product and work into a lather</li> <li>Rinse well and dry hands completely</li> </ul>
<b>Uses</b> <ul style="list-style-type: none"> <li>Handwash to help decrease bacteria on the skin</li> <li>Recommended for repeated use</li> </ul>	<b>Inactive ingredients</b> Dodecylbenzene sulfonic acid, Triethanolamine salt, Cocoadopropyl betaine, Glycerol, 1,3-propanediol, Ammonium lauryl sulfate, Coconut monoethanolamide, Sodium Chloride, Fragrance, Dye, Water
<b>Warnings</b> For external use only <ul style="list-style-type: none"> <li>When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.</li> <li>Stop use and ask a doctor if irritation or rash appears and lasts</li> <li>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</li> </ul>	

Sold By Rite-Kem, Inc. | 703 Westmoreland Drive  
662-840-6060 | Tupelo, MS 38801  
NDC 73943-948-05



# Klean-Hands

Antimicrobial Hand Soap

Formulated for food service and health care professionals who wash hands frequently and require the protection of an antimicrobial soap.

FDA Registered



- Utilizes the quick-acting antimicrobial agent (PCMX) to kill germs
  - Pleasant scent
  - Powerful degreasers
  - Soothing to the skin.
- Ideal schools, health clubs, offices and recreation areas
  - Rich Lather
  - High foam enhances cleaning
- Performs equally well in hard and soft water
  - Conditions as it cleans

12 ounces (354.9mL)

Drug Facts	
<b>Active ingredient</b> Chloroxylenol 0.3% <b>Purpose</b> Antibacterial Hand Soap	<b>Directions of Use</b> <ul style="list-style-type: none"> <li>Wet hands</li> <li>Apply a small amount of product and work into a lather</li> <li>Rinse well and dry hands completely</li> </ul>
<b>Uses</b> <ul style="list-style-type: none"> <li>Handwash to help decrease bacteria on the skin</li> <li>Recommended for repeated use</li> </ul>	<b>Inactive ingredients</b> Dodecylbenzene sulfonic acid, Triethanolamine salt, Cocoadpropyl betaine, Glycerol, 1,3-propanediol, Ammonium lauryl sulfate, Coconut monoethanolamide, Sodium Chloride, Fragrance, Dye, Water
<b>Warnings</b> For external use only <ul style="list-style-type: none"> <li>When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.</li> <li>Stop use and ask a doctor if irritation or rash appears and lasts</li> <li>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</li> </ul>	

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NDC 73943-948-01



## KLEAN-HANDS

klean-hands liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC: 73943-948
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	0.3 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
PROPANEDIOL (UNII: 5965N8W85T)	
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
DODECYLBENZENESULFONIC ACID (UNII: 60NSK897G9)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	

<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73943-948-01	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/18/2020	
2	NDC:73943-948-02	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/18/2020	
3	NDC:73943-948-03	18927 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/18/2020	
4	NDC:73943-948-04	208198 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/18/2020	
5	NDC:73943-948-05	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2021	



*Formulated for food service and health care professionals who wash hands frequently and require the protection of an antimicrobial soap.*

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  - Pleasing scent
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- Ideal schools, health clubs, offices and recreation areas
  - Rich Lather
  - High foam enhances cleaning
- Performs equally well in hard and soft water
  - Conditions as it cleans

12 Fluid Ounces



Tupelo, MS 38801  
662-840-6060  
www.ritekem.com

### Drug Facts

Active ingredient	Purpose	Directions
Chloroxylenol 0.3%	Antimicrobial	- Wet hands - Apply a small amount - Rinse well and dry
Uses		<i>Inactive ingredients</i>
- Handwash to help decrease bacteria on the skin - Recommended for repeated use		Dodecylbenzenesulfonate Cocoamidopropyl dimethylamine Ammonium lauryl sulfate monoethanolamine Fragrance, Dye
Warnings		
For external use only When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask a doctor if irritation or rash appears and lasts		
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/18/2020	

**Labeler** - Rite-Kem Incorporated (786892927)

### Establishment

Name	Address	ID/FEI	Business Operations
Rite-Kem Incorporated		786892927	manufacture(73943-948)