

**PANROSA ANTIBACTERIAL HAND GREEN APPLE- chloroxylenol gel**  
**Panrosa Enterprises, Inc.**

*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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**Panrosa Antibacterial Hand Soap - Green Apple**

***Drug Facts***

***Active ingredient***

Chloroxylenol 0.25%

***Purpose***

Antibacterial

***Uses***

- for hand washing to decrease bacteria on the skin

***Warnings***

**For external use only.**

**When using this product**

- avoid contact with eyes. In case of eye contact, flush with water.

**Stop use and ask a doctor if**

- irritation and redness develops.

**If pregnant or breast-feeding,**

ask a health professional before use

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

***Directions***


- pump into hands, wet as needed
- lather vigorously for at least 15 seconds
- wash skin, rinse and dry thoroughly

***Inactive ingredients***

Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Cocamide MEA, Sodium Chloride, Glycerin, Disodium EDTA, PEG-150 Distearate, Citric Acid, Fragrance (Parfum), Methylisothiazolinone, Methylchlorisothiazolinone, FD&C Yellow No.5, FD&C Blue No.1.

**Package Labeling:**

# Transparent formulation

<p><b>Drug Facts</b></p> <p><b>Active ingredient</b>      <b>Purpose</b> Chloroxylenol 0.25%.....Antibacterial</p> <p><b>Uses</b> ■ for hand washing to decrease bacteria on the skin</p> <p><b>Warnings</b>      For external use only. When using this product ■ avoid contact with eyes. In case of eye contact, flush with water. Stop use and ask a doctor if ■ irritation and redness develops. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b> ■ pump into hands, wet as needed ■ lather vigorously for at least 15 seconds ■ wash skin, rinse and dry thoroughly</p> <p><b>Inactive Ingredients</b> Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Cocamide MEA, Sodium Chloride, Glycerin, Disodium EDTA, PEG-150 Distearate, Citric Acid, Fragrance (Parfum), Methylisothiazolinone, Methylchlorisothiazolinone, FD&amp;C Yellow No. 5, FD&amp;C Blue No. 1.</p>	 <p>moisturizing &amp; soften</p> <h2>ANTI-BACTERIAL HAND SOAP</h2>  <p>GREEN APPLE scented</p> <p>16.9 FL OZ (500mL)</p>	<p>Panrosa Enterprises, Inc. 550 Monica Circle Corona, CA 92880 U.S.A.</p> <p><b>MADE IN U.S.A.</b></p>  <p>6 51669 10025 1</p>
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## PANROSA ANTIBACTERIAL HAND GREEN APPLE

chloroxylenol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50302-015
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	2.5 mg in 1mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)

METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50302-015-50	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/01/2020	

**Labeler** - Panrosa Enterprises, Inc. (859957578)

Revised: 8/2020

Panrosa Enterprises, Inc.