

SMART FOAMING ANTIBACTERIAL- pcmx, hand soap soap

Midlab Incorporated

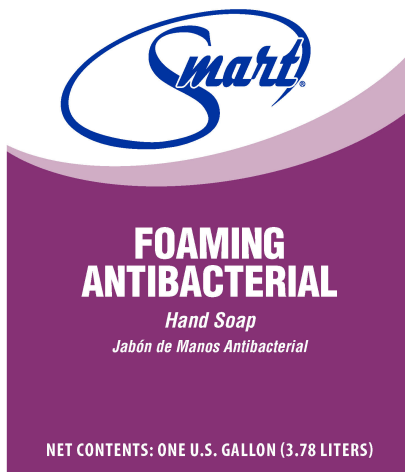
Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Principal Image

This product is a foaming antiseptic hand soap that effectively removes bacteria with normal use.

| Drug Facts | Purpose |
|---|---------------------------|
| Active Ingredient PCMX 0.1% | Antibacterial Handwashing |
| Uses • Handwash to help decrease bacteria on the skin. | |
| Warnings For external use only. Do not use in the eyes. In case of contact, immediately flush eyes 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. | |
| Directions • Apply a small amount, covering hands with product for 30 seconds. Lather and rinse. • Children under 6 years of age should be supervised when using this product. | |
| Inactive Ingredients Water, Lanolin-Alcohol, Sodium Lauryl Ether Sulfate, 4-chloro-3, 5-dimethylphenol, Fragrance, Yellow 5, Red 40. | |

FOR INDUSTRIAL AND INSTITUTIONAL USE ONLY



INFORMACIÓN DEL PRODUCTO

Ingrediente Activo: PCMX al 0.1%. Propósito: Agente Antibacteriano

Usos: Lavamos que ayuda a disminuir la presencia de bacterias en la piel.

Advertencias: Para uso externo únicamente. No use el producto en los ojos. En caso que ocurra contacto, enjuáguese los ojos inmediatamente. Deje de usar el producto y contacte a un doctor si ocurre y persiste una irritación.

MANTÉNGASE FUERA DEL ALCANCE DE LOS NIÑOS.

Si es ingerido, obtenga atención médica inmediata o contacte al Centro de Control por Envenenamiento inmediatamente.

Instrucciones: Aplique una pequeña cantidad, cubriendo manos con el producto por 30 segundos. Espuma y enjuague. Los niños menores de 6 años deben ser supervisados por un adulto cuando usen este producto.



SOUTHEASTERN
PAPER GROUP
50 Old Blackstock Rd.
Spartanburg, SC 29591
800.858.7230 | sepg.com

Product No:
003982

MADE IN U.S.A. | HECHO EN EEUU.

10314-00219

Active Ingredient

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indications and usage

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| SMART FOAMING ANTIBACTERIAL | | | |
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| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70542-603 |
| Route of Administration | TOPICAL | | |
| Active Ingredient/Active Moiety | | | |
| | Ingredient Name | Basis of Strength | Strength |
| | CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q) | CHLOROXYLENOL | 0.1 g in 1 L |
| Inactive Ingredients | | | |

| Ingredient Name | Strength |
|--|----------|
| LAURAMINE OXIDE (UNII: 4F6FC4M18W) | |
| SODIUM LAURETH SULFATE (UNII: BPV390UAP0) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| METHYLCHLOROISOTHIAZOLINONE/METHYLISOTHIAZOLINONE MIXTURE (UNII: 15O9QS218W) | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |

Product Characteristics

| | | | |
|----------|--------|--------------|--|
| Color | orange | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70542-603-41 | 3.78 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/31/2019 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 05/31/2019 | |

Labeler - Midlab Incorporated (047371463)

Registrant - Midlab Incorporated (047371463)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------|---------|-----------|------------------------|
| Midlab Incorporated | | 047371463 | manufacture(70542-603) |

Revised: 6/2019

Midlab Incorporated