

SMART DEFENDER- pcmx, dishwashing and hand soap soap

Midlab, Inc

Principal label

This product is a thick antiseptic hand soap that effectively removes dirt and bacteria with normal use and is enhanced with emollients for softer, smoother hands.

Drug Facts	
Active Ingredient	Purpose
Chloroxylenol (0.1%)	Antiseptic
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. Add water, lather and rinse.	
• Children under 6 years of age should be supervised when using this product.	
Inactive Ingredients	
Water, Cocamidopropyl Betaine, Sodium Lauryl Sulfate, Sodium Laureth-3 Sulfate, Sodium Chloride, Propylene glycol, Propenediol, Fragrance, Methylchlorothiazinone, Methylthiothiazinone, Yellow 5, and Red #0.	



Este producto es un jabón para manos antiséptico espeso que elimina la suciedad y las bacterias en su uso habitual, y está enriquecido con hidratantes para que las manos queden más suaves y tersas.

Información del Medicamento	
Ingrediente Activo	Finalidad
Cloroxileno (0.1%)	Antiséptico
Usos	
• Lavado de manos para disminuir las bacterias en la piel.	
Advertencias	
Solo para uso externo.	
No lo use en los ojos. En caso de contacto, lívete inmediatamente los ojos con agua.	
Suspenda su uso y consulte a un médico si aparece y persiste una irritación o sarpallido.	
MANTENER FUERA DEL ALCANCE DE LOS NIÑOS. En caso de ingestión, busque asistencia médica o contáctese con un centro de toxicología de inmediato.	
Instrucciones	
• Aplique una pequeña cantidad y cubra las manos con el producto durante 30 segundos. Haga espuma y enjuague.	
• Se debe supervisar a los niños menores de 6 años cuando utilicen este producto.	
Ingredientes Inactivos	
Agua, cocamidopropil betaina, lauril éter sulfato de sodio, Sodium Laureth-3 Sulfate, cloruro de sodio, propilenglicol, propenediol, fragancia, metilclorotiazinona y metiltioctiazinona, amarillo 5 y rojo #0.	



Product No:
002676

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

Active

1848049201

Drug Facts	
Active Ingredient	Purpose
PCMX 0.1%	Antibacterial Handwashing
Uses	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • Apply a small amount, covering hands with product for 30 seconds. Add water, lather and rinse. • Children under 6 years of age should be supervised when using this product. 	
Inactive Ingredients	
Water, Sodium Olefin Sulfonate, Sodium Lauryl Ether Sulfate, Sodium Chloride, Sodium Sulfate, Fragrance, Methylchloroisoithiazolinone, Methylisoithiazolinone, Boric Acid, Yellow 5, Red 40.	

OTC Purpose

Drug Facts	
Active Ingredient PCMX 0.1%	Purpose 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. Add water, lather and rinse. • Children under 6 years of age should be supervised when using this product.	
Inactive Ingredients Water, Sodium Olefin Sulfonate, Sodium Lauryl Ether Sulfate, Sodium Chloride, Sodium Sulfate, Fragrance, Methylchloroisothiazolinone, Methylisothiazolinone, Boric Acid, Yellow 5, Red 40.	

Indications and Usage

Drug Facts	
Active Ingredient	Purpose
PCMX 0.1%	Antibacterial Handwashing
Uses	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • Apply a small amount, covering hands with product for 30 seconds. Add water, lather and rinse. • Children under 6 years of age should be supervised when using this product. 	
Inactive Ingredients	
Water, Sodium Olefin Sulfonate, Sodium Lauryl Ether Sulfate, Sodium Chloride, Sodium Sulfate, Fragrance, Methylchloroisothiazolinone, Methylisothiazolinone, Boric Acid, Yellow 5, Red 40.	

Warnings

Drug Facts

Active Ingredient

PCMX 0.1% Antibacterial Handwashing

Purpose

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. Add water, lather and rinse.
- Children under 6 years of age should be supervised when using this product.

Inactive Ingredients

Water, Sodium Olefin Sulfonate, Sodium Lauryl Ether Sulfate, Sodium Chloride, Sodium Sulfate, Fragrance, Methylchloroisoithiazolinone, Methylisoithiazolinone, Boric Acid, Yellow 5, Red 40.

Ask Doctor

Drug Facts

Active Ingredient

PCMX 0.1% Antibacterial Handwashing

Purpose

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. Add water, lather and rinse.
- Children under 6 years of age should be supervised when using this product.

Inactive Ingredients

Water, Sodium Olefin Sulfonate, Sodium Lauryl Ether Sulfate, Sodium Chloride, Sodium Sulfate, Fragrance, Methylchloroisoithiazolinone, Methylisoithiazolinone, Boric Acid, Yellow 5, Red 40.

KOOROC

Drug Facts	
Active Ingredient	Purpose
PCMX 0.1%	Antibacterial Handwashing
Uses	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • Apply a small amount, covering hands with product for 30 seconds. Add water, lather and rinse. • Children under 6 years of age should be supervised when using this product. 	
Inactive Ingredients	
Water, Sodium Olefin Sulfonate, Sodium Lauryl Ether Sulfate, Sodium Chloride, Sodium Sulfate, Fragrance, Methylchloroisoithiazolinone, Methylisoithiazolinone, Boric Acid, Yellow 5, Red 40.	

Dosage and Admin

Drug Facts	
Active Ingredient	Purpose
PCMX 0.1%	Antibacterial Handwashing
Uses	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • Apply a small amount, covering hands with product for 30 seconds. Add water, lather and rinse. • Children under 6 years of age should be supervised when using this product. 	
Inactive Ingredients	
Water, Sodium Olefin Sulfonate, Sodium Lauryl Ether Sulfate, Sodium Chloride, Sodium Sulfate, Fragrance, Methylchloroisothiazolinone, Methylisothiazolinone, Boric Acid, Yellow 5, Red 40.	

Inactive ingredients

Drug Facts	
Active Ingredient	Purpose
PCMX 0.1%	Antibacterial Handwashing
Uses	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • Apply a small amount, covering hands with product for 30 seconds. Add water, lather and rinse. • Children under 6 years of age should be supervised when using this product. 	
Inactive Ingredients	
Water, Sodium Olefin Sulfonate, Sodium Lauryl Ether Sulfate, Sodium Chloride, Sodium Sulfate, Fragrance, Methylchloroisothiazolinone, Methylisothiazolinone, Boric Acid, Yellow 5, Red 40.	

SMART DEFENDER

pcmx, dishwashing and hand soap soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70542-707
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
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM SULFATE (UNII: OYPR65R21J)	
METHYLCHLOROISOTHIAZOLINONE/METHYLISOTHIAZOLINONE MIXTURE (UNII: 15O9QS218W)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
BORIC ACID (UNII: R57ZHV85D4)	
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	

Product Characteristics

Color	orange	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70542-707-41	3.78 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/23/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	05/23/2019	

Labeler - Midlab, Inc (047371463)

Registrant - Midlab, Inc. (047371463)

Establishment

Name	Address	ID/FEI	Business Operations
Midlab, Inc		047371463	manufacture(70542-707)

Revised: 11/2023

Midlab, Inc